

*Prepared for:*

Transport Canada and  
Community of Federal  
Regulators

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*June, 2018*

Risk Based Regulatory Delivery –  
Review and Toolkit of Modern  
Practices

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## Executive Summary

### 1.1 Introduction

As part of its regulatory modernization agenda, Transport Canada (TC) commissioned Public Risk Management Institute (Prism Institute) to undertake a preliminary study that included a global scan of current practices in risk based regulatory delivery. This study is also an introductory action of the newly constituted Community of Practice (COP) on risk based regulatory delivery under the aegis of the Community of Federal Regulators (CFR) and in response to the December 2017 report from the [Advisory Council on Economic Growth](#)<sup>1</sup> recommendations for modernizing Canada's regulatory frameworks. These recommendations which were subsequently included as part of Government of Canada's budget 2018 highlighting the need for catalyzing innovation across the economy through regulations that accommodate emerging technologies and business models especially in high-potential sectors, drive coordination between agencies and jurisdictions both within Canada and internationally and, promote efficient and predictable regulation.

The objectives of the study involved identifying innovative approaches and methods being used, their advantages and limitations, and developing a set of recommendations that TC could consider for implementation. In addition, TC envisions that the outcomes of the study would also help the CFR to establish priorities for its COP on risk based regulatory delivery and ultimately benefit other federal regulatory agencies and departments in successfully meeting the expectations identified in Budget 2018. This report provides the results and findings of the study including a broad set of recommendations and proposed next steps for TC and the CFR.

The study was conducted over two phases: Phase I involved undertaking an online survey of primarily Canadian federal and provincial regulatory agencies to understand the current status of risk-based approaches, maturity of agencies and departments and opportunities of advancements and continuous improvement. The online questionnaire for Phase I specifically focused on gaining a broad regulatory and legislative context of the departments and agencies contributing to the survey. The survey captured information on their current regulatory governance models, the nature and maturity of their risk-based decision-making frameworks including their risk assessment methods, and approaches and associated challenges with communicating risk and driving internal and external change.

Phase II of the study focused on exploring innovative practices amongst a few progressive agencies in Canada, Europe and Australia. Phase II was carried out through interviews and discussions with those responsible for regulatory delivery across sectors including food safety, transportation,

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<sup>1</sup> Advisory Council on Economic Growth, "Investing in a Resilient Canadian Economy", December 2017

technical safety, worker safety and occupational health, drinking water, biosecurity, chemical safety, energy, healthcare and environment. Topics ranging from smart and responsive regulations, regulatory governance and delivery, regulatory innovation using disruptive technologies, program implementation challenges and successes and change management were covered during these interviews and discussions. Due to constraints in time and budget, this phase of the study was limited in its jurisdictional and sectoral coverage including Ontario, British Columbia, United Kingdom, Germany, Australia, and Finland. Some of the material presented in the study have also been obtained from literature searches and a report from the [World Bank](#)<sup>2</sup>. However, these practices provide adequate knowledge and concepts to serve the objectives of the study.

The analyses of the responses to the questionnaire for Phase I yielded findings that included several challenges and limitations. Many of these challenges and limitations are being addressed by progressive and forward-thinking agencies globally. Phase II focused on identifying some of these agencies towards gaining a deeper understanding of their approaches, criteria for successes and lessons learned. The findings from this assessment will help formulate a strategy and a broad plan for TC and CFR to consider as they progress on their modernization agenda and also help other agencies to follow along the way.

## 1.2 Findings

The summary of the challenges and limitations identified in Phase I of the study are described below across three key themes:

### 1.2.1 Regulations and Regulatory Governance

- Legislation was not considered as a barrier for risk-based approaches; however, was seen as a limiting factor for data sharing and addressing interconnected risks across jurisdictions
- There is a consistent lack of senior management accountability for the risk management role
- There is a lack of clear distinction between corporate and regulatory risk management causing potential conflict between mandate and organizational risks
- Departments believe that they are inadequately staffed for current and future expectations especially in areas of risk-based approaches and innovative regulatory methods
- There is a greater need for emphasis on transparency and reporting on regulatory performance
- Risk based decision making is constrained by lack of a dialogue on risk thresholds

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<sup>2</sup> World Bank, 2017: “Internet of Things – The New Government to Business Platform”.

### 1.2.2 Risk Based Regulatory Delivery

- Largely qualitative methods used due to data and evidence limited to those collected through internal mechanisms (e.g., inspections) and constrained by regulatory barriers to sharing with other agencies and external sources
- In addition to data challenges, competency and resource capacity constrain agencies in applying formal risk assessment methods
- Despite the advantages of filling data gaps, most departments don't have any immediate plans or incentives to use innovative approaches for utilizing data through disruptive technologies possibly indicating lack of awareness and understanding of such technologies
- Despite increasing interconnectedness and interdependencies of risks, there is limited integration across risks, programs, sectors and departments; however, there appears to be a healthy dialogue between science and decision making within departments and agencies

### 1.2.3 Program Implementation and Change Management

- Contrary to most emerging international best practices, agencies continue to assume greater burden of responsibility indicating a lack of trust of the regulated
- Agencies continue to heavily impose an enforcement focused culture with very limited incentives for good performers
- Agencies, however, are keen to explore alternate regulatory oversight models and methods which provide them with flexibility and choices
- Lack of formal frameworks and support systems hamper agencies to engage internal and external stakeholders in communicating and managing change particularly in the context of disruption

## 1.3 Emerging Practices

Concepts and practices that are emerging and addressing some of the challenges and limitations identified above, through the work being done by progressive agencies who contributed to Phase II of the study, in areas of regulation development, regulatory delivery and implementation. Though the study covered modern practices in regulations, policies and directives the emphasis was more on regulatory delivery and implementation approaches. Key findings include:

### 1.3.1 Smart Regulations, Strategies and Directives

Broad policy directives such as the [Growth Duty Directive \(UK, 2017\)](#) establishes that any person exercising a regulatory function must have regard to the desirability of promoting economic

growth (“growth duty). It requires regulators to understand emerging business models, processes or products that may present a challenge to the existing regulations or the way the regulator operates, and should seek, where appropriate, to develop suitable responses which encourage appropriate innovation.

[UK’s Industrial Strategy, 2017](#) sets out a long-term plan to boost the productivity and earning power of people throughout the UK. In an effort to create a responsive and agile regulatory environment, the UK Government has established £10m Regulators’ Pioneer Fund to help regulators develop innovative approaches aimed at getting new products and services to market using a sandboxes approach. Several innovative regulations and regulatory policies are being envisioned as part of this strategy.

In 2017, the Australian Energy Regulator (AER), Energy Networks Australia and Energy Consumers Australia established a project entitled [NewReg](#): towards consumer-centric energy network regulation to trial new regulatory pathways designed to ensure consumers are engaged much earlier in the regulatory process, which in turn would improve regulatory design and approvals processes.

Government of Ontario has undertaken several innovative initiatives over the years to drive and establish regulations that are progressive, responsive and outcome focused. Most recently, Ontario Cutting Unnecessary Red Tape Act (CURT) which received Royal Assent on November 14, 2017 requires all ministries to offset every dollar of new administrative costs to businesses by removing old and unnecessary costs, remove unnecessary burdens through new or amended regulations, and recognize those who have a good compliance record and lower their costs by reducing requirements while maintaining robust environmental, health and safety requirements and other public interest protections. To increase harmonization, the legislation requires greater cooperation with other jurisdictions and adoption of international or national standards, where appropriate, when developing or reviewing regulations.

In addition, several examples of risk and outcome focused regulations have been in place in for several years in the technical and electrical safety, occupational health and safety, seniors’ care, health and energy sectors in Ontario and British Columbia. The newly promulgated “Safe Food for Canadians” regulations under the Canadian Food Inspection Agency is an example at the federal level.

Procurement, which is typically seen as a major barrier for innovation, has been addressed in the UK. The UK government has developed and implemented an approach whereby 2 central government departments (the Government Digital Service and Crown Commercial Service) have established a digital market place( <https://www.digitalmarketplace.service.gov.uk/> ). It’s a ‘one stop shop’ for public sector organisations where they can find a wide range of digital/data services.

It is designed to increase standardisation, interoperability, economies of scale and realise efficiencies.

The Standards Council of Canada has commissioned Underwriters Laboratories to develop a “Guideline for Managing Risks in the Public Interest in a Regulatory Context”. This guideline developed using principles of international standards development, once published (likely at the end of 2018), will provide guidance to regulatory agencies and departments to apply risk assessment and risk management techniques in a consistent and effective manner including addressing primary issues such as setting risk thresholds.

### **1.3.2 Alternate Regulatory Delivery Models and Methods**

According to the UK Government, regulatory delivery is *the means by which policy expertise and practical experience are brought together to ensure that regulation is effectively delivered in ways that reduce burdens on business, save public money and properly protect citizens and communities*. A combination of smart legislative instruments and innovative regulatory practices, certain alternative regulatory delivery models and methods are emerging as successful means to achieve regulatory delivery goals. These models and methods can be categorized into at least three bins:

#### 1.3.2.1 Third-Party Delivery Models

Historically, there have been several examples of “third-party” delivery of regulations and policies in sectors including accounting and taxation, professional practices, and some industrial sectors and applications. The delegated authority model (DAA), however, has proven to be a successful “third-party” delivery mechanism especially for the purpose of achieving regulatory delivery goals such as those identified in this study. Successful DAA applications are emerging in Ontario and BC in the sectors including technical safety, electrical safety, retirement homes, circular economies and others. Typically supported by outcome or risk-based regulations, these models have been able to implement innovative delivery methods especially in times of disruption through the use of regulatory and non-regulatory tools. Inadequate regulatory governance, public perceptions, and change management issues are seen as key challenges and limitations with the model.

#### 1.3.2.2 Risk and Cost Market Based Cost Recovery Methods

Increasing pressures on governments and regulators to make cost reductions, budgetary constraints and changing market dynamics have induced creative means of maintaining or redesigning regulatory delivery practices. In particular, legislative amendments have allowed regulators to recover costs for their regulatory oversight and services. Examples of market segmentation and risk-based approaches have emerged as practices through the DAA models in Ontario and BC, in drinking water standards and health care sectors in the UK. Examples include market size driven licensing and registration fees, cost recovery for the conduct of inspections

including non-compliance follow ups and incident investigations. However, true benefits of a cost recovery have not yet been explored through these approaches. While, for example, compliant businesses may benefit from fewer inspections when risk-based approaches are used, risk-based fees and incentives have not yet been tested.

#### 1.3.2.3 Alternative assurance, compliance and enforcement Approaches

Regulated self-assurance approaches such as the [UK Primary Authority](#) provides businesses to receive assured and tailored advice on meeting environmental health, trading standards or fire safety regulations through a single point of contact. Implementing through legislation, the primary Authority approach enables businesses to invest with confidence in products, practices and procedures, knowing that the resources they devote to compliance are well spent. Similar approaches exist in the drinking water and civil aviation sectors in the UK.

Realizing that a “one-size fits all” is not an effective approach in the food safety sector, the UK Food Standards Agency through its “[Regulating our Futures](#)” strategy is working on implementing a target operating model built on a foundation of a risk based market segmentation. Using a combination of smart licensing and registration, risk-based segmentation, assurance and intervention methods, the model is expected to facilitate a delivery model that will be dynamic and flexible to adapt as circumstances change and technology develops in the future.

[Ethical business practices and regulations](#), greater applications of alternate dispute resolutions (ADR), increasing roles for ombudspersons, industry associations’ led compliance assurance approaches have also been identified as existing or emerging practices.

Innovative quantitative risk assessment tools using internal and external sources of data have been developed by the Electrical Safety Authority of Ontario, BC Technical Safety, UK Drinking Water Inspectorate, Retirement Homes Regulatory Authority of Ontario, UK Food Safety Agency that allow these agencies to prioritize their inspections and allocate resources in a smart manner. While there is limited published evidence of their successes possibly due to short implementation periods, the agencies have indicated early successes to these programs particularly with effective resource management and burden reduction.

#### **1.3.3 Innovative/Disruptive Technologies and Practices for Regulatory Delivery**

Examples of most exciting and innovative advancements are emerging primarily in the actual delivery and implementation of regulations using traditional or alternate regulatory delivery models described earlier. Reliable and trustworthy risk assessments are those that have been able to address and reduce sources of uncertainties. Use of disruptive technologies for data collection, analysis and decision support is receiving the most attention particularly as they help address the limitations of traditional risk assessment approaches. Public-private-academic partnerships and

collaborative approaches operating in sandbox environments to test the role of disruptive innovations and technologies are setting the stage for a potential revolution in the regulatory delivery space. While most if not all of these experiments are still very much in conceptual, pilot or proof of concept states, scaled implementation is likely to happen in the very near future. However, challenges with data governance, policy limitations, relevant business models and incentives and costs remain as outstanding issues.

The reviewed innovative/disruptive regulatory practices suggest the need for the following elements:

#### 1.3.3.1 Partnership, Collaboration, and Sandboxes

Public-private-academic partnership has emerged as a key characteristic for successful execution of pilots and possible scaled implementation of disruptive technologies and innovations for regulatory delivery. Governments and regulators have typically provided the necessary infrastructure, funding, sandbox environments, and coordination to organize the pilots. In some instances, such as the use of [Catapults](#) in the UK, governments have established “third-party coordinators” to organize pilots. CFR’s COP, for example, can be seen as a third-party coordinator. Academic institutions provide the necessary knowledge and capacity infrastructure while the private sector participation is needed to operate real-life operating environments. Fraunhofer Institute in Germany, Alan Turing Institute in the UK, University of British Columbia in British Columbia, and University of Queensland in Australia are examples of academic institutions participating in partnerships focused on introducing disruptive innovations in the regulatory space. Private sector participation also induces innovations and opportunities for businesses to participate as “equal” players in the regulatory system. Major players like IBM and CISCO and several startup companies are engaged in pilots in the surveyed jurisdictions.

Governments play a key role in creating the necessary sandbox environments for testing disruptive technologies. Apart from the UK catapults example, Germany through its Federal Ministry of Transport and Digital Infrastructure supports the development of [digital test beds](#) in the public realm, which provide industry and the research community with an opportunity to gain experience and provide policymakers with answers to a number of fundamental questions to enable them to take the correct transport policy decisions in safety and efficiency. Digital test beds are set up as “laboratories with real-life conditions”, on motorways, in urban and rural environments and in a cross-border context.

#### 1.3.3.2 Disruptive Technologies and Innovations

Disruptive technologies play a significant role in innovative regulatory delivery. They can be used for:

- collecting and transmitting data on compliance and risk factors relevant for regulatory oversight and reduce sources of uncertainty in traditional data collection approaches;
- modeling, analyzing and predicting compliance performances and behaviors that can be used to support decisions such as allocating inspection resources, targeting inspections and audits, and monitoring the value chains
- responding to known and emerging risks including policy changes, delivery strategies and methods, business incentives including market enhancements, and enforcement tools.

This study suggests that regulators are just beginning to realize the potential benefits for the use of disruptive technologies for data collection such as the use of [IoT sensors to remotely inspect food establishments](#) (UK). UK's Department for the Environment, Food and Rural Affairs (DEFRA) has developed a blockchain Proof of Concept (PoC) with IBM that helps to monitor compliance through the meat supply chain. Finland is currently testing "Skype" inspections of chemical facilities in remote locations to reduce travel time and improve efficiencies. The Queensland government in partnership with academia and the private sector is working on the development of systems that include location tracking, smart sensors and image recognition of fish species which are designed to replace slow and costly manual logbooks with automated real-time monitoring. Automated technology will save fishers time and money by reducing the burden to record their daily catch and fishing effort in traditional hard copy logbooks. The regulator, Fisheries Queensland, will receive more accurate information in real time rather than waiting for logbooks to be sent in and data entered, giving the community greater confidence in the quality of data.

The study reveals that the most significant use of disruptive technologies has involved the application of a combination of artificial intelligence and machine learning tools for risk assessment of inspection and other sources of compliance data primarily for the purposes of resource allocation, target setting, and inspection prioritization. Examples of such applications have emerged in the drinking water (UK Drinking Water Inspectorate), technical and electrical safety (Electrical Safety Authority of Ontario, BC Technical Safety), and health care (UK Care Quality Commission) and are described later in this document.

As the [World Bank report](#) suggests, the most extensive application of disruptive technologies such as Internet of Things in the public sector domain have been more focused on delivery of services such as in the context of municipal and city applications. The adoption of such technologies for regulatory delivery is still primarily in concept stages.

#### 1.3.3.3 Capacity Building and Change Management

Implementing disruptive technologies and innovations in regulatory delivery will bring significant changes in the workforce and support structures not only within businesses and the regulated

sectors but also in regulatory organizations. A significant challenge to the disruptions would be presence and adequacy of competent professionals as also the capacity and awareness to understand and embrace change.

The UK Food Standards Agency is already working towards addressing the future of regulatory inspections by scoping out possible partnerships for working with academic institutions in designing programs and curriculum focused on creating “future” inspectors. The UK Drinking Water Inspectorate has a “secondment” program for industry to allow its employees to take on roles as inspectors alongside their inspection team to understand the regulatory delivery environment and share knowledge and expertise.

Agencies with the objective of adopting and implementing alternative and innovative regulatory delivery approaches have begun developing and implementing change management frameworks based on best practices in behavioral economics and other emerging concepts in behavioral sciences. While the frameworks exist, agencies with success have had to design and tailor very specific change management strategies taking into account their mandates, the stakeholder needs and expectations, and the maturity of the regulated sector. In addition to proactively engaging internal stakeholders particularly in gaining their trust and confidence while implementing technologies such as AI (BC safety), agencies find it beneficial to engage stakeholders in the design and development of disruptive solutions (UK Food Standards Agency). Time and effort is required to gain the acceptance of stakeholders including internal operations teams such as inspections. As experienced by the UK CQC, it required clear and continued demonstration of benefits and positive impacts of the technology-based approaches with their inspections to create awareness and build confidence.

## **1.4 Recommendations**

Though the study was carried out over a short two-month period and was limited in its scope and coverage, the findings from the study provide enough knowledge to identify and develop a broad set of recommendations for Transport Canada and the CFR to consider particularly over the short and medium term for implementation. The recommendations can also be used by the Taskforce created under Canada’s Cabinet Directive to implement the commitments made in the Budget 2018 to further their objectives and goals. It is recommended that TC and CFR consider the following two areas of focus:

### **1.4.1 Phased Pilot Study**

#### 1.4.1.1 Phase I – Risk Assessment

In the immediate or short term, it is recommended that TC design and execute a risk assessment study that is primarily focused on utilizing innovative/disruptive practices and technologies with the following objectives as a minimum:

- Evaluate the feasibility of disruptive technologies for data collection (e.g., Internet of Things), data transmission (Blockchain), and data analysis (e.g., AI/Machine Learning)
- Examine the impact of these technologies in addressing uncertainties and limitations with traditional risk assessment methods and models
- Evaluate the policy/regulatory challenges and opportunities for addressing interconnected and interdependent risks such as inter-jurisdictional barriers, procurement, and constraints for scaled implementation
- Evaluate the socio-economic implications such as stakeholder awareness and acceptance, impacts on future business models, and other related factors
- Identify other factors such as capacity and competency needs within the agencies, knowledge tools and opportunities for further research.

For the purposes of designing and executing the pilot, the following steps should be considered:

- Identify and select a priority sector and a lead agency; it is recommended to select a sector impacting multiple regulatory domains/agencies to test interconnected and interdependent risks (e.g., safe cross-border transport of products such as food or hazardous materials)
- Identify a facilitating coordinator such as the CFR's COP
- Seek and engage partners for study (private, academic and other regulators including examining the possibility of international partners)
- Identify and design sandbox environments for undertaking pilot studies

Phase II of the pilot can focus on the review and examination of alternate regulatory delivery models including those described in this report. This phase can either be initiated in parallel with Phase I, or at completion of Phase I. The two phases would help establish program design and implementation frameworks required for scaling. The scaled implementation of the programs can continue to be carried out in the sandbox environments or executed directly in real-life conditions.

### **1.4.2 Knowledge Sharing and Global Networking**

In addition to continuing current knowledge sharing strategies and plans established by the CFR, it is recommended that the CFR coordinate the participation of departments and agencies in

international initiatives and networks. In particular, it is recommended that CFR participate in the newly formed International Network for Regulatory Delivery (global network of experts on modern regulatory delivery) established by the UK Department of Business, Industrial and Energy Strategy (BEIS) with the UK Government and facilitated by University of Oxford. Other networks including existing federal-provincial-territorial committees such as the Canada's National-Provincial Advisory Committee (NPSAC) coordinated by Standards Council of Canada, the OECD Network of Economic Regulators are also working on similar areas of interest.

In addition, it is recommended CFR and its member agencies also use their sector-specific networks to further examine opportunities for coordinated research and engagement in regulatory delivery pilots. Existing regulatory networks in health, environment, food security, civil aviation and those established through multi-lateral initiatives such as Trade Agreements provide platforms for knowledge sharing and common pilots.

## Acknowledgements

Prism Institute would like to specially thank Sylvain Souigny, Lori Buck and Hanif Mawji with Transport Canada for sponsoring and supporting the conduct of the study. Prism Institute would like to express gratitude to Alyssa Daku with the Canadian Food Inspection Agency and Dhurata Ikonomi with the Community of Federal Regulators for providing advice and guidance in undertaking the study. The team at CFR are also acknowledged for organizing and conducting the online survey. Prism Institute would like to acknowledge Karen Hussey with the Centre for Policy Futures at the University of Queensland for providing the Australian case studies as part of this report. Vasumathi Srikanth of Prism Institute is also acknowledged for conducting the survey analysis and reviews of the report. Prism Institute would like to acknowledge Prasanna Lal Das with the World Bank for allowing to use content from the report, *Internet of Things – The New Government to Business Platform* and Stefan Beisswenger from Germany for linking the authors of this report with the German Department of Transport and Digital Infrastructure.

Prism Institute would especially like to thank the following experts representing the various agencies engaged as part of the study:

- Graham Russell, UK Office of Product Safety and Standards
- Nina Purcell, UK Food Safety Standards Agency
- Leigh Sharpington, UK Food Standards Agency
- Marcus Rink, UK Drinking Water Inspectorate
- Christopher Hodges, University of Oxford
- David Gledhill, UK Care Quality Commission
- Abraham van Poortvliet, BC Technical Safety
- Joel Moody, Ontario Electrical Safety Authority
- Paul Pham, Ontario Retirement Homes and Regulatory Authority
- Sujoy Dey, Ontario Ministry of Labour
- Nicholas Koch and Lennart Schulze, German Department of Transport and Digital Infrastructure
- Minna Paivinen and Tanja Heinimaa, Finnish Chemicals and Safety Agency
- Claire Andersen, Fisheries Queensland

## 1. Background and introduction

CFR organized an international workshop on risk based regulatory delivery in Ottawa on December 13th, 2017 where a Community of Practice on Risk based Regulatory Delivery was launched. The workshop provided opportunities for an exchange of ideas and practices between Canadian federal and provincial regulators and their international counterparts. The workshop generated a report that included learnings and successes from the participating agencies and generated recommendations from the Workshop Report as a key input while undertaking the project to ensure continuity and momentum generated from the workshop and to provide further details and strategic directions for implementing the identified priorities.

In its December 2017 report, the Advisory Council on Economic Growth identified three priority areas for establishing an agile regulatory system designed for the new economy:

- Catalyze innovation across the economy through regulations that accommodate emerging technologies and business models, especially in high-potential sectors.
- Drive coordination between agencies and jurisdictions, both within Canada and internationally.
- Promote efficient and predictable regulation.

In response to these recommendations, Canada's Budget 2018 proposes to pursue a regulatory reform agenda focused on supporting innovation and business investment. The goal is to make the Canadian regulatory system more agile, transparent and responsive, so that businesses across the country can explore and act on new opportunities, resulting in benefits for all Canadians. The approach specifically includes conducting targeted reviews, over the next three years, of regulatory requirements and practices that are bottlenecks to innovation and growth in Canada, with an initial focus on agri-food and aquaculture, health/bio-sciences, and transportation and infrastructure, including emerging technologies such as autonomous vehicles.

The Government also proposes to introduce legislation to reduce the regulatory burden faced by businesses. This includes streamlining Canada's *Customs Tariff* legislation in order to simplify its structure and administration. This measure will reduce the overall complexity of the legislation, which will ease administrative burden and reduce compliance costs for Canadian businesses and government.

As a continuation to the outcomes of the workshop and the need to identify clear tasks and actions for the Community of Federal Regulators (CFR) to undertake and/or facilitate, this initiative with the support from Transport Canada (TC) was undertaken with the following broad objectives:

- **Scan of current State of Risk-Based Regulatory Delivery**
  - Undertake a general scan of provincial and federal regulators within Canada and internationally on the current state of risk based regulatory delivery with a focus on agencies with responsibilities in public safety, food, transportation, product safety, worker health and safety, environment and climate change
  
- **Looking into the Future**
  - Undertake a focused review of advanced regulatory agencies in Canada and internationally to understand their innovative approaches and delivery models, identify key elements of success, challenges and limitations, and opportunities for shared learnings and collaborations
  - Develop recommendations and opportunities for pilot studies for mature and leading Canadian federal agencies and departments on innovative regulatory delivery models and methods

The study is designed to identify innovative approaches and methods being used, their advantages and limitations, and developing a set of recommendations that TC could consider for implementation. In addition, the study also helps the CFR to establish priorities for its COP on risk based regulatory delivery and ultimately benefit other federal regulatory agencies and departments in successfully meeting the expectations identified in Budget 2018. This report provides the results and findings of the study including a broad set of recommendations and proposed next steps for TC and the CFR. The recommendations can also be used by the Taskforce created under Canada's Cabinet Directive to implement the commitments made in the Budget 2018 to further their objectives and goals.

## 2. Scope of study and expected outcomes

### 2.1 Phase I: Scan of Current State of Regulatory Delivery

Regulators and departments primarily within the Canadian federal government and members of the CFR along with selected Canadian provincial and municipal agencies were surveyed using an online questionnaire, developed by Prism Institute and executed by the CFR team, to understand their context, structures and programs, and status of implementation of risk based regulatory delivery. The questionnaire (see Annex I) was used to conduct a jurisdictional scan to establish program features and maturity levels across these organizations under the following broad themes:

- Regulatory context
- Governance
- Risk assessment
- Risk management
- Risk communication and change management

### 2.2 Phase II: Looking to the future - Interviews with Advanced/Modern Regulators

In this phase, Prism Institute conducted detailed interviews with agencies and experts internationally, who are currently working on or have established innovative and modern regulatory delivery models and frameworks geared towards the future. Alternate regulatory delivery models, use of smart and disruptive technologies and programs, innovative governance structures etc. were the focus of the interviews. Annex II provides details of the range of specific topics covered during the interviews. The results of the interviews are expected to position the more advanced agencies within the federal government of Canada to learn from, benchmark against and interact with such international agencies and experts.

### 2.3 Recommendations for next steps

The findings from the survey and interviews were used to assist the COP along with Transport Canada (study sponsor) to identify potential pilot studies that could be conducted to help design and implement innovative regulatory delivery models and help advance federal agencies be prepared for future challenges and to leapfrog into leading risk based regulatory institutions.

### 3. Part 1 Scan of Current State of Regulatory Delivery - Findings and analysis

The online survey had 32 respondents including regulators from departments within Canadian federal government, provincial and municipal agencies. While the respondents did not answer all the survey questions, analysis of responses have been done based on the percentage of the total number of respondents<sup>3</sup>. Detailed survey results are included in Appendix III to the report. The key findings from the survey under the broad themes as identified in point 2 above are summarized here:

#### 3.1 Regulatory Context

Survey results indicate that legislation is not a barrier for use of risk-based approaches in regulatory delivery. Majority of those surveyed (76%) responded that the legislation supports risk-based delivery of regulation in their respective jurisdictions. It was noted however, that the legislative support was not consistent within same Federal department, i.e., some legislative jurisdictions within the same broad department do not support risk -based delivery of regulations.

#### 3.2 Governance

A majority of the responses (78%) indicate that a formal risk management framework exists across most organizations. However, a clear separation between corporate and regulatory risk management is not common indicative of potential conflict in understanding and management of risks in the context of fulfilling legislative mandate versus organizational risks. Only half of those surveyed believe there exists direct accountability for regulatory risk management at the senior management level. While 50% of those surveyed said that their organization has established risk thresholds, less than a third use a national or international standard as a benchmark in the policy documents or other reasonable quantitative measurements to set the thresholds. Less than half of those surveyed undertake external peer reviews and validation of their risk- based decision framework. Most of those surveyed believe there is inadequate staffing for effective implementation of risk-based decision-making framework. It was noted that in several instances,

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<sup>3</sup> As an example, for a question with 20 positive responses, 5 negative responses and balance no responses, the percentage of positive responses for our analysis has been calculated as 63% (20/32)

there were conflicting responses from respondents belonging to the same ministry or department although responsible for regulation under different legislative mandates. This indicates different jurisdictions within same department likely work in silos with limited flow of information between them.

### 3.3 Risk Assessment

Nearly 70% of those surveyed confirmed that their respective organizations use risk assessment to establish strategic priorities and slightly over half also use it to allocate organizational resources. However, most of the risk assessment is based on qualitative data, and this is further limited to mostly data obtained from within the organization's own database. Roughly 87% of those surveyed indicated that quantitative approaches to risk assessment are used only sometimes and less than half use national or international standards for risk assessment. There is limited sharing of data between agencies as well as use of data from external stakeholders for risk assessment. In cases of organizations with multiple mandates, only 46% of risk assessments are integrated across the silos. For organizations that have overlapping mandates with other departments the integration is much lower at roughly 30%. Majority of those surveyed (64%) indicated that their organization does not plan to use new technologies (e.g., Internet of things, artificial intelligence, behavioural economics etc.) in the next one to two years.

### 3.4 Risk Management

Decision-making is largely outcome focused, although there is variation in how often decisions are based on outcomes. A number of factors are factored into the risk management and decision-making process including cost to both the regulator and the regulated, public perception, political climate and trade agreements, etc. A greater proportion of burden of responsibility of managing risks is borne by the regulator (up to 63%) indicating a lack of confidence in the regulated. The regulated are not consistently incented for good performance based on risk- 14% responded they are incented always, 54% responded that they are incented sometimes. This is further reinforced by the fact that decisions are mainly compliance and enforcement focused (up to 82%). Further, those surveyed responded the organization assumed a high to medium burden of responsibility in 28% to 34 % of cases respectively. More than 50% of those surveyed have a healthy risk assessment-risk management feedback mechanism. A majority of the regulators are planning to adopt alternate regulatory delivery models such as regulated self-assurance, fee recovery, multi-agency co-ordinated inspections, etc.

### 3.5 Risk Communication and Change Management

Half of the respondents indicated that Agencies had formal procedures for communication of risk-based decision making within the organization. However, nearly 59% of the agencies did not have a formal framework for communication with the external stakeholders. More than half of those surveyed confirmed that external experts were not used to inform its risk-based decision-making framework. There was no formal change management framework in place except in about 34% of those surveyed and the majority of the respondents confirmed that they faced significant challenges in influencing change to the risk-based decision-making framework.

## 4. Phase II: Looking into the Future

This part of the study focused on the elements and features of modern and innovative regulatory frameworks being practiced and implemented by agencies in Canada, UK, Finland, Australia and Germany. Specifically, alternate regulatory delivery models, use of smart and disruptive technologies and programs, innovative governance structures etc. were the focus of the interviews. Annex II provides details of the range of specific topics covered during the interviews.

Due to time and budgetary constraints and the urgency for the report, agency selection for this phase was based on literature review and other publications, participants from the CFR workshop on risk based regulatory delivery in December 2017, existing regulatory networks and outreach efforts.

Detailed interviews were conducted with the following agencies:

- Electrical Safety Authority – Ontario
- Technical Safety – British Columbia
- Food Standards Agency – United Kingdom
- Care Quality Commission – United Kingdom
- Drinking Water Inspectorate – United Kingdom
- Department of Transport and Digital Infrastructure – Germany
- Fisheries Queensland – Australia
- Finnish Chemicals and Safety Agency (Tukes) - Finland

In addition to the conduct of these interviews, additional material for the report was gathered through participation at several international conferences and workshops in the UK and Australia, and through document reviews provided by various regulatory and governmental agencies, multilateral agencies, and academic institutions who did not otherwise participate in the interviews.

This section of the report highlights key elements and findings arising out of the detailed interviews conducted. The next section which discusses conclusions and recommendations also includes information gathered through other sources mentioned above. For the purposes of consistency and standardization, this section is structured by contacted agency and contains the following sub-sections:

- Agency Introduction and Background
- Motivating Factors for Innovation
- Innovative Approaches to Regulatory Delivery
- Critical Success Factors, Lessons Learned and Future Direction

## 4.1 Electrical Safety Authority (ESA)

### 4.1.1 Introduction and Background

ESA is a Delegated Administrative Authority (DAA) acting on behalf of the Government of Ontario with specific responsibilities under Part VIII of the *Electricity Act, 1998* and the *Safety and Consumer Statutes Administration Act, 1996*. ESA is responsible for administering regulation in four key areas:

- Ontario Electrical Safety Code (Regulation 164/99);
- Licensing of Electrical Contractors and Master Electricians (Regulation 570/05);
- Distribution Safety (Regulation 22/04); and
- Product Safety (Regulation 438/07)

With a mission to improve electrical safety for the well-being of the people of Ontario, ESA promotes and undertakes activities which enhance public electrical safety including training, inspection, authorization, investigation, registration, enforcement, audit, and other regulatory and non-regulatory public electric safety quality assurance services. ESA has established systematised decision making frameworks and procedures to prioritise regulatory activities and deploy resources, principally relating to inspection and enforcement, based on an assessment of the risks that regulated firms/activities pose to the regulator's objectives.

### 4.1.2 Innovation Motivating Factors

Rapid technological change is transforming the electricity and energy sector. In order to keep pace with the change and influenced by the objectives of the leadership to shift from focusing on illegal activities to harmful activities, ESA is looking to expand to the use of a wider range of tools, shift in Investments including experimentation with a new toolkit wherein some organizational units act as incubators and drivers of new methods. This is expected to help shift to organize around and focus on addressing priority harms and institutionalize the Harm Reduction Approaches.

### 4.1.3 Innovative Approaches

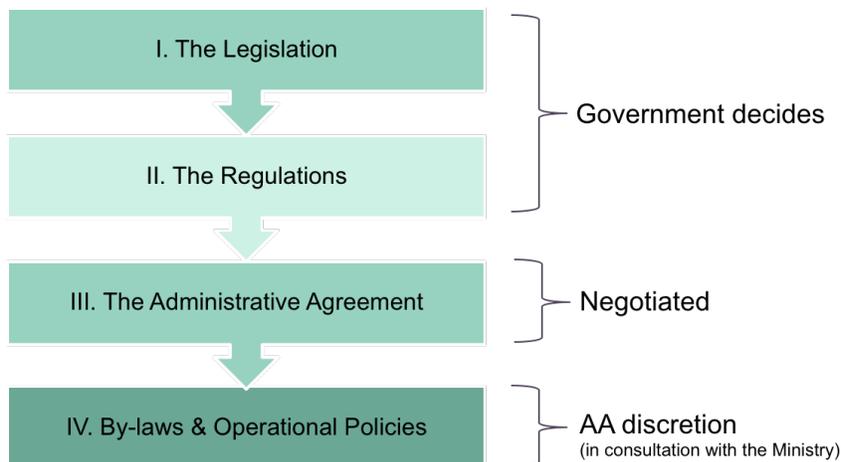
The following innovative approaches to regulatory delivery are showcased in this report for ESA:

- Alternate regulatory delivery model
- Innovative/Disruptive Practices for risk assessment
- Public-private-academic partnerships

#### 4.1.3.1 Alternate Regulatory Delivery Model

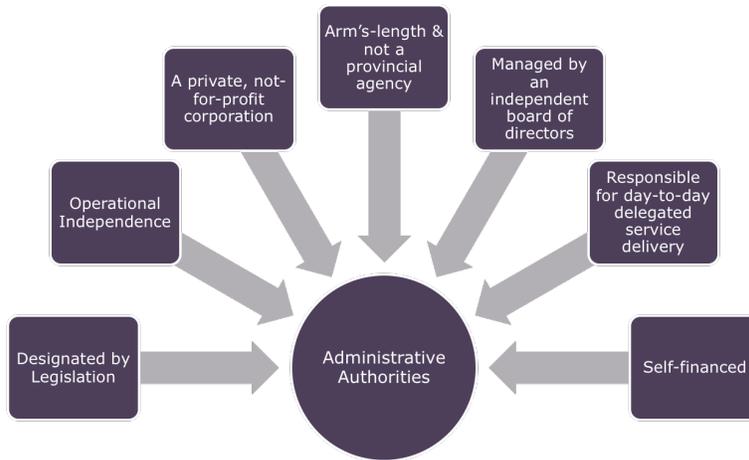
ESA, as described earlier, is a Delegated Administrative Authority, and is recognized innovative alternative regulatory delivery model.

The DAAs in Ontario were established as not-for-profit corporate structures that derive their authority from government through Administrative Agreements. Under this model, the Ministry responsible for the DAA retains overall responsibility for setting and controlling the governing legislation and regulations, providing governance oversight of the DAAs with respect to the legislation, and accountable to the public on their performance and effectiveness. While the government is responsible for designing, making and monitoring the legislation and regulation, the DAA is delegated responsibility to administer legislation in accordance with the law and an administrative agreement with the government. The governance of the DAAs can be best illustrated by the figure below.



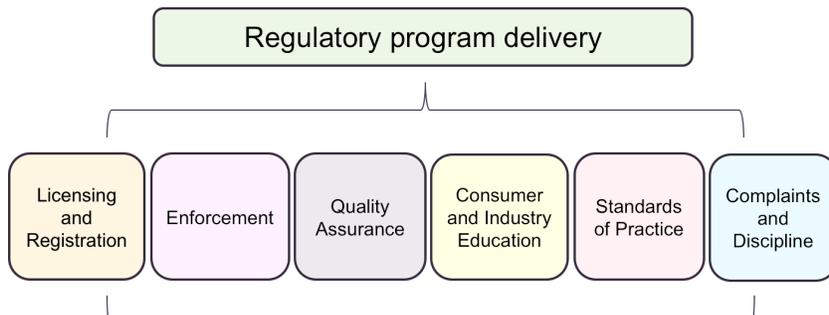
**Source: Ontario Ministry of Government and Consumer Services**

The DAAs themselves are set up as private, not-for-profit corporations managed by an independent board of directors. The DAAs are arm’s length and not considered as agencies of the province. Despite being designated by legislation they are self-financed and operate independently as illustrated by the figure below.



**Source: Ontario Ministry of Government and Consumer Services**

The DAAs are responsible for the day-to-day administration of the designated legislation and the regulatory functions of the DAA typically include those shown in the figure below:



**Source: Ontario Ministry of Government and Consumer Services**

Some DAAs also have the authority to adjudicate disputes.

The DAA appoints persons to carry out statutory functions under the delegated legislation (e.g., Registrar, Inspectors, Statutory Directors etc.). DAAs are also responsible for electing a majority of Board members and the Board’s Chair.

The DAAs are responsible for managing its financial and operational affairs. DAAs are financed by fees from industry members or for services rendered, and typically do not receive ongoing funding from government. DAAs set fees in accordance with processes and criteria approved by the Minister. Oversight is provided by the Ministry who conduct reviews and may comment on DAA’s financials. The DAAs are considered to be outside Government Public Accounts (not a “controlled entity”). While most DAAs currently cannot be audited directly by Ontario’s Auditor General, that model is being modified and legislation is being put in place to change it.

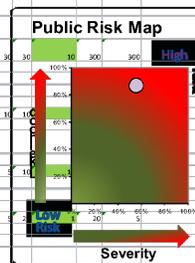
ESA was created as a product of the split that occurred with Ontario Hydro was split.

#### 4.1.3.2 Risk Based Oversight of Electric Wiring Work

Data collected through their field inspections and external sources including Canadian Institute of Health Information, Coroners' Office of Ontario, Ministry of Labour (MOL), Office of the Fire Marshal and Emergency Management, and Workplace Safety and Insurance Board of Ontario (WSIB) help ESA gain a comprehensive understanding of electrical risks in Ontario. Electrical risks are measured and quantified using first principles in epidemiology thereby helping the organization in characterizing the risk of harm and measuring against risk thresholds.

One such source of risk was identified as electrical renovation and wiring work conducted either by individuals such as homeowners or by registered contractors. ESA has shifted to a risk-based inspection approach to managing this electrical safety risk especially in the context of an increasing volume of such activities. The Risk Tool illustrated in the figure below, using Python language so as to incorporate self-learning capability. Developed internally, the weighting factors associated with the risk factors are self-learning based to reflect the changes in the model upon completion of inspections and audits. The tool helps to establish priorities and has been peer reviewed. The model has been in place for over a year now.

Likelihood	WHO THE INSTALLER	Type of Installer		Index	Rank	Max	P-Weighting	P-Max	Probability		
		1	2								
Likelihood	Type of Installer	1. ECRA Licensed CC-IVAC Gas Fitter F.A. Install.	1	10	Homeowner/Volunteer/Non-Competent Employer	3	10	7	70		
		2. Competent Employer/Employee Non-Registered Trade	2	10							
		3. Homeowner/Volunteer/Non-Competent Employee/Tenant/Owner	3	10							
	History of Performance	1. Applicant with less than 4 percent defect and no I&OP	1	30	Poor performance or DIT	4	30	30	300	300	
		2. Applicant with between 4 - 10 percent non I&OP/property defect	2	30							
		3. No history	3	30							
	Installation in the last 6 mths	1. Poor performance or DIT	1	30	Public Vulnerable (Long Term Care, hospitals, etc)	5	10	10	60%	60%	
		2. Restricted (lock and key) or require effort	2	10							
		3. Electrical Trade Only	3	10							
	Assessability	1. Worker Only	1	10	Equipment Replacement/IM Maintain	2	10	10	20%	20%	
		2. Public General/Private Residence	2	10							
		3. Public Vulnerable (Long Term Care, hospitals, special needs, schools, day care)	3	10							
	Complexity	1. Use for the next 2-600	1	10	Totals	30	510	495			
		2. Equipment Replacement/IM Maintain	2	10							
		3. Complex/New Installation - Other	3	10							
WHAT THE INSTALLATION	Era of Facility	1. Built after 2000	1	20	Between 1975-1990	3	20	20%	20%	20%	
		2. Between 1990-2000	2	20							
		3. Between 1975-1990	3	20							
		4. Between 1950-1975	4	20							
		5. Built prior to 1950	5	20							
Building Classification	1. Industrial - Warehouses, Fab & Production shop, Outdoor garages	1	10	Assembly, public gathering - school, churches, etc	4	10	10	10	10		
	2. Commercial/Institutional - Retail Store, Office Bldg, Hospital, Commercial Farming	2	10								
	3. Residential - Homes, Townhouses, Family Farm, Motels, Hotels	3	10								
	4. Assembly, public gathering - school, churches, arena, theatre, restaurant, playground	4	10								
Scope of Work	1. <750 V <100 A - branch circuits/feeders	1	5	Patient Care Area/Life Safety/Smoke Control	5	12	20	1	20	12	
	2. <750 V 100-400 A including services	2	20								
	3. 750 V-5000 A including services	3	20								
	4. >750 V - High Voltage	4	20								
	5. Patient Care Area/Life Safety/Smoke Control	5	12								
	6. (Classified) Hazardous Location and/or parallel generation	6	20								
WHERE LOCATION OF INSTALLATION	Public Exposure	1. Less than 10 people affected a month - short duration (remote areas)	1	15	More than 31 people a day affected	4	15	1	15	15	
		2. 1-10 people a mth affected, short R, long duration	2	15							
		3. 11-10 people a day affected, short and long duration	3	15							
	Environment Factor	1. Dry Indoors	1	20	Dry Indoors	1	3	20	1	20	3
		2. Wet Location/low User Interaction	2	20							
		3. Wet Underfoot	3	20			26	20			
		4. Wet Location User Interaction	4	20			26	20			
		5. Duct/Parties or Corrosive	5	20			26	20			
		Totals					3	55	30		



#### **4.1.4 Critical Success Factors, Lessons Learned and Future Direction**

The DAA model was designed to have flexibility. It has allowed the ESA to look beyond administering a regulatory mandate but focusing on actual outcomes, reduction in harm. Mandate boundaries may prevent governments from acting. However, the DAA models allow to interpret mandate as broad as public safety.

An example of the flexibility of the model particularly when addressing interdependent and interconnected risks involved a case study with electrical stove top hazards. Electric stove top fires were identified as harm to society based on reported incidents. While ESA did not have direct regulatory authority over stovetops, it was considered an electrical source of harm as it was an electrical product. Working with the Ontario Fire Marshall, local fire services, and standards development organizations (SDO), ESA undertook extensive research and certain designs along with behavioral causes as causing significant risks in community housing complexes. Working with industry and SDOs, ESA was modified design standards for coil top stoves. As a means to implement and evaluate the effectiveness of the decisions, ESA was able to undertake a pilot working with community authorities to retrofit their appliances. ESA was able to demonstrate that with such devices they have had no fires over 8 years since implementation and with significant cost savings.

The delivery mode is highly influenced by externalities affecting the decision-making culture within the organization. ESA sees that it is in its best interest to take government's mandate into account and incorporate into its strategic planning process but avoid being influenced to make decisions unlike government agencies. Any influence from government can come through formal channels only. Key to success is to balance that relationship with government to address political climate risks. As a DAA, ESA perceives that it is in much better shape to deal with political changes because decision-making processes is well established.

ESA has identified data privacy, integrity, protection and related issues when using smart technologies. It has developed its own code for privacy since it is not mandated under the Freedom of Information and Privacy Act. ESA has developed memoranda of understanding with external agencies to collect and share data with several caveats built in to address data privacy issues.

ESA intends to focus on external capacity building, education, and future planning including training programs for stakeholders including risk-based approaches. ESA also intends to introduce more pilots/sandbox environments used for testing new technologies, ideas and innovations. ESA has already begun using public-private-academic partnership models for undertaking some of its pilots including one on addressing risks with the underground economy. Other examples of

these projects currently underway include work with universities on managing non-compliances in bars, pubs, and taverns, behavioral research around why and how electricians make decisions; non-occupational electrical injury strategies involving children in partnership with Sick Kids Hospital, Sunnybrook Hospital, St Johns, and local fire services.

## 4.2 Technical Safety BC

### 4.2.1 Introduction and Background

Technical Safety BC (formerly BC Safety Authority) is a delegated administrative authority that oversees the safe installation and operation of technical systems and equipment across the province of British Columbia. In addition to issuing permits, licenses and certificates, we work with industry to reduce safety risks through assessment, education and outreach, enforcement, and research.

Technical Safety BC operates within a legislative and regulatory framework that includes:

- *Safety Authority Act*
- *Safety Standards Act* and Regulations
- *Railway Safety Act* and Regulations
- *Freedom of Information and Protection of Privacy Act*
- *Workers Compensation Act*
- *Ombudsperson Act*
- *Offence Act*

### 4.2.2 Innovation Motivating Factors

Key drivers to create a dedicated organization for the delivery of regulatory oversight include the desire to increase the responsiveness to industry needs and simultaneously meet or exceed in the administration of regulatory requirements. Against this back-drop, Technical Safety BC has developed a risk-based approach and have set thresholds both for enterprise and public safety risks. Thresholds are made available in the public domain and are the organization is currently in the process of developing a framework and engaging stakeholders on risk acceptability thresholds.

### 4.2.3 Innovative Approaches

Technical Safety BC has introduced data analytics tools in two main areas:

- Risk based resource allocation using Machine Learning and statistical sampling plans
- Contractor performance for improving compliance and creating competition

Using a combination of data generated through inspections and investigation along with permits and declarations, machine learning is used to predict the risks associated with regulated assets in BC. The machine learning tools scan the information, analyze, predict the chance of finding medium, high or severe hazards (levels 3, 4, and 5 on a 5-point scale) and if the percentage is above a threshold, the tool prompts an inspection by a safety officer. The predictions made by the machine learning tools are verified empirically by safety officers. Predictions are made daily and training of the model is done once every 2-4 weeks. Safety officers are informed daily on

inspection priorities but significant changes to resource allocation done is more on annual basis (though that may change in the future). After having piloted it in a sector the model has been scaled across electrical and gas installations.

Technical Safety BC views the importance of connecting with the community of stakeholders such as contractors and making sure information is pushed out to these regulated organizations to help them be aware of their performance. An example of one such application involves the creation of a client safety profile. Contractors can get information on their profile, such as those employees who are taking permits and how well do they do. Many contractors access the information and use it to communicate with their employees and staff. Data such as compliance performance of individual contractors in comparison to provincial averages; compliance rates or pass rates etc. are made available and are updated daily.

#### **4.2.4 Critical Success Factors, Lessons Learned and Future Direction**

The game changer for introducing ML was by hiring statisticians. As opposed to sending an inspector multiple times, algorithms were designed to look at different decision-making options. A significant learning while testing is that ML based models require large amounts of data. They were several technical challenges to get the tools functional, and change management was a big factor. Gaining the trust and acceptance of safety officers with over 25 years of experience who challenged the accuracy of the machine learning tools as opposed to their expertise and experience was a major challenge. Transparency of the functioning of machine learning tools are not clear and a key success factor was balancing machine intelligence and human intelligence. In order to address change management issues, the data analytics team worked closely with operations including influencing them to take ownership of the program. The approach provides leeway to balance ML with local knowledge of the safety officer.

Technical Safety is examining the ethics around how to interact with the stakeholder community including what information should be making public. Legislation is limited in this domain. While Technical Safety BC has realized the benefits of meeting contractors and contractor associations more than in the past, they see the publicizing of information generated by such tools as impacting the relationships.

Pilots are seen as highly valuable and at the same time also quite disruptive to the organization. Technical Safety has consciously limited its pilot studies to approximately 2 months and aimed to collect as much information as possible including the expected and unexpected within the timeframe. The organization has found that the size and design of the pilots as adequate enough to scale up and put the tools into production.

Technical Safety BC, in designing their pilots, have found academic institutions to be great partners. In addition to building future capacity by creating space for the students to work on innovative projects, they have found the total costs for executing pilots to be effective while engaging academic institutions.

## 4.3 UK Food Standards Agency (FSA)

### 4.3.1 Introduction and Background

FSA is an independent government department working across England, Wales and Northern Ireland with a mandate to protect public health and consumers' wider interests in food. The main objective of the Agency in carrying out its functions is to protect public health from risks which may arise in connection with the consumption of food (including risks caused by the way in which it is produced or supplied) and otherwise to protect the interests of consumers in relation to food.

The Food Standards Agency is responsible for ensuring that an effective regulatory regime is in place to verify that food businesses meet their obligation to ensure food is safe and what it says it is. The FSA and local authorities take appropriate action to correct this when they do not.

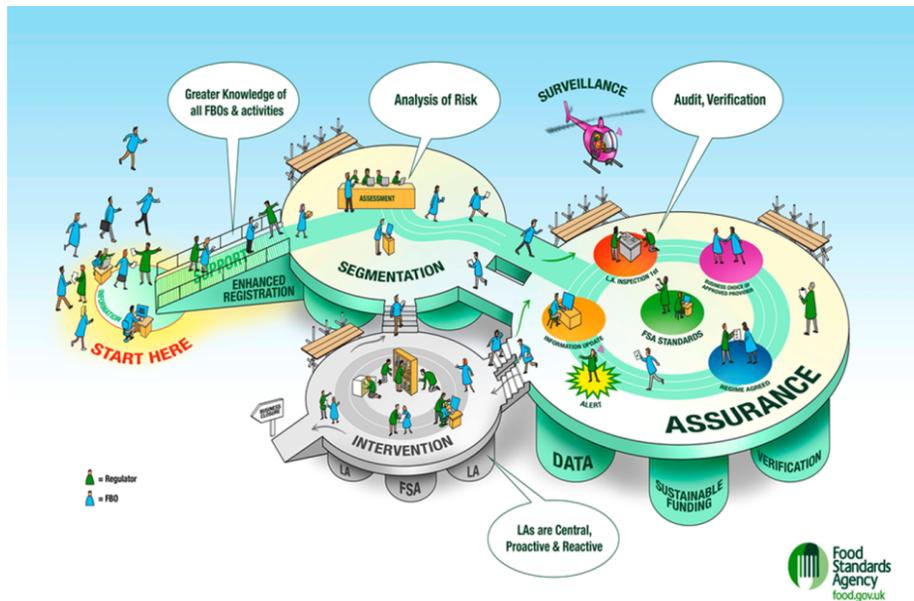
### 4.3.2 Innovation Motivating Factors

The UK Food Standards Agency (FSA) recently published a paper outlining progress with the “Regulating our Future (ROF)” programme (<https://www.food.gov.uk/sites/default/files/rof-paper-july2017.pdf>). The stated aims of the programme are to update what is described as an outdated, “one size fits all” regulatory model, where there is insufficient flexibility to adopt new approaches that are proportionate to risks, and financially and operationally sustainable. The changing food landscape, including longer, more complex supply chains, new retail and distribution models, a more mature assurance industry, etc., are thought to provide not just challenges but also opportunities to manage food safety risks in a more holistic, data and technology centric way.

The framework will revolve around a number of core principles set by the FSA:

- Businesses are responsible for producing food that is safe and should be able to demonstrate that they do so.
- Consumers have a right to information to help them make informed choices about the food they buy – businesses have a responsibility to be transparent and honest in their provision of that information.
- FSA and regulatory partners’ decisions should be tailored, proportionate and based on a clear picture of UK food businesses.
- The regulator should take into account all available sources of information
- Businesses doing the right thing for consumers should be recognised; action will be taken against those that do not.
- Businesses should meet the costs of regulation, which should be no more than they need to be.

FSA has introduced a Target Operating Model (TOM) as part of the Regulating our Future (ROF) program as shown in the illustration and described below:



FSA will introduce a new digitally-enabled approach that will make it easier for food businesses to get information and guidance to help them comply with safety and standards regulations before they start trading. This will also improve the approach to registration, to make it easier for new businesses to understand what is required of them. FSA intends to maximise the value derived from the registration information by developing a digital solution for real time access to registration details of all food businesses in England, Wales and Northern Ireland. This will enable the FSA to have oversight of all food businesses and provide better information on which to identify and manage risk across the food chain.

As part of a market segmentation approach, FSA will analyse a larger range of parameters relating to food safety and authenticity, factors not just related to the product type and volumes, but also to the performance and compliance of the businesses to design a flexible approach to inspection and intervention, with priorities being assigned commensurate to the risks posed to the consumer.

FSA is evaluating the possibility of providing flexibility in how businesses prove their compliance with the rules and regulations, such as through the use of private auditing schemes and digitally enabled technologies to provide assurance data. The intent is to reduce the amount of duplication in checks and inspections, reducing regulatory burden on good performers and re-allocating resources to poor performing businesses.

The FSA intends to use a variety of sources of information to undertake surveillance and horizon scanning, including from an expanded role for the National Food Crime Unit and better use of intelligence from industry and international partners to design and implement intervention schemes for non-compliant businesses.

### **4.3.3 Innovative Approaches**

As part of the ROF program and specifically the enhanced registration step, FSA has introduced an ROF digital service to ensure:

- citizen users can provide the minimum information necessary for them to officially digitally register a food business with the appropriate Authority and enable the operation of a business rules (risk engine) to facilitate inspection prioritisation;
- FSA and local authority users have access to that data, in a timely enough manner, to maintain oversight of all known food businesses and the inspection regime prescribed to that business by the relevant authority;
- Data standards are established to enable all relevant parties capture and update information about food businesses in a consistent way.

At its heart it's about capturing and exploiting data to drive improved, risk-based business processes and enhanced experiences for citizens, businesses and regulators- at local and national level. In addition to the ROF digital service, FSA is looking to make greater use of third party data and businesses' own assurance systems to support regulation. These include new and emerging innovations, enterprises and technology that have the potential to provide a range of data that could support the future regime. These are likely to use digital tools and software, such as smartphone apps and cloud-connected sensors, with their own approaches to data analysis and management. FSA is engaged with a wide range of stakeholders, using short duration feasibility studies involving a number of Local Authorities, technology companies and food businesses. For example, a recent study with Cambridge City Council and several food businesses set out to evaluate whether:

- businesses felt more supported using digital all in one solutions for the regulated assurance of food safety,
- data collected via a food safety management system assisted environmental health officers in identifying businesses remotely to target their inspections more efficiently,
- there could be an improvement in the transparency of data shared between the business and the regulator.

In another study, FSA has worked with high risk street food businesses (market stalls, concessions at stadia etc.) alongside three London authorities to assess whether wireless refrigeration sensors could be relied upon by operators and regulators to automatically monitor the temperature of key kitchen equipment and used to improve food safety standards in these sectors.

One study that is currently underway is working with rural authorities in south west England to explore whether food businesses prefer using digital or traditional methods for food business registrations, and information from the online portal to improve efficiency in the delivery of official controls.

Finally, FSA is looking to initiate a study examining 'menu management system' technology. This technology allows for menus to be digitised so that food allergens, intolerances and nutritional information data can be created, stored and updated both for the benefit of the business, the regulator, and a personalised experience for the customer.

Recognizing that the data in the Food Business Operator system was much better (quality and much more granular) than FSA data, in early 2018 FSA has developed a proof of concept using blockchain which provided the results of the inspection not just to the last farmer but also to all of the other farmers that owned that animal. It uses the ear tag and information from the animal passport to collect the data. Meat Inspectors enter data about conditions into the Food Business Operator (FBO) system. These are batch uploaded to the blockchain by the vet once the data has been approved. The vet, FSA, FBO and farmer can access the data. FSA is starting to develop dashboards for data visualisation and once this is done are hopeful that the industry will adopt this (or a similar equivalent) system or systems.

The system uses Linux Hyperledger as a fabric and because it was commissioned through a government framework contract the code etc. will be available for others to copy / use. For traceability and to maximise value there is the possibility of having data on the blockchain about the animal from its birth through its life course.

FSA continues to see the municipal government (Local Authorities or LAs) as key to delivery in the new regulatory system being developed. FSA is updating and improving the way in which it provides oversight of their performance. To this effect, FSA has developed a digitally enabled Balanced Scorecard: a tool which can use additional internal and external data to help provide a more rounded and more up-to date-picture of performance. It also enables them to more easily visualise performance data on a national basis. By providing LAs with access to a version of the tool, they will more easily be able to benchmark against other authorities which should provide a driver for service improvement.

Initial versions of the tool for FSA use and the tool for local authorities have been developed and are being tested with a view to making improvements. The FSA version will be ready early, so they can start using it to aid performance monitoring. The LA version will be tested further with a small number of LAs over the summer and then made available more widely in the autumn. FSA is also planning to develop and introduce mobile versions of the tool and anticipate these being ready by the end of 2018.

The UK has developed and implemented an approach whereby 2 central government departments (the Government Digital Service and Crown Commercial Service) have established a digital market place. <https://www.digitalmarketplace.service.gov.uk/> It's a sort of 'one stop shop' for all public sector organisations (central govt, devolved administrations, local authorities/councils), where they can find a wide range of digital/data services. It's designed to increase standardisation, interoperability, economies of scale and realise efficiencies. The 'sweetener' for organisations that are obliged to buy through the market place is that all of the suppliers are pre-approved. Commercial organisations apply to participate via a number of distinct commercial frameworks, each designed to meet particular needs (e.g. an individual or company, selling specific skills or the provision of a particular service). The vetting/due diligence/risk assessment is undertaken centrally.

#### **4.3.4 Critical Success Factors, Lessons Learned and Future Direction**

FSA have been running the blockchain POC in live for over 2 months and there has been a good data match between the blockchain data and FSA's historical data collection system. FSA plans to extend the pilot to a further 5 plants over the coming months with the pilot ending in the summer.

FSA is working with the professions (environmental health and trading standards) and various bodies that develop standards. In addition, the FSA is undertaking scoping for possible partnerships with universities to develop work stream that are looking at skills and competencies required to deliver on the ROF program. These may include the ability to use data, systems audits, visual inspections.

Regulators continue to be uncomfortable with endorsing the private sector as a paragon of virtues, as they see this as regulatory capture. Burden of proof that would be required to demonstrate the value of innovative approaches and technologies. In addition, it is important to gauge perceptions of citizens and consumers. In this regard, FSA is planning an extensive program of engagement of consumers.

## 4.3 UK Drinking Water Inspectorate

### 4.3.1 Introduction and Background

The UK Drinking Water Inspectorate (DWI) was formed in 1990 to provide independent reassurance that public water supplies in England and Wales are safe and drinking water quality is acceptable to consumers.

The main Drinking Water Inspectorate activities are as follows:

- Technical audit of water companies covering the operating practices of water companies;
- Assessment of water company sampling programmes and results;
- Assessment of incidents potentially affecting drinking water quality or sufficiency;
- Handling enquiries from the public;
- Investigation of consumer complaints about drinking water quality;
- Agreeing and managing water company programmes for improving drinking water quality including the Inspectorate's input into Ofwat periodic review of water prices;
- Enforcement activities;
- Management of the Inspectorate's scientific evidence and Defra's water quality and health research programme;
- Management of Product approvals;
- Management of industry data;
- Oversight of local authority enforcement of regulations for private water supplies.

### 4.3.2 Innovation Motivating Factors

DWI observed that, while mean zonal compliance, (a measure of compliance against 39 parameters averaged over water supply zones), in England and Wales stood at 99.96% in 2016 and this was vastly better than 20 years earlier, performance had reached a “plateau” over the last dozen years. Compliance is a statutory requirement of the companies and the UK and to incentivise anything less than 100% would not be compliant with the duties set out in law. The financial regulator for this sector therefore required 100% compliance and the financial implications for non-compliance was significant. As the financial penalties for companies were significant, strategies were employed to narrow the margin of non-compliance by seeking to focus on easy wins rather than those failures which were of a greater importance to the consumer but harder to solve. Examples included increasing sample numbers of parameters unlikely to fail and consequently increasing the percentage compliance without the need to reduce the number of failures, or, increasing flushing activity to reduce the chance of detecting metal failures in a zone, which has a disproportionate effect upon the MZC calculation, (since the metric is an average of all zones rather than an overall percentage). DWI was keen to change the approach and focus more on changing behaviors. The intent was to focus companies on outcomes that affect consumer

confidence and their health and safety rather than focusing on compliance statistics. In addition to compliance, there were 511 incidents in 2016 of which 184 were more serious and required further investigation. These incidents often harm consumer confidence when they receive discoloured water, or water with an unacceptable taste and odour, or they have been asked to take action such as boiling or not to use their water. Considering these together with compliance presents a wider approach in analysing what went wrong in each of these cases to focus on future risk mitigation.

### 4.3.3 Innovative Approaches

Two new drinking water quality measures were introduced: The first, The Compliance Risk Index (CRI) allows companies to move away from the current monitoring programme (based on sample numbers) to a risk based monitoring methodology to assess compliance. The second, The Event Risk Index (ERI), allows companies to move away from the current event response categorisation to a risk based methodology to assess consumer impact of events and promote proactive risk mitigation.

CRI is a measure designed to illustrate the risk arising from treated water compliance failures and follows the principles of “better regulation” to scrutinise company performance on the basis of their risk of failing to meet the requirements of the Regulations.

The following outlines the broad principles of the CRI measure.

- the significance of the parameter failing the standards in the Regulations (the Parameter score)
- the cause of the failure; the manner of the investigation of the failure by the company; and any mitigation put in place by the company (the Assessment score)
- the location of the failure within the supply system taking into account the proportion of the company’s consumers affected (the Impact score).

Compliance failures for different parameters do not pose equal risk to consumers. The standards in the regulations are based on different criteria: whilst some are set on a human health basis, others are based on aesthetic concerns, as indicators or for other reasons. This means that the risk posed from non-compliance with a parameter standard varies depending on the reason for the standard. The CRI Parameter score reflects this difference and scores determined for each as follows:

<b>Basis for standard</b>	<b>Score</b>
Health Risk	5
Health Risk Indicator	4

Aesthetic	3
Regulatory Impact	2
Non Health Risk Indicator	1

All compliance failures are assessed to ensure that the wellbeing and interests of consumers were protected by best practice in management of compliance failures. Obviously, a well-managed compliance failure with appropriate and speedy mitigation action poses a lower risk to consumers. The DWI also considers the root cause of the failure and whether the company’s actions led to or increased the likelihood of the failure, and whether further remedial action is necessary.

Therefore, the DWI Inspector’s assessment has been assigned a score for CRI shown below:

<b>DWI Inspector assessment</b>	<b>Score</b>
Enforce	5
Covered by legal instrument	4
Enforcement considered	4
Recommendations made	3
Suggestions made	2
Satisfactory investigation did not identify	1
Trivial	1
Unlikely to recur	1
Incorrect data	0
Outside operational limits	0

The impact score varies depending upon where in the supply chain the failure occurs:

- For company assets this impact element relates to the size of the asset (output of water treatment works and capacity of service reservoirs).
- For failures occurring in water supply zones (WSZ) the impact will tend to relate to the size of the whole zone. The impact will therefore default to the population of the whole WSZ.
- ERI like CRI is a measure designed to illustrate the risk arising from water quality events and also follows the principles of “better regulation” to scrutinise companies on the basis of their risk of failing to meet the requirements of the regulations. It uses the same broad principles of CRI where reported events are assessed to ensure that the wellbeing and interests of consumers were protected by best practice in management of events (including mitigation of the impacts and recovery). Obviously, a well-managed event with appropriate

and speedy mitigation action poses a lower risk to consumers. The DWI also considers the root cause of the event and whether the company's actions led to or increased the likelihood of the event, and whether further remedial action is necessary.

#### **4.3.4 Critical Success Factors, Lessons Learned and Future Direction**

The methodology took nearly 3 years to develop and implement. There has been a wide acceptance of the methodology by the utility companies preferring these measures over MZC as well as the acceptance and alignment of the new metrics with the financial regulator. They have been able to use the methodology as a more objective and evidence-based means to establish priorities for their companies and companies do not feel unfairly penalised by the methodology of MZC. They have also been able to negotiate the financial framework with financial regulators reducing potential financial harm as they are focused on more risk prevention.

DWI has introduced a novel scheme that invites companies to join its inspections team and work on field inspections for a period of 6 months. This allows for company employees participating in the program to understand the culture and dynamics of the inspection process which they can take and educate and build awareness within their companies but also across the industry.

Measurements may be taken at the time of sampling with the use of such equipment as is suitable for the purpose. For instance, monitoring at water treatment plants, continuous sampling and analysis of Ph, turbidity oxygen content, flouride are permitted but should be subject to a system of quality control to an appropriate standard to allow for the use of these data sources in lieu of sampling. DWI is currently working with the water industry body to determine the framework for this methodology.

## 4.4 Other Case Studies

### 4.4.1 Fisheries Queensland

Fisheries Queensland manages the sustainability and allocation of fisheries and forestry resources for all Queenslanders. This is vital to create the basis for profitable businesses and enjoyable recreational fishing experiences for locals and visitors. The organization ensures fisheries remain sustainable and productive by monitoring, determining and controlling access and development as needed; providing education and enforcing fishing regulations to promote equitable access to fisheries resources; maintaining supplies of state owned forest products and quarry materials to industry.

Queensland's commercial fishers operate regional businesses across more than 7000 kilometres of coastline, providing employment and fresh seafood to their local communities and overseas. Effective monitoring of these commercial fisheries is vital to ensuring healthy fish stocks that will support thousands of Queensland jobs, but current approaches are costly, time consuming, and prone to inaccuracies. Fisheries Queensland, through the *Sustainable Fisheries Strategy 2017-2027*, is committed to improving monitoring and research for fisheries management. Currently, most of the agency's monitoring data comes from commercial fishers filling out paper logbooks and calling an automated voice recognition system to report on quota. These approaches are costly and time consuming for government, but also place considerable burden on the fishers. The cutting-edge solutions that Fisheries Queensland are exploring have the potential to almost completely eliminate this burden, while providing with accurate, real-time information needed to effectively manage Queensland's fisheries.

Through the Advance Queensland Small Business Innovation Research (SBIR) program, the agency is working with two innovative start-ups to develop cutting-edge systems which can track fishing activity and location, as well as use cameras, sensors and machine learning to automatically recognise the types and quantities of fish caught and discarded.

### 4.4.2 German Federal Ministry of Transport and Digital Infrastructure

The Federal Ministry of Transport and Digital Infrastructure has established a digital test bed that allows the testing of innovations in the field of digitalization of transport. The Digital Motorway Test Bed was established together with the Free State of Bavaria, the German Association of the Automotive Industry (VDA) and the Association for Information Technology, Telecommunications and New Media (Bitkom).

The goals of the Digital Motorway Test Bed, which is a pilot study planned till 2020, include:

- Promoting innovation: Testing automated and connected vehicles under real life conditions
- Promoting research: Supporting selected research projects on intelligent transport and digital infrastructure conducted by universities and research institutions
- Creating acceptance: Increasing societal acceptance and visibility of automated and connected vehicles by testing systems in real traffic situations
- Infrastructure: Establishing guidance for developing appropriate and forward-looking infrastructure to support automated and connected driving

The test bed focuses on two thematic areas:

### **1. Automated and connected driving**

The bed provides opportunities for testing and further developing new technologies by automotive industry, suppliers, telecommunications companies and research institutes. The tests are carried out in real traffic on the A9 motorway. Tests are carried out at the responsibility of users. All measures are based on the applicable legal framework.

### **2. Intelligent infrastructure**

In order to tap the full potential of the digitalized road, different intelligent infrastructure measures are to be trialed and refined on the Digital Motorway Test Bed. Bluetooth sensors have been installed for the detection of incidents and to calculate journey times. Infrastructure also includes warning of road works and improved monitoring of the traffic situation by making use of vehicle data. Another feature includes automatic and reliable detection of wrong-way drivers as a result of the establishment of telematics systems.

Additional infrastructure is being planned to provide relevant information for the overall assessment of the condition of structures, tools that allow section-based road ice forecasts using weather data and sensors and supplying information on the weather-related condition of roads.

In order to ensure ideal conditions on the Digital Test Bed, basic infrastructure facilities are provided for use by all companies and research establishments:

- ***High-speed mobile communications coverage:*** Short transmission times with high speeds in an infrastructure-based network

- **Communication via vehicle Wi-Fi:** Direct communication between vehicles via dedicated short-range Communication (DSRC) networks
- **Fast LAN connection:** Direct transmission of large amounts of user information via a central point of contact at selected locations of the Digital Test Bed
- **Mobility Data Marketplace as standardized interface:** Providing up-to-the-minute and high-precision traffic information via a standardized interface
- **Highly precise map:** Providing a high-precision reference map of the area with an accuracy of +/- 2 cm and, in doing so, supporting users' own quality assurance efforts related to map material

#### 4.4.3 Finnish Chemicals and Safety Agency (Tukes) – Finland

[The Seveso-III-Directive \(2012/18/EU\)](#) aims at the prevention of major accidents involving dangerous substances. Tukes is a competent Seveso authority in Finland and conducts Seveso inspections across establishments subject to the Directive in Finland. In addition to about 325 Seveso establishments, there are about 370 establishments that Tukes conducts inspections at, based on Finnish legislation.

The inspection, which normally takes a day, consists of auditing e.g. the process safety management system, safety actions, accident scenarios, risk assessment and management of change. The site visit and discussions with workers are an important part of the inspection in order to compare the practices to the plans.

##### **Case study of Skype inspections**

In 2017-18, Tukes established a project with the main aim of foreseeing what inspection would look like in 10 or 20 years. Additionally, short term development (e.g. inspection reports, co-inspections with other authorities, inspections themes, and practices in “self inspections”) were done. Tukes tested different types of inspections such as consolidated inspections across a group of companies (Concern inspection) and Skype inspections. The feedback both from operators and other authorities has been positive and encouraging. In the future, Tukes has plans to further digitize its Seveso inspections.

The first Seveso inspection with Skype was organized in September 2017. In addition to the operator and Tukes, the environmental and OSH authorities participated in the audit. Due to remote inspection, authorities didn't have to travel to site and saved working time. Tukes sent the agenda with several questions to the operator in advance. More time was spent on preparing the material than normal inspection, but writing the report was faster than normal.

The inspection of a chemical plant normally takes all day, but the Skype inspection took only three hours. It was estimated, however that the total workload in Skype inspection is not different from traditional inspection. The work of the Skype inspection is divided into several days and in that way, it helps to schedule other tasks.

The site visit (normally walking around the site) was discussed in advance but quite a successful solution was also found. Prior to the inspection, Tukes asked the operator to take several photos from the site, e.g. tanks, safety basins for tanks and pipelines. The location and time stamp of the pictures was marked on the site map to help validate the images. In the future it may be possible to have online-video from the site. Drones which are already in use in mining supervision in Tukes, may also be considered.

## 5. Conclusions and Recommendations

As part of its regulatory modernization agenda, Transport Canada (TC) commissioned Public Risk Management Institute (Prism Institute) to undertake a preliminary study that included a global scan of current practices in risk based regulatory delivery. This study is also an introductory action of the newly constituted Community of Practice (COP) on risk based regulatory delivery under the aegis of the Community of Federal Regulators (CFR). Canada's Budget 2018 directs government agencies to modernize its regulatory frameworks for catalyzing innovation across the economy and for regulations to accommodate emerging technologies and business models especially in high-potential sectors.

The objectives of the study involved identifying the current state of risk based regulatory delivery within the federal agencies and identify gaps and limitations. The objectives also include the identification of innovative approaches and methods being used by agencies globally and an assessment of their advantages and limitations leading to the development of a set of recommendations that TC and CFR could consider for implementation.

Conducted over two phases the study focused on sectors including food safety, transportation, technical safety, worker safety and occupational health, drinking water, biosecurity, chemical safety, energy, healthcare and environment. Due to constraints in time and budget, this phase of the study was limited in its jurisdictional and sectoral coverage including Ontario, British Columbia, United Kingdom, Germany, Australia, and Finland. Some of the material presented in the study have also been obtained from literature searches and a report from the [World Bank](#)<sup>4</sup>. However, these practices provide adequate knowledge and concepts to serve the objectives of the study.

Phase I of the study, which looked at the current state of risk based regulatory delivery, identified the following findings in themes including regulatory governance, regulatory delivery, and program implementation and change management. Some of the key findings include:

- Legislation was not considered as a barrier for risk-based approaches; however, was seen as a limiting factor for data sharing and addressing interconnected risks across jurisdictions
- There is a consistent lack of senior management accountability for the risk management role
- There is a lack of clear between corporate and regulatory risk management causing potential conflict between mandate and organizational risks
- Departments believe that they are inadequately staffed for current and future expectations especially in areas of risk-based approaches and innovative regulatory methods

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<sup>4</sup> World Bank, 2017: "Internet of Things – The New Government to Business Platform".



- There is a greater emphasis on transparency and reporting on regulatory performance
- Risk based decision making is constrained by lack of a dialogue on risk thresholds
- Largely qualitative methods used due to data and evidence limited to those collected through internal mechanisms (e.g., inspections) and constrained by regulatory barriers to sharing with other agencies and external sources
- In addition to data challenges, competency and resource capacity constrain agencies in applying formal risk assessment methods
- Despite the advantages of filling data gaps, most departments don't have any immediate plans or incentives to use innovative approaches for utilizing data through disruptive technologies possibly indicating lack of awareness and understanding of such technologies
- Despite increasing interconnectedness and interdependencies of risks, there is limited integration across risks, programs, sectors and departments; however, there appears to be a healthy dialogue between science and decision making within departments and agencies
- Contrary to most emerging international best practices, agencies continue to assume greater burden of responsibility indicating a lack of trust of the regulated
- Agencies continue to heavily impose an enforcement focused culture with very limited incentives for good performers
- Agencies, however, are keen to explore alternate regulatory oversight models and methods which provide them with flexibility and choices
- Lack of formal frameworks and support systems hamper agencies to engage internal and external stakeholders in communicating and managing change particularly in the context of disruption

Phase II of the study identified concepts and practices that are emerging and addressing some of the challenges and limitations identified above, through the work being done by progressive agencies in areas regulation development, regulatory delivery and implementation. Though the study covered modern practices in regulations, policies and directives the emphasis was more on regulatory delivery and implementation approaches. Specifically, the study revealed the following findings:

- Need for smart regulations, strategies and directives to provide broad strategic direction, flexibility and agility in responding to changes in the business environments and for implementing risk based regulatory delivery methods
- The use of alternate regulatory delivery models and methods to ensure that regulations are effectively delivered in ways that reduce burdens on business, save public money and properly protect citizens and communities
- Use of innovative/disruptive technologies and practices to develop reliable and trustworthy risk assessments and for decision support.

- Establishing strong public-private-academic partnerships and collaborative approaches operating in sandbox environments to test the role of disruptive innovations and technologies are setting the stage for a potential revolution in the regulatory delivery space.
- Focus on capacity building and communication strategies to understand and embrace change.

The UK Food Standards Agency is already working towards addressing the future of regulatory inspections by working with academic institutions in designing programs and curriculum focused on creating “future” inspectors. The UK Drinking Water Inspectorate has a “secondment” program for industry to allow its employees to take on roles as inspectors alongside their inspection team to understand the regulatory delivery environment and share knowledge and expertise.

Though the study was carried out over a short two-month period and was limited in its scope and coverage, the findings from the study provide enough knowledge to identify and develop a broad set of recommendations for Transport Canada and the CFR to consider particularly over the short and medium term for implementation. The recommendations can also be used by the Taskforce created under Canada’s Cabinet Directive to implement the commitments made in the Budget 2018 to further their objectives and goals. It is recommended that TC and CFR consider the following two areas of focus:

#### **1.4.1 Phased Pilot Study**

##### 1.4.1.1 Phase I – Risk Assessment

In the immediate or short term, it is recommended that TC design and execute a risk assessment study that is primarily focused on utilizing innovative/disruptive practices and technologies with the following objectives as a minimum:

- Evaluate the feasibility of disruptive technologies for data collection (e.g., Internet of Things), data transmission (Blockchain), and data analysis (e.g., AI/Machine Learning)
- Examine the impact of these technologies in addressing uncertainties and limitations with traditional risk assessment methods and models
- Evaluate the policy/regulatory challenges and opportunities for addressing interconnected and interdependent risks such as inter-jurisdictional barriers, procurement, and constraints for scaled implementation
- Evaluate the socio-economic implications such stakeholder awareness and acceptance, impacts on future business models, and other related factors
- Identify other factors such as capacity and competency needs within the agencies, knowledge tools opportunities for further research.

For the purposes of designing and executing the pilot, the following steps should be considered:

- Identify and select a priority sector and a lead agency; it is recommended to select a sector impacting multiple regulatory domains/agencies to test interconnected and interdependent risks (e.g., safe cross-border transport of products such as food or hazardous materials)
- Identify a facilitating coordinator such as the CFR's COP
- Seek and engage partners for study (private, academic and other regulators including examining the possibility of international partners)
- Identify and design sandbox environments for undertaking pilot studies

Phase II of the pilot can focus on the review and examination of alternate regulatory delivery models including described in this report. This phase can either be initiated in parallel with Phase I, or at completion of Phase I. The two phases would help establish program design and implementation frameworks required for scaling. The scaled implementation of the programs can continue to be carried out in the sandbox environments or executed directly in real-life conditions.

#### **1.4.2 Knowledge Sharing and Global Networking**

In addition to continuing current knowledge sharing strategies and plans established by the CFR, it is recommended that the CFR coordinate the participation of departments and agencies in international initiatives and networks. In particular, it is recommended that CFR participate in the newly formed International Network for Regulatory Delivery (global network of experts on modern regulatory delivery) established by the UK Department of Business, Industrial and Energy Strategy (BEIS) with the UK Government and facilitated by University of Oxford. Other networks including existing federal-provincial-territorial committees such as the Canada's National-Provincial Advisory Committee (NPSAC) coordinated by Standards Council of Canada, the OECD Network of Economic Regulators are also working on similar areas of interest.

In addition, it is recommended for CFR and its member agencies also use their sector-specific networks to further examine opportunities for coordinated research and engagement in regulatory delivery pilots. Existing regulatory networks in health, environment, food security, civil aviation and those established through multi-lateral initiatives such as Trade Agreements provide platforms for knowledge sharing and common pilots.

# Annexes

## Annex I - Survey Methodology – Phase I (Online Questionnaire)

### I. Regulatory Context

1. Name of the agency
2. Type of agency (Government, Crown, Delegated Authority, Other)
3. Regulated Sector (e.g., health, environment, food etc.)
4. Legislative references (e.g., names of regulations etc.)
5. Does the legislation require/support risk-based regulatory delivery?

### II. Governance

6. Is there direct accountability for public/regulatory risk management at the senior management level (e.g., Chief Risk Officer etc.)?
7. Is there a risk management policy?
8. Is there clear separation between corporate (enterprise) risk management and regulatory/public/mandate risk management in the policy?
9. Is a national or an international risk management standard referenced for guidance in the policy or related documents?
10. If so, what?
11. Does the agency have its own risk management or risk-based decision-making framework?
12. Has the agency established risk thresholds, acceptable levels of risk, and/or risk-benefit-cost trade off points?
13. Does the agency used as low as reasonably practicable (ALARP) principles for establishing thresholds?
14. Does the agency measure and report on the performance of its decision-making framework?
15. Does the agency undertake external peer reviews and validations of all or parts of its risk-based decision-making framework?
16. Is the agency adequately resourced and staffed to effectively implement and maintain its risk-based decision-making framework?

### III. Risk Assessment

17. Does the agency use risk assessment to establish its strategic regulatory priorities?
18. Does the agency use risk assessment to allocate its resources?

19. Has the agency adopted national/international standards for risk assessment?
20. Does the agency use quantitative approaches to risk assessment (never, always, sometimes)?
21. Are the risk assessments evidence (data, observations, tests, etc.) based (50% or greater)?
22. Are the risk assessments based on the agency's own data (inspections, incidents etc.)?
23. Does the agency proactively obtain data from other agencies (never, always, sometimes)?
24. Does the agency proactively obtain data from external stakeholders (never, always, sometimes)?
25. Does the agency use or plan to use technologies (Internet of Things, AI, Block Chain, behavioral economics, crowdsourcing etc.) for data gathering within the next 1-2 years?
26. Are risk assessments integrated internally (if agency has multiple lines of businesses or mandates)?
27. Are risk assessments integrated externally (with other overlapping organizations)?

#### **IV. Risk Management/Decision Making**

28. Are decisions outcome (risk thresholds etc.) focused (never, always, sometimes)?
29. Does the agency undertake formal options analysis to determine appropriate risk management decisions (never, always, sometimes)?
30. Are costs to the agency factored into the risk-based decisions (never, always, sometimes)?
31. Are costs to the "regulated" factored into the risk-based decisions (never, always, sometimes)?
32. Are factors (public perception, political climate, trade agreements etc.) other than risks and costs factored into decisions (never, always, sometimes)?
33. Is there a risk management-risk assessment feedback mechanism?
34. Does the agency assume a burden of responsibility of managing risks/ensuring compliance through its decisions (low, medium, high)?
35. Are decisions compliance and enforcement focused (low, medium, high)?
36. Are the "regulated" incented for performance on the basis of risk (never, always, sometimes)?
37. Are alternate regulatory delivery models (regulated self-assurance, third-party, fee recovery, multi-agency coordinated inspections etc.) being used or planned within the next 1-2 years?

#### **V. Risk Communication and Change Management**

38. Has the agency established formal procedures for communicating (and consulting) on its risk-based decision-making framework internally?

39. Has the agency established formal procedures for communicating (and consulting) on its risk-based decision-making framework externally?
40. Does the agency proactively engage external experts through formal advisory groups/panels to inform its risk-based decision-making framework?
41. Has the agency developed a change management framework to assist its internal stakeholders?
42. Does the agency experience challenges in influencing change to a risk-based decision-making framework (low, medium, high)?

## Annex II - Survey Methodology – Phase II (Focused Interviews)

Agencies identified through already conducted research, the survey conducted in Part I and other informational means with well-established and successful risk-based decision-making frameworks will be contacted through interviews to gather detailed information on their delivery models, risk frameworks and associated risk assessment/management methodologies, and program implementation. Specifically, the following elements at a minimum will be covered as part of the interview process.

### 1. Regulatory Delivery Models

- Type of delivery models (conventional, alternate)
- Drivers for alternate delivery mechanisms
- Policy/legislative basis for alternate delivery
- Governance structures
- Stakeholder consultation approaches
- Public/stakeholder perception and responses to alternate delivery
- Internal responses and perceptions, change management learnings
- Measurement methods
- Approaches and challenges in Risk acceptability/threshold determinations
- Critical success factors and learnings
- Cost recovery, incentives, business value propositions
- Political climates and decision-making culture

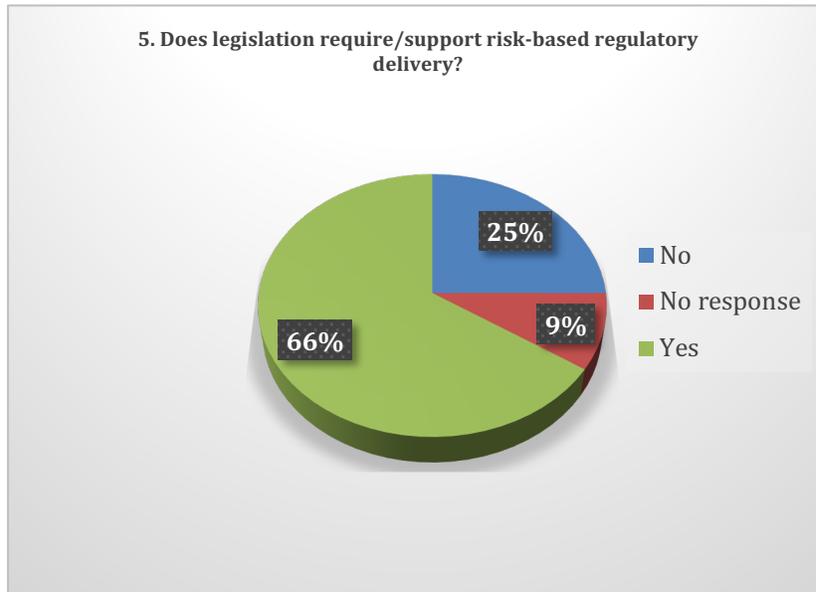
### 2. Risk Frameworks (Risk assessment/management methodologies)

- Adopted national/international standards
- Description of risk-based decision-making frameworks
- Risk assessment methods and techniques used
- Methods for estimating, communicating and managing uncertainty in risk assessments
- Evidence/data gathering methods
- Use of smart technologies and innovative methods for evidence gathering
- Role of the “regulated” in the evidence gathering
- Data privacy, integrity, protection and related issues when using smart technologies
- Built-in incentives for data provision, technology deployment
- Involvement of external parties in design and development
- External peer reviews, consultations and feedback mechanisms

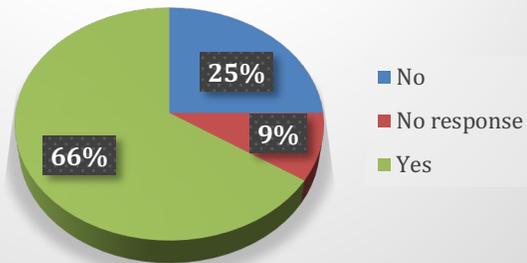
### 3. Program Implementation

- Organizational/governance structures
- Roles and responsibilities
- Policies and guidelines
- Change management
- Internal Capacity building, resource allocation, and funding models
- External capacity building, education, and future planning
- Types of pilots/sandbox environments used for testing new technologies, ideas and innovations
- Public-private-academic partnership models
- Procurement of services (challenges and innovations)
- Methods for scaling from pilots to full implementation
- Performance measurement and oversight

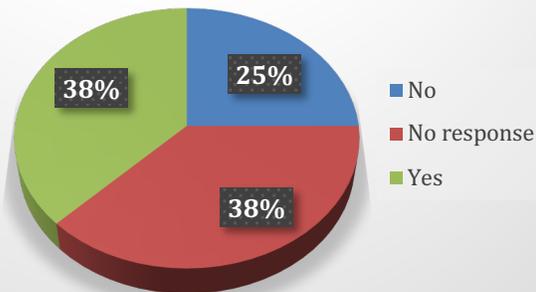
## Annex III – Results of Phase I Survey



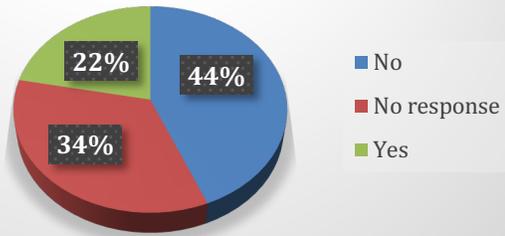
7 Does your organization have a risk management policy?



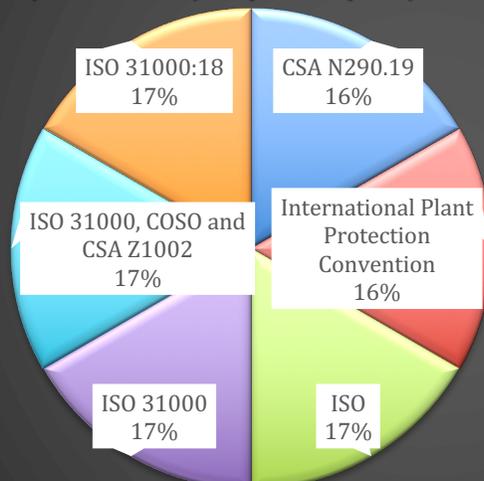
8. Is there a clear separation between corporate (enterprise) risk management and regulatory/public/mandate risk management in the policy?



9. Is a national or an international risk management standard referenced for guidance in the policy or related documents?

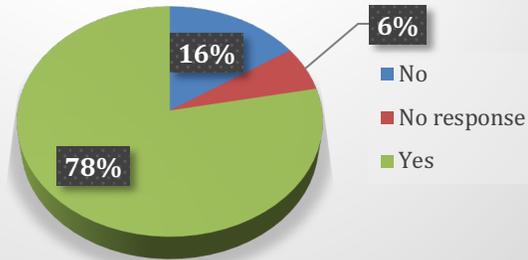


10. If you selected yes, please specify:

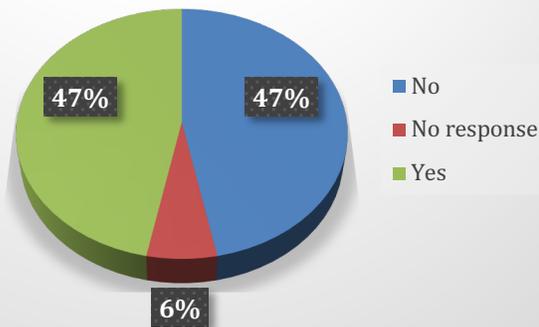


- ▣ CSA N290.19
- ▣ International Plant Protection Convention
- ▣ ISO
- ▣ ISO 31000
- ▣ ISO 31000, COSO and CSA Z1002
- ▣ ISO 31000:18
- ▣ (blank)

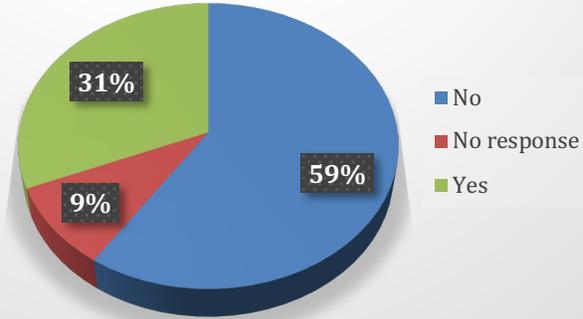
**11. Does your organization have its own risk management or risk-based decision-making framework?**



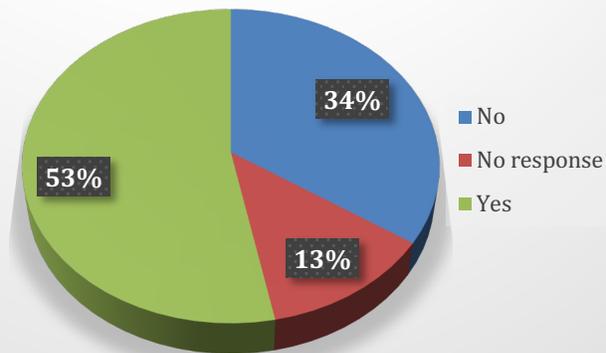
**12. Has your organization established risk thresholds, acceptable levels of risk, and/or risk-benefit-cost trade off points**



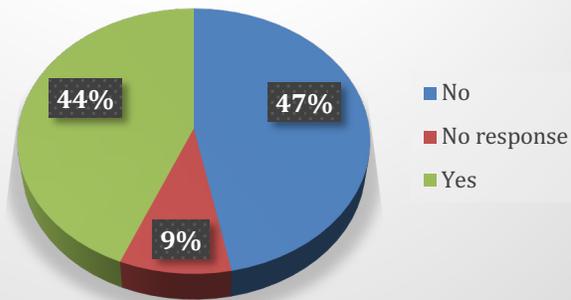
**13. Does your organization use as low as reasonably practicable (ALARP) principles for establishing thresholds**



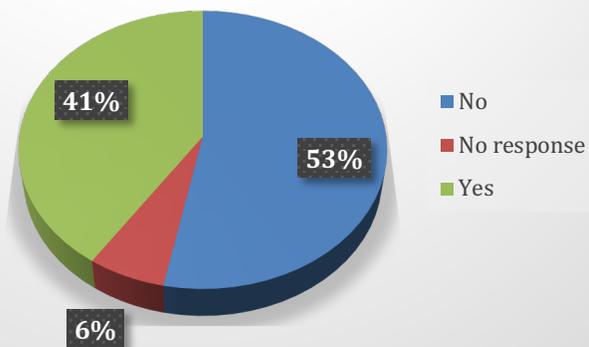
**14. Does your organization measure and report on the performance of its decision-making framework?**



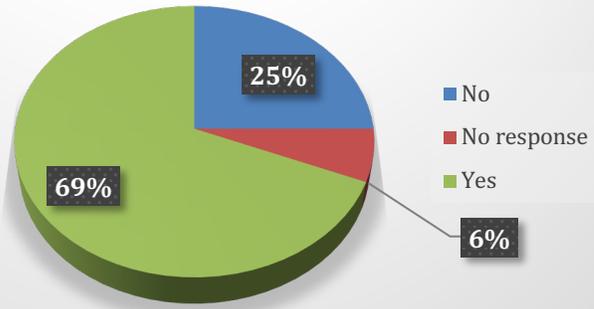
**15. Does your organization undertake external peer reviews and validations of all or parts of its risk-based decision-making framework?**



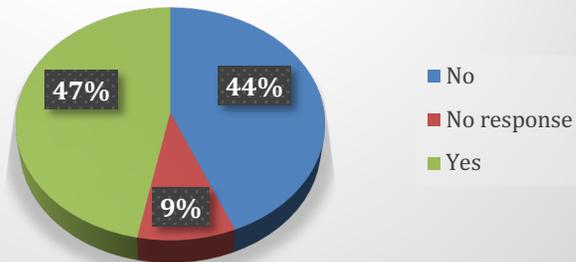
**16. Is your organization adequately resourced and staffed to effectively implement and maintain its risk-based decision-making framework?**



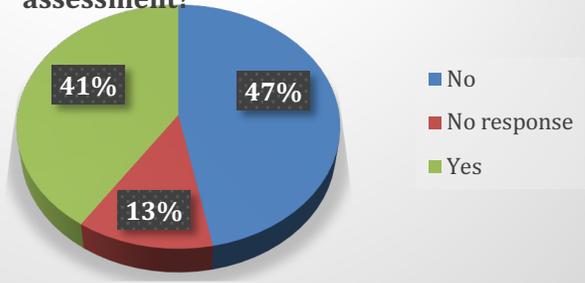
17. Does your organization use risk assessment to establish its strategic regulatory priorities?



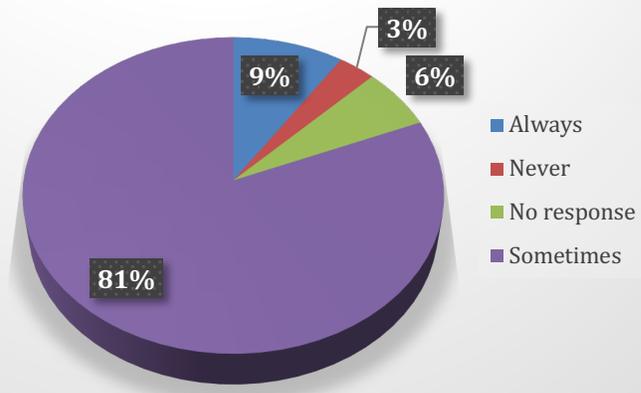
18. Does your organization use risk assessment to allocate its resources?



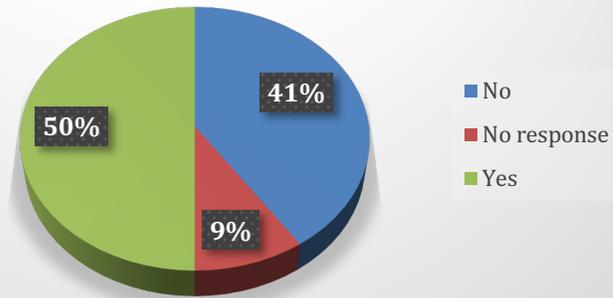
**19. Has your organization adopted national/international standards for risk assessment?**



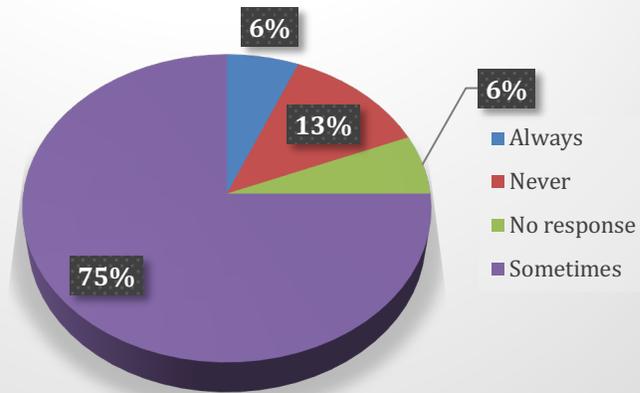
**20. Does your organization use quantitative approaches to risk assessment?**



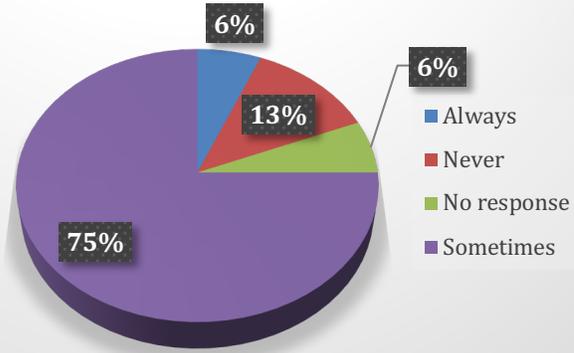
**21. Are the risk assessments evidence (data, observations, tests, etc.) based (50% or greater)?**



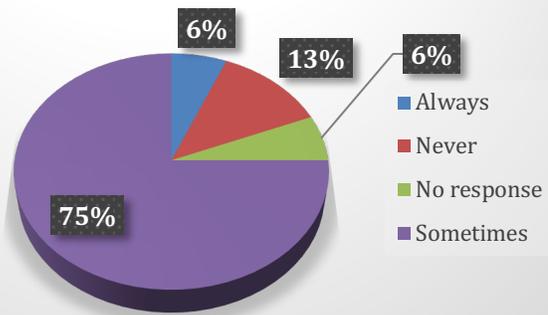
**22. Are the risk assessments based on the organization's own data (inspections, incidents etc.)?**



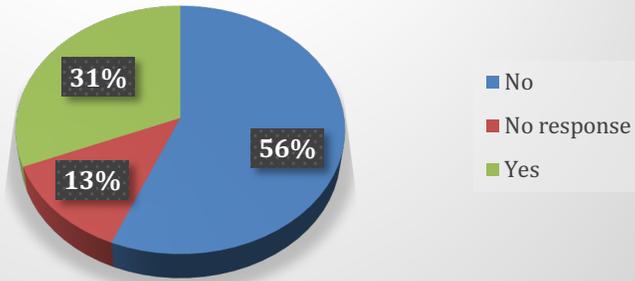
**23. Does your organization proactively obtain data from other agencies?**



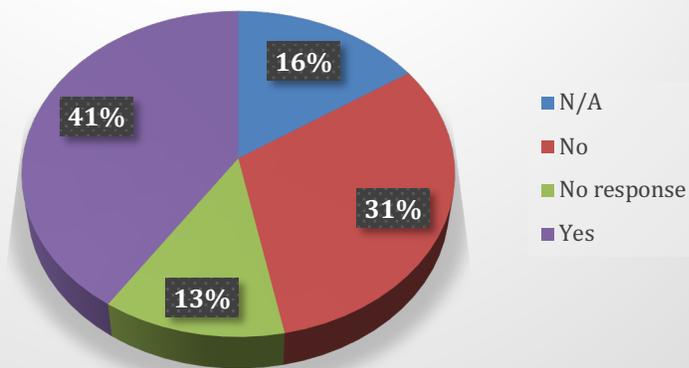
**24. Does your organization proactively obtain data from external stakeholders?**



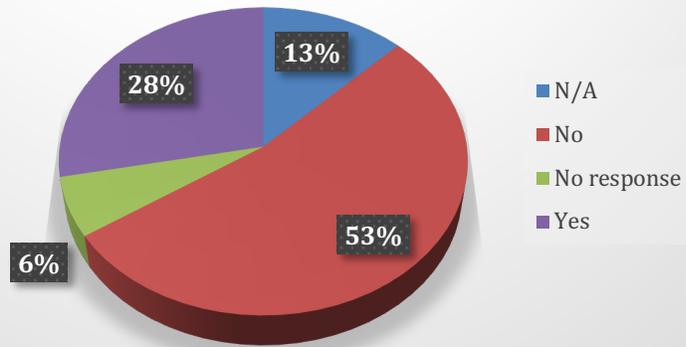
**25. Does your organization use or plan to use technologies (Internet of things, artificial intelligence, blockchain, behavioral economics, crowdsourcing etc.) for data gathering within the next 1-2 years?**



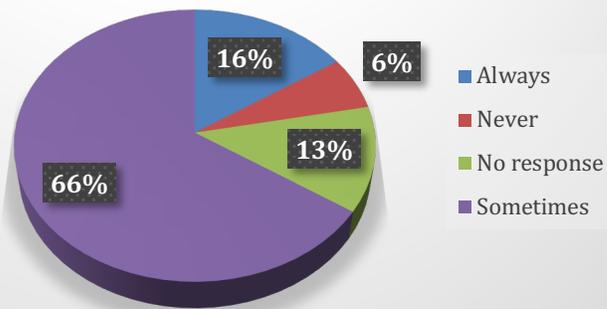
**26. Are risk assessments integrated internally (if agency has multiple lines of businesses or mandates)?**

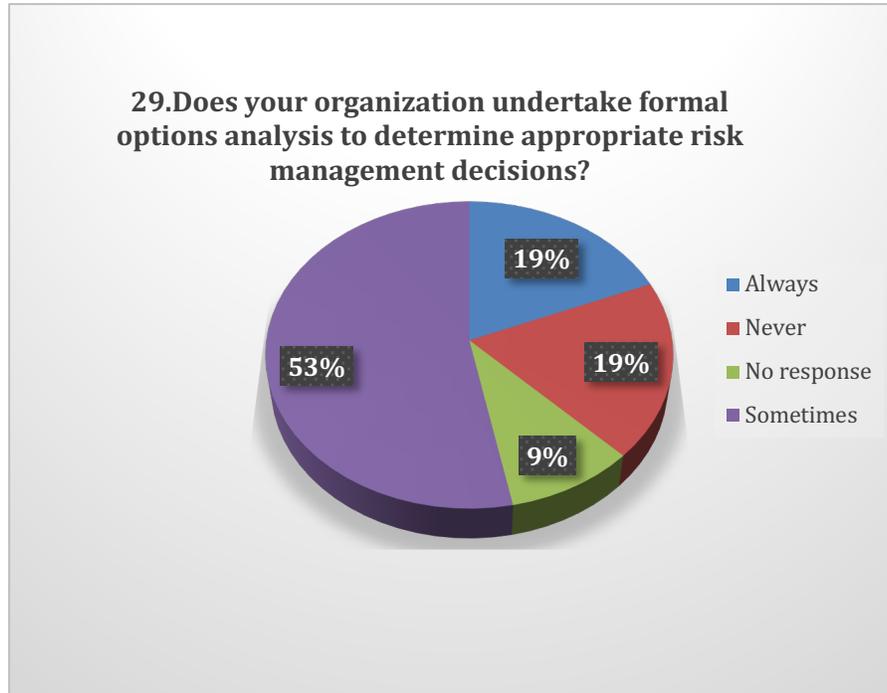


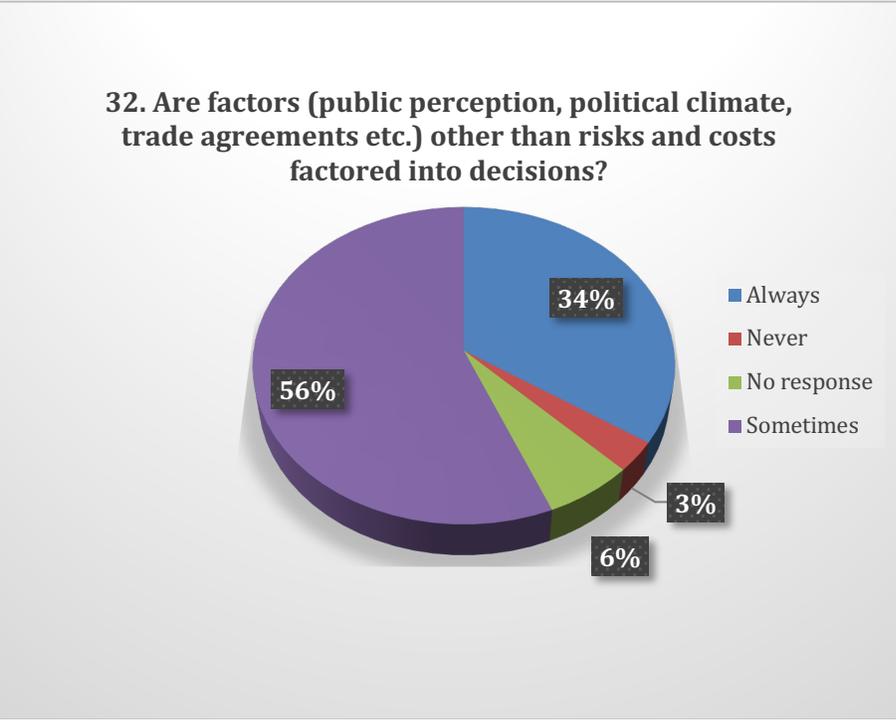
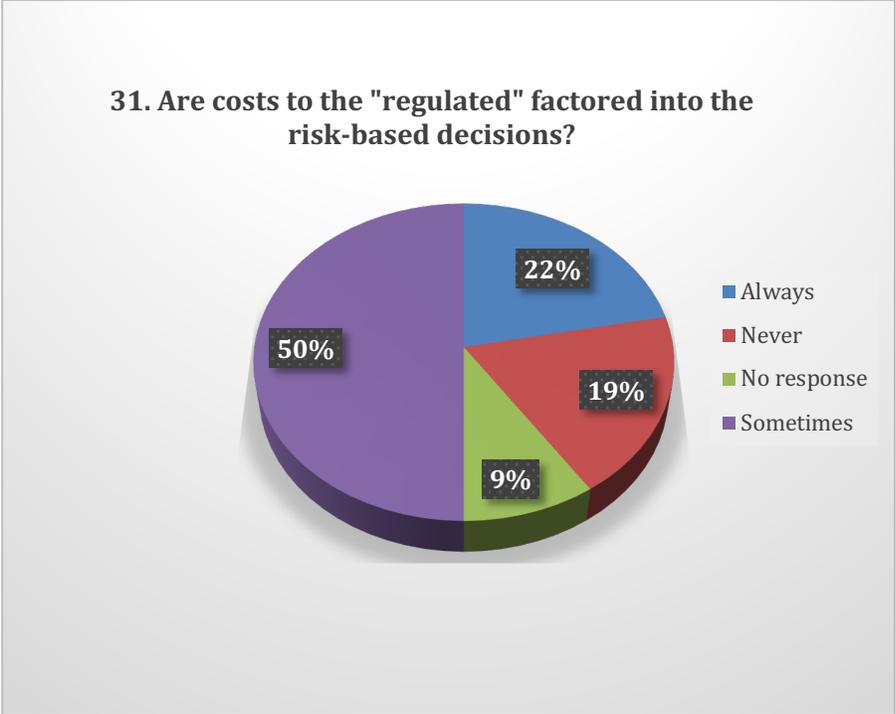
**27. Are risk assessments integrated externally (with other overlapping organizations)?**



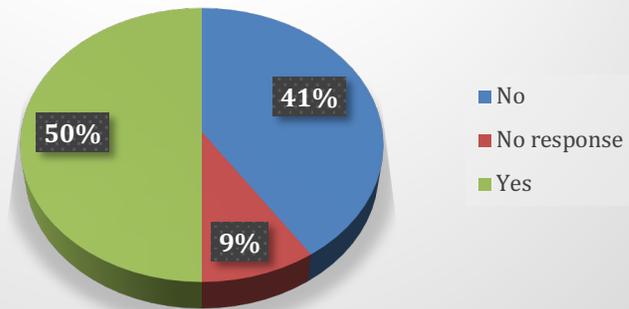
**28. Are decisions outcome (risk thresholds etc.) focused?**



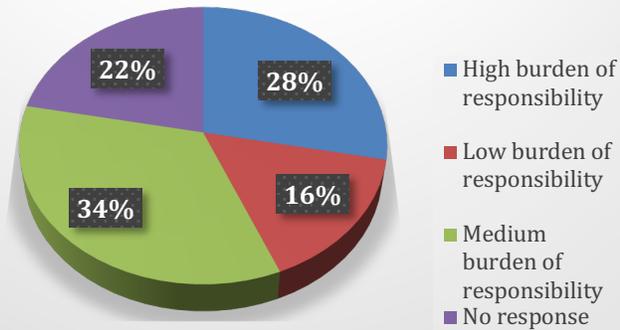




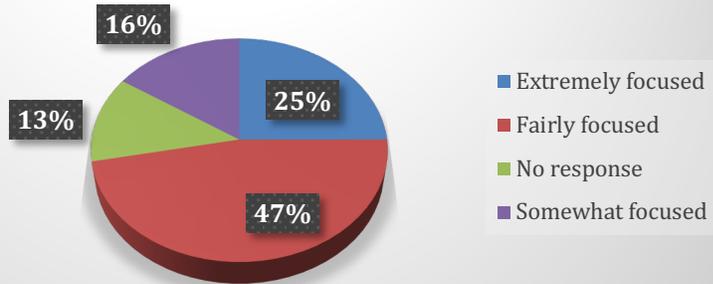
**33. Is there a risk management-risk assessment feedback mechanism?**



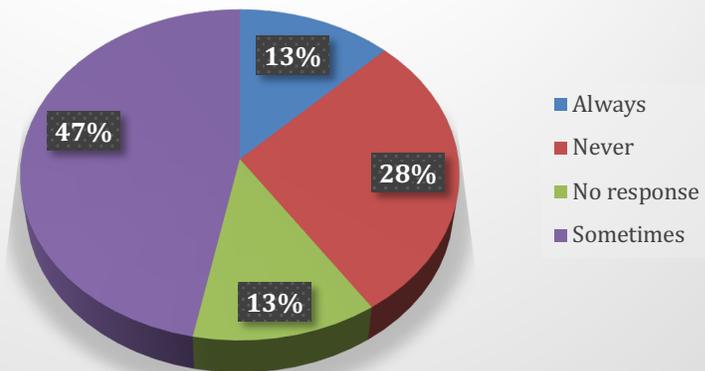
**34. Does your organization assume a burden of responsibility of managing risks/ensuring compliance through its decisions?**



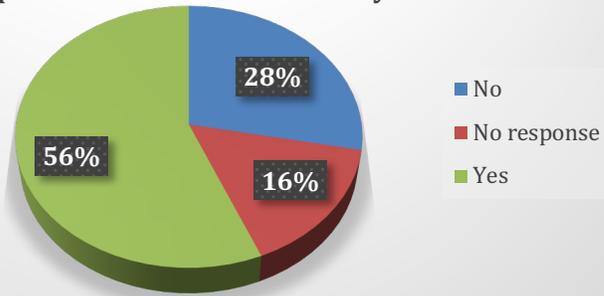
**35. Are decisions compliance and enforcement focused?**



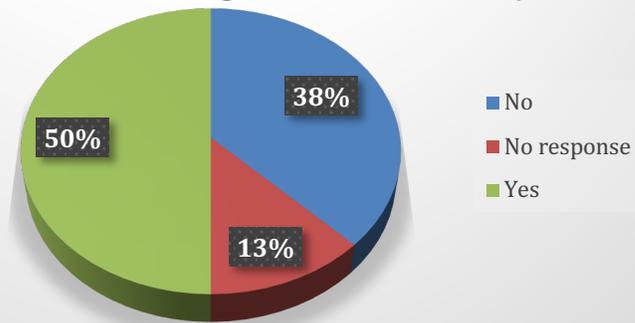
**36. Are the "regulated" incented for performance on the basis of risk?**



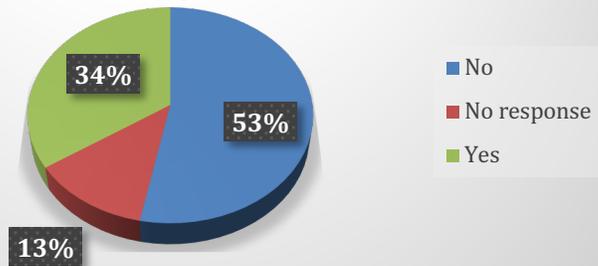
**37. Are alternate regulatory delivery models (regulated self-assurance, third-party, fee recovery, multi-agency coordinated inspections etc.) being used or planned within the next 1-2 years?**



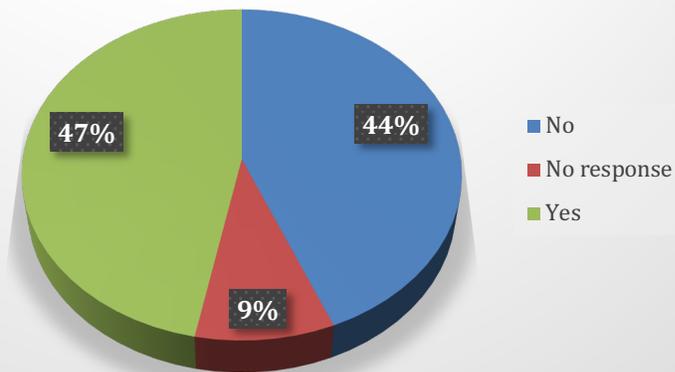
**38. Has your organization established formal procedures for communicating (and consulting) on its risk-based decision-making framework internally?**



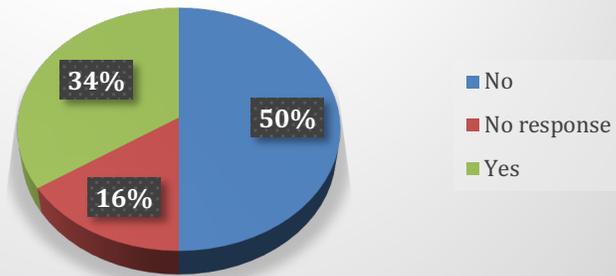
**39. Has your organization established formal procedures for communicating (and consulting) on its risk-based decision-making framework externally?**



**40. Does your organization proactively engage external experts through formal advisory groups/panels to inform its risk-based decision-making framework?**



**41. Has your organization developed a change management framework to assist its internal stakeholders?**



**42. Does your organization experience challenges in influencing change to a risk-based decision-making framework?**

