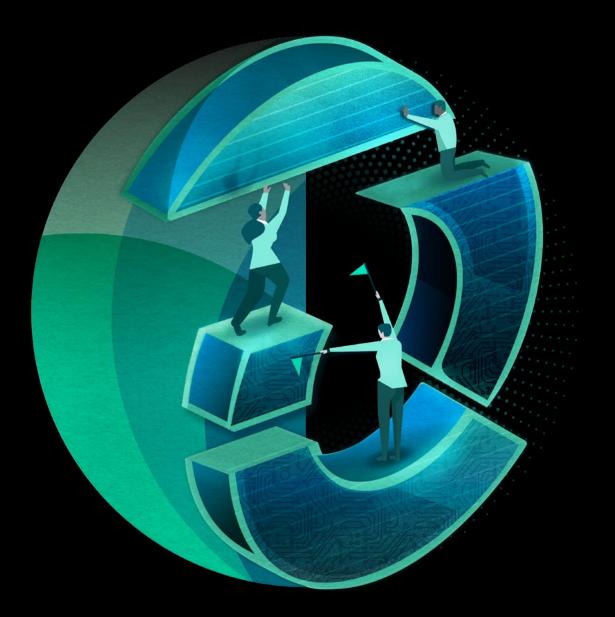
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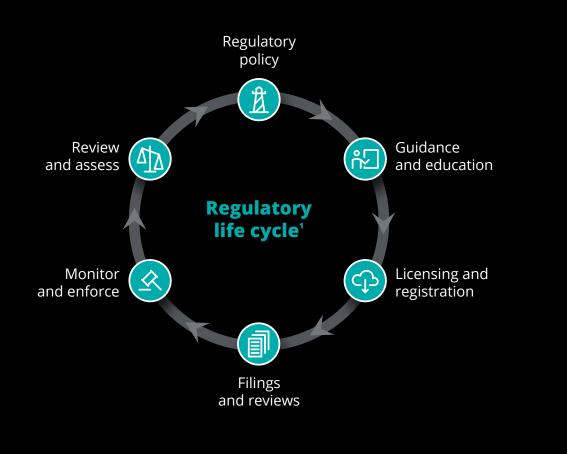
Regulatory recharge: Modernization in an age of disruption

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By the numbers across Canada<sup>2</sup>

**Regulators:** 

**500**+

Core government entities:

entities: regulators: 160+ 150+

Independent

Self-governing professional bodies:



# Introduction

# Regulation is a core function of government and key to the smooth functioning of modern, complex societies.

Effective regulation means more competitive and prosperous economies, safer and healthier populations, fairer treatment of workers and customers, protection of vital systems and infrastructure, progress in the fight against climate change—and greater public confidence in the capacity of government to get things right.

The regulatory function involves establishing and ensuring compliance with rules that give effect to more general requirements laid out in legislation. Regulatory mandates can involve oversight of massive undertakings or entire sectors or be surgically focused on permitting a particular activity. A wide range of departments, ministries, and agencies perform regulatory roles: some of Canada's 500 regulators report directly to ministers; others are more autonomous but still sit within government; and still others are self-governing professional bodies.

It's getting harder to be a regulator. Many of the challenges that regulators face aren't new, but they've been amplified in recent years by many factors, including the pandemic. There are, however, emerging practices and innovations that create openings not only for meeting those challenges, but also for transforming how the very goals of regulation are achieved.

This is a moment when regulatory leaders have an opportunity to rethink and reshape how they deliver the critical mandates given to them by elected representatives and thereby maximize their contribution to the well-being of their fellow Canadians. The need to act is urgent.

This document surveys the biggest pressures on regulators and some of the most effective strategies and tools available for building more agile, engaged, and resilient organizations. It isn't intended to be exhaustive, but rather to offer information and ideas that forward-thinking leaders can draw on. We hope it will help spark some important conversations and fuel discussions that are already under way. And we welcome your feedback.





# The big challenges

### Across Canada and around the world, regulators are faced with six big, intersecting challenges:

costs to business, public expectations of stronger protection, demands for greater equity, accelerating technological change, resource constraints, and organizational culture and talent issues.

Let's examine each in more detail.

Costs to business

Regulations can apply to for-profit corporations, public sector and not-for profit organizations, and individuals. That said, their focus is usually on creating the frameworks within which businesses operate. And businesses have long expressed concern over what is sometimes called the regulatory burden: the cumulative number of rules that industry has to know and follow.

The way such concerns are conceptualized and expressed is changing. In an era when there's widespread recognition of the need to cut carbon emissions, ensure that medical products are safe, and deal with the most egregious online content, businesses are talking less about the simple metric of the number of rules.

Canada ranked No. 53 globally on the World Economic Forum's "burden of government regulation" indicator.<sup>3</sup>

## (命)

Instead, they're concentrating on what they see as unnecessarily complicated and rigid requirements, slow and unpredictable approval processes, and a lack of coordination among regulators. All this, they say, is exacerbated by "us-and-them" attitudes that make communication and consultation with regulators difficult and frustrate efforts to ensure that rules work as intended and compliance doesn't entail avoidable costs.

The upshot is pressure on regulators to revise requirements that make it more difficult and expensive for businesses to compete, and to move toward proposals for more focused, flexible, and collaborative regulatory systems.

In 2016, an average Canadian SME had to make

75 regulatory submissions

to meet requirements.<sup>4</sup>

### Public expectations of stronger protection

A second challenge is rising public expectations around the protection by regulators of health and safety, customer rights, and the environment. These are often accompanied by skepticism regarding the capacity of public institutions to deliver and worries that regulators will become too cozy with, and ultimately be "captured" by, the industries they oversee. Even before 2020, these pressures were growing. Lockdowns, the rising numbers of cyberattacks, wildfires, and other disasters related to climate change, and a more general sense of destabilization have only added to the challenge.

OECD evidence shows that values, such as high levels of integrity, fairness, and openness of institutions, are strong predictors of public trust. Similarly, government's competence—its responsiveness and reliability in delivering public services and anticipating new needs—is crucial for boosting trust in institutions.<sup>5</sup> As keen observers have noted, poor regulation and distrust of regulators can undermine confidence in democracy.<sup>6</sup> Yet in the age of 24/7 news and social media, regulatory failures, however rare, get amplified quickly. Regulators are pressed by popular opinion and elected officials to strengthen protections, minimize the occurrence and severity of failures, and respond rapidly and unambiguously when failures do happen.

Achieving perfect results isn't possible, especially in the face of the other challenges discussed in this paper. However, that doesn't make strengthening protections and minimizing failures any less necessary. Regulators' credibility depends on demonstrating, every day, that they can deliver on their responsibilities consistently, impartially, and professionally.

### Demands for greater equity

Alongside public expectations of strong protections are rising demands that all government bodies, regulators included, do more to ensure equity, diversity, and inclusion, and engage with Indigenous peoples in ways that respect their unique history and rights in Canada.

Various movements have brought these demands to the fore, among them *Idle No More, Me Too*, and *Black Lives Matter*. But the drive for change transcends particular moments and has become embedded in a broad consensus about the areas in which a broadening of opportunity and a deepening of respect are imperative.

Women are insisting on an end to gender bias, sexual harassment, and glass ceilings. Racialized minorities are calling out systemic racism and calling for substantive equality. And Indigenous peoples—increasingly supported by the courts, political leaders, and the public at large—are demanding concrete action to respect treaties and the Honour of the Crown, advance reconciliation, and, after so many years of discrimination and marginalization, improve economic prospects for their communities.



This social change creates an additional layer of expectations and requirements. Some are similar for most organizations, regardless of their mandates or activities. Others are more specific to regulators that make decisions—such as the approval of major projects like railway or pipeline construction—that could affect Indigenous rights or interests.

## **67**%

of citizens around the world expect their governments to do more to fight climate change.<sup>7</sup>

## **61%**

of citizens around the world believe that government does not understand emerging technologies enough to regulate them properly.<sup>8</sup>



06



"The Government of Canada recognizes that meaningful engagement with Indigenous peoples aims to secure their free, prior and informed consent when Canada proposes to take actions which impact them and their rights, including their lands, territories and resources."<sup>9</sup>

### Global adoption of

cryptocurrencies has soared across low, middle-, and highincome countries in recent years. Regulators worldwide are still evaluating how to address the novel issues posed by digital currencies. For years, most central banks and treasury departments have focused on risk-based reporting and containment policies for virtual assets. Meanwhile, these markets have grown exponentially, with global adoption increasing by more than 2300% since 2019 and 881% in the last year alone.<sup>10</sup>



Accelerating technological change



A fourth challenge in the regulatory space is the accelerating pace of technology development in areas such as AI, quantum computing, and data harvesting-and its widespread, disruptive effects. The practical implications for the regulatory function relate both to the activities and products being regulated and to internal systems.

Because regulation is all about establishing parameters, it has traditionally relied on some stability over time in the external environment. However, the volume, velocity, and volatility of technological change and data generation means that there's far less predictability-and visibility-around how things work today, never mind how they'll work tomorrow. Goods, services, and business models are in a state of constant, rapid evolution, and the rules, along with the practices for ensuring compliance, have trouble keeping pace. 

This external-facing problem is mirrored by the rapid rust-out of regulators' own systems. Not so long ago, periodic IT investments were enough to keep regulators running. Today, that just isn't sufficient—yet with limited financial and technical capacity, regulators struggle to maintain systems that can handle demand, avoid crashes, and take full advantage of the range of available functionalities.

## By 2019,

economic activity in the digital sector made up almost the same share of Canada's economy as mining, oil and gas combined.<sup>11</sup>

## 50%

of business executives in Canada reported that the pandemic has sped up their adoption of technologies, leading to the overhauling of business models.<sup>12</sup>

# of Canadian businesses that have

83%

### **Augmented Reality**

(AR) and Virtual Reality (VR) markets are projected to reach \$1.2 trillion by 2030—a compound annual growth rate of 42%.15

## **By 2025**

the total number of IoT devices is expected to grow to 70 billion (from 10 billion in 2019).<sup>16</sup>

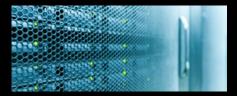


## By 2023,

70% of all enterprises are expected to be using intelligent edge devices (autonomous vehicles, VR, IoT devices, etc.).<sup>17</sup>

08





adopted AI agree that the technology will generate a great impact on their industry over the next 5–10 years.<sup>13</sup>

## ву 2025

the volume of global data created every day is expected to reach 463 zettabytes—the equivalent of 212 million DVDs per day!<sup>14</sup>





## 13% to 36%

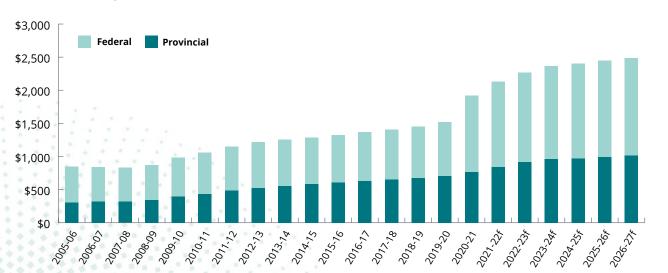
of people in 14 countries believe that 5G presents health risks.<sup>18</sup>

### 5 Resource constraints

A fifth challenge faced by regulators is shared by many organizations: funding that often seems to fall short of what's needed to do the job. This may be a particularly difficult issue for regulators, though, since their activities sometimes lack the sort of cachet that tends to attract new resources—except, perhaps, after a serious incident or emergency, when demands for more effective regulation can surge. Most of the time, regulators grapple with what feels like a mismatch between the number of entities and rules they're asked to oversee and the funds they're allocated for doing so.

This problem will grow in the coming years. Even as the range of challenges facing regulators puts pressure on their budgets, governments will likely act to bend cost curves downward and reduce the large deficits run to mitigate the impacts of the pandemic, particularly if interest rates rise. Tougher fiscal restraint is coming, and regulators that are funded with taxpayer dollars will almost certainly be asked to discharge their increasingly complex mandates while taking no more-and in many cases, less—from the public purse.

### Total federal and provincial debt (\$B)<sup>19</sup>



### 6 **Organizational culture and talent**

The final challenge regulators must contend with is the one that's most internal: issues around organizational culture and the recruitment and development of diverse workforces with essential competencies. Because of their mandates and histories, regulators often have organizational cultures that are relatively rules-oriented and inclined toward continuity—and staff with lengthier-than-average tenures within the same organization. Key expertise may reside mostly in the heads of long-term employees, and regulators can find it difficult to attract topnotch candidates, who often perceive regulatory institutions as staid and don't realize how stimulating and impactful the work of regulators can be.

Given their responsibilities, there are reasons for regulators to draw on their experience and carefully assess situations and options before acting. But in a world where change is accelerating, demands on regulators are increasingly fluid, and diversity is an asset, too much caution and too little agility and openness to innovation undermine rather than safeguard regulators' ability to perform their roles.

transfer. These efforts will have to before them.





Many regulators have made efforts to foster equity and inclusion, smart risk management, adaptability, and knowledge be redoubled for regulators to meet expectations and seize the opportunities



# The big opportunities

### This combination of challenges is daunting. But the inflection points where status quo approaches are stressed and scrutinized can create space for transformation.

The question is not whether regulators will continue to deliver mandates that protect health and safety, consumer and customer rights, the environment, and a well-functioning, competitive economy. Those fundamental mandates are more important than ever. The question is how regulators can do so most effectively and efficiently in the second quarter of the twenty-first century.

A variety of emerging practices and strategies provide answers to that question. Some are overarching applicable across the full spectrum of regulatory activity—while others fall primarily into one of three areas: regulatory frameworks, regulatory operations, and people and culture. Which mix of responses makes sense for each regulator will, of course, depend on its particular circumstances, but few will fail to find elements relevant to their challenges and objectives.

### **Overarching strategies**

Whatever they're responsible for doing and wherever their primary challenges lie, regulators can benefit from strong governance, modern engagement and feedback methods, and the lessons of behavioural insights and humancentred design.

Strong governance rests on a set of organizational structures, roles, and processes that accomplish three goals. First, they protect the integrity, impartiality, and independence of regulators' decisionmaking to ensure there's no real or perceived political interference or undue influence by regulated industries or other parties. That can be achieved through a mix of institutional autonomy, process transparency and internal policies and procedures that clearly define who has what authorities and accountabilities. Second, they ensure that internal review and approval procedures are robust enough to provide sound oversight, but not so heavy as to waste resources and unnecessarily slow decision-making. Regulators' processes often tilt toward excessive layering and duplicative reviews. Streamlining can yield immediate improvements in efficiency and agility, freeing resources for reallocation to more value-added activities. Third, they preserve an appropriate balance between the immediate demands of deliverywhich typically consume the bulk of regulators' resources—and attention to longer-term trends and developments that may have significant implications for regulatory frameworks, operations, and workforces.



"A 'customer' focus—indeed, some would say compulsive attention to customer satisfaction and a commitment to listening to feedback—must be at the heart of any successful organization's vision and culture. Such a customer orientation—with a relentless focus on the needs of the public and the concerns of the regulated community—has not been at the heart of government practice, but should be."<sup>20</sup>

### Daniel Etsy Professor of Environmental Law and Policy at Yale University

### In France, the **Electronic Communications**, Postal and Print Media Distribution **Regulatory Authority** (ACERP) oversees the country's telecommunications sector. A key challenge faced by the regulator was achieving nationwide connectivity and fair and effective competition by giving end-users (consumers) a participatory role in the regulatory processes.

ACERP implemented three main consumer-facing platforms to set up a 360-degree feedback loop into the regulatory process:

- The publication of maps displaying comparison of network coverage
- A reporting platform to document operator issues
- A search engine on available internet technologies

These data inflows allow ACERP to investigate and address consumer complaints, identify systemic issues, and establish an open data portal for third-party evaluations and modelling.<sup>21</sup>

### Modern methods of public, stakeholder, and staff engagement

can also have major impacts. Once, it was enough to publish regulatory proposals and wait for written submissions or to send an occasional memo to employees informing them of management decisions. Such approaches aren't sufficient during a "noisy" time when attention is fragmented and, in the case of Indigenous (and in certain contexts, other) groups, consultation is a legal obligation. Today's regulators can use e-engagement tools like crowdsourcing, online surveys, and virtual town halls and roundtables to secure meaningful input from a wide range of industry representatives, subject-matter experts, minority group representatives, interested Canadians, and their own employees. They can also establish mechanisms for sustained, structured, in-depth dialogue with the parties most directly affected by their mandates. By implementing more robust, multichannel, and transparent engagement strategies, regulators can: respond to the imperatives of reconciliation; help make regulatory frameworks, operations, and workforces more responsive to industry realities and public expectations; and raise confidence in their capacity to listen to input and deliver results.

That engagement can happen not just when regulatory frameworks and operational practices are being designed, but also after they're implemented, as part of regular ex post evaluations of their effectiveness and responsiveness to shifting realities. Such evaluations should also include data analysis and Al-based reviews that help regulators determine: if the frameworks are achieving their goals; if those frameworks contain outdated, duplicative, or defunct provisions; and whether rule-sets and the regulator's actions and decisions are as consistent and impartial (including free from unconscious gender or racial bias) as possible. Reviews informed by an array of data and feedback loops should happen on a reasonably frequent basis to help avoid a "regulate and forget" scenario and to facilitate the early identification and correction of any gaps, inefficiencies, or biases.

Finally, all regulatory activity can benefit from the application of the rapidly developing field of **behavioural** insights, human-centred design, and system design. Each can be drawn upon to craft consultations and evaluations, regulatory text, operational approaches, and workplace strategies that are attuned to people's experiences. They also take account of their interests and motivations, encourage expected behaviours, and discourage undesired ones. And importantly, they consider the interactions between and cumulative impacts of the full gamut of rules. Such techniques can make significant contributions to maximizing the attainment of regulatory goals while minimizing complexity and costs.

### **Regulatory frameworks**

Regulatory frameworks are comprised of the actual text of regulations, along with less-binding policies and guidance material issued by regulators to explain and elaborate on that text.

In designing modern frameworks, regulators should start with thoughtful, deliberate instrument choice based on considerations of **proportionality**, and rigorous **impact assessment** that goes beyond financial cost-benefit analysis to take the implications of different approaches into account across a broad set of factors. Careful, well-grounded instrument choice helps determine whether the most appropriate way of achieving a goal is a mandatory rule or a more flexible policy statement, guideline, or education campaign. Binding regulations may be the right choice, for example, when there's reason to believe an urgently required step will only be taken by industry if it's made mandatory. Clarity and enforceability are sometimes essential. Too often, however, binding regulations are simply the default, and inadequate consideration is given to "softer" alternatives that can be more easily fine-tuned as experience is gained.

COVID-19 in the EU.<sup>22</sup>





The European Medicines Agency (EMA) supports the development of medicines that address unmet medical needs. In the interest of public health, applicants may be granted a conditional marketing authorization (CMA) for such medicines on less comprehensive clinical data than normally required when the benefit of immediate availability outweighs the risk inherent in the fact that additional data is still required.

CMAs can be granted for medicines designed for human use if they are intended for treating, preventing, or diagnosing seriously debilitating or lifethreatening diseases. These approvals are also granted during public health emergencies, when less comprehensive and non-clinical data may be accepted. Approvals can be combined with rolling reviews of data during the development of a promising medicine to further expedite the evaluation.

As of January 2022, the EMA has fast-tracked five vaccines (with four more under review) and six medical treatments (with two more under review) to treat



The **United Kingdom's Financial Conduct Authority** (FCA) runs a regulatory sandbox as part of its broader Project Innovate. The sandbox allows businesses to test unconventional propositions in the market with real consumers. This arrangement is for authorized and unauthorized organizations and technology businesses looking to deliver innovation in the UK financial market. The sandbox offers them:

- The ability to test products and services in a controlled environment
- Reduced time to market
- Support in identifying appropriate consumer protection safeguards
- Better access to finance

Since its launch in 2016, the FCA has run seven cohorts. The 2021 cohort saw 58 applicants, of which 13 were accepted and allowed to test their products and services related to the COVID-19 pandemic, with a focus on: detecting fraud, supporting the financial resilience of vulnerable consumers, and improving access to finance for SMEs.<sup>23</sup>

is an emphasis on regulatory frameworks that are reasonably outcomes-based, not weighed down with overly detailed, prescriptive provisions that apply to narrowly defined entities. Excessive granularity increases the risk that rules will quickly become outdated as technologies and business models rapidly evolve. It also inhibits the development of innovative new ways of achieving policy objectives. Emphasizing principles, activities, and results mitigates those risks by keeping the focus on ends rather than means. That said, overly general regulatory language also entails risks namely, uncertainty about who's covered and what counts as compliance. The optimal balance in each case depends in part on what's being regulated. The more technical or contentious the matter, the greater the rationale for specificity. Regulators can test what will work through experimentation in regulatory "sandboxes," where specific issues and/or sectors are targeted using less traditional approaches. The advantage of using a sandbox is that it allows for a controlled trial based on cooperation and communication between the regulators and regulated entities. If an innovative approach proves effective, it can then be adopted more generally. If it doesn't, any damage is limited, easily explained and readily fixed, thanks to the explicit purpose and restricted scope of the experiment.



One way of reconciling a need for relatively detailed requirements (where it exists) with the desire to permit innovative approaches to achieving policy goals—approaches that might not have been imagined at the time regulations were developed—is to include "meet or beat" provisions in regulations or their governing statute. Such provisions allow regulators, following a rigorous assessment, to exempt a regulated entity from compliance with a specific obligation if that entity can demonstrate that it's able to implement an alternative approach that will produce equal or better outcomes with respect to the purpose of the obligation.

A final, cutting-edge strategy for reducing the risk that regulatory frameworks will become outdated is **regulation as code**, where rules are algorithm-based and evolve in response to changing conditions. Experiments with such approaches are just starting—and a host of questions around transparency/opaqueness and the risk of bias must be considered—but for certain types of regulatory frameworks, they have transformative potential.

equivalent results.

In 2020, eight airlines asked the CTA for exemptions from this requirement, stating that their standard terms of service already remove liability limits for mobility devices.

In its decision, the CTA determined that Air Canada's and Jazz's terms unambiguously waive the liability limits for mobility devices and, applying the *meet-or-beat principle*, granted exemptions to those airlines. The language in other airlines' terms was found to be less clear, however, and their requests were denied.<sup>24</sup>



The Canadian Transportation Agency (CTA) created the Accessible Transportation for Persons with Disabilities Regulations (ATPDR) to remove and prevent barriers to travel by persons with disabilities. A transportation provider can be exempted from a requirement if the CTA determines that an alternative approach proposed by the provider would achieve better or

One provision of the ATPDR obligates airlines to proactively inform passengers who use mobility devices that they can make a special declaration that lifts standard liability limits if their mobility device is damaged in transit.

Under the "Better Rules" framework, New Zealand is experimenting with using code to write regulations and standards, making them digitally accessible and adaptable to different situations and evolving circumstances.

Rules-as-code allows for data-based simulations to identify new solutions to issues, the ingestion of coded rules directly into government and business systems to simplify implementation and reduce discrepancies, the development of service approaches that avoid compliance issues, and the delivery of public services via digital platforms.<sup>25</sup>



## **Regulatory operations**

Regulatory operations are where the bulk of regulators' resources are spent. They include a broad set of activities undertaken to implement regulatory frameworks.

Traditionally, the focus in regulatory operations has been on a mix of licensing—giving individuals or businesses permission to undertake a regulated activity after confirming that they meet certain criteria—and enforcement checking if individuals or businesses have satisfied a regulatory requirement and imposing consequences if they haven't.

The compliance continuum <sup>26</sup>			
Ø	Promoting compliance	The Canadian Food Inspection Agency (CFIA) provides products and services to help industry understand and follow regulations.	
	Verifying compliance	The CFIA conducts inspections to check that requirements are being met. When and where to inspect is based on risk information.	
	Responding to non-compliance	The CFIA takes action to control immediate risk,and may choose from various enforcement options to compel a regulated party back into compliance.	
		These address an immediate risk to human, plant, or animal health, or the environment. Taking enforcement actions: Depending on the situation,	
	Applying control measures	the CFIA can send a written notice, issue and administrative monetary penalty or suspend a facility registration.	
		<b>Offering recourse:</b> As provided by law, a regulated party may challenge the CFIA's regulatory response.	
		Industry takes corrective action to achieve compliance.	

### One strategy that regulators can use to strengthen operational effectiveness is to design and deploy a **comprehensive** compliance assurance continuum.

It starts with meaningful outreach and education that recognizes that most regulated entities want to comply with their obligations but may not always be aware of what they are or how best to proceed. Outreach and education are especially important where an application entails a complex process of reviews and approvals by multiple regulators—and perhaps a requirement to consult Indigenous groups or various stakeholders—and/ or where regulated entities are smaller or foreign and have less experience with regulatory frameworks. From outreach and education, regulators can move to monitoring strategies that rely not just on comparatively time-consuming site visits (though in some contexts, inspections will be necessary), but also on selfreporting by regulated entities; remote data-gathering using tools like sensors, drones, and the internet of things (IoT); collection of relevant information in the public domain (such as signals gleaned from trends in social media posts); contributions from the public through "citizen science"; and—where issues are discovered—warnings with deadlines for compliance.

### As a final step, regulators can turn to the "hardest" options: enforcement measures such as orders, licence revocations, fines, and prosecutions. Such tough measures are sometimes justified by willful noncompliance with important regulatory requirements and may be necessary to encourage compliance more generally and ensure a level playing field among competitors. But they should be used sparingly, particularly with entities that usually satisfy regulatory requirements and have made good-faith efforts to address any non-compliance issues.

Adoption of a complete compliance assurance continuum should be accompanied by **risk-based strategies** for targeting compliance monitoring and enforcement resources. Such

strategies draw on objective evidence to determine where the likelihood of noncompliance is higher and where the impact of non-compliance would be greater—an analysis that's then used to direct outreach, monitoring, and enforcement efforts. Regulators can't be everywhere: the universes they oversee are too big. Risk-based targeting reflects this reality, improving the return on investment of compliance budgets while reducing reporting- and inspection-related demands on regulated entities with exemplary records. That said, a portion of compliance assurance resources, however modest, should be reserved for randomized rather than risk-based oversight activities, to account for any gaps in risk-assessment methodologies.

OSINERGIM, Peru's economic and infrastructure regulator oversees the energy and mining sectors for compliance and monitoring. Supervising electrical and mining facilities is complicated and risky. It can be logistically difficult to perform an assessment of their infrastructures. Time, for example, can be a constraint as transmission lines are often very long—just one kilometre of a transmission line takes eight hours to supervise on average.

The FDA intends to monitor the performance of these companies continuously, with real-world data. Scorecards and corresponding Pre-Cert levels could go up or down based on performance and effectiveness data. Moving forward, the FDA is looking to further test and iterate the approach and launch a fully functioning program.<sup>28</sup>

Note: Based on the Canadian Food Inspection Agency compliance continuum.



- OSINERGIM deployed drones extensively in its monitoring and compliance operations to collect virtual/visual evidence for compliance enforcement. With precise and timely data, the regulator was able to:<sup>27</sup>
- Reduce time spent on the site supervision from 8 hours to supervise one kilometre of a transmission line to about 2 hours
- Identify 50 possible risky situations to access remote areas and locations
- Reduce average supervision costs from US\$820 to US\$380
- Reduce site supervision time requires from 18 days to 2 days

As part of its **Digital Health Innovation Action Plan**, the **Food and Drug** Administration (FDA) created a Software Precertification (Pre-Cert) Pilot **Program** for eligible digital health developers that demonstrate a culture of quality and organizational excellence based on objective criteria—for example, excelling in software design, development, and testing. The idea behind this is to allow the FDA to accelerate time to market for lower-risk health products and focus its resources on those posing greater potential risks to patients. Pre-certified developers are able to market lower-risk devices without additional FDA review, or with a simpler premarket review.

The Danish Safety Technology Authority (SIK) scans physical and digital commerce outlets for dangerous and non-compliant consumer products. Finding and tracking dangerous goods was a big challenge for traditional market surveillance regulators. Case handlers had to conduct labour-intensive online searches to uncover dangerous goods.

To address this challenge, SIK developed an AI tool called AIME to assist with the surveillance of e-commerce marketplaces. AIME uses image recognition and machine learning to identify dangerous and non-compliant products for sale online. The tool scans images looking for patterns and searches blogs, comments, and news sites to detect dangerous goods. The intelligent process reduces a lot of the resource-demanding work related to product safety by working automatically to keep the EU a safer place.<sup>29</sup>

### Data-based risk assessment is one example of **digitalization and automation**: IT transformations that

see regulators using the same sort of technologies as many regulated entities. Digitalization and automation can significantly improve the full range of regulatory operations by simplifying and standardizing processes; minimizing the investment of staff time in everything from licence application processing to case management to report generation; facilitating "big data" analysis in support of regulatory activities and evaluations; enhancing data security and stakeholder trust through the use of blockchain and similar technologies; and giving businesses more paperless selfservice options. And as the number of digitalization and automation offerings and customers continues to grow, fit-forpurpose IT transformations are becoming increasingly affordable.

Regulatory operations can also benefit from increased collaboration among **regulators** in the setting of rules and the delivery of their services and backoffice support. Collaboration requires working across organizational silos and can take various forms. Regulators can, for example, work together to maximize consistency and minimize duplication in regulatory requirements across agencies and jurisdictions, both nationally and internationally. Similarly, where a proposed project or activity is subject to approval by multiple regulators, for example, they can implement an integrated, predictable process through which the applicant can submit information, receive feedback and requests, and obtain timely decisions.

Even where permitting doesn't cut across regulators, they can still work to increase their data-sharing, which has the potential to reduce reporting demands for industry and enhance regulators' ability to pick up early warning signs of possible non-compliance. While doing so may require IT system modifications or updated approaches to privacy policies and practices (such as legislative amendments permitting inter-ministerial data transfers), the payback can be substantial. Regulators can also empower one another's compliance officers to conduct inspections on their behalf-or even "light touch" reviews while on-site for other purposes—to reduce the number of visits from regulatory staff that any one business has to host. This could also increase the aggregate number of inspections that can be carried out by the community of regulatory organizations. And regulators can look at potential efficiencies in common services for corporate functions, where economies of scale have a significant impact. Such arrangements work most smoothly when there are clear understandings regarding the allocation of shared services, and governance that is responsive to any concerns around service and offers quick resolutions.



Finally, regulatory operations may benefit from **funding models that do** not rely exclusively on the public **treasury**. One option that's already being used by some regulators is payment of regulatory fees or user charges by industry. For ministries of finance, this approach has appeal as a way of relieving fiscal pressure. For regulators, it offers enhanced funding predictability and operational autonomy. For regulated entities—despite inevitable concerns about new costs—it can help strengthen dialogue with regulators. Another creative funding option is the monetization of data held by the regulator, where value is added by conducting some form of analysis and the regulator has the legal authority to sell the results in the market.

Both options depend on the regulator having the authority to collect moneys and hold them in an account that permits funds to be added and removed over time, rather than expiring at the end of the fiscal year.



The COVID-19 pandemic has increased pressures on regulatory resources and capabilities across jurisdictions. These challenges are driving new models of collaboration and resource-sharing amongst regulators.

Since the beginning of 2021, occupational health and safety inspectors and multi-ministry teams of provincial offences officers in Ontario have conducted more than 19,500 COVID-related workplace inspections and investigations. During those visits, inspectors issued over 15,000 orders and over 450 COVID-19 related tickets and stopped unsafe work related to COVID-19 a total of 24 times.<sup>30</sup> "While progress has been achieved in making the federal public service more representative, much work remains to be done. All Canadians applying to public service jobs should have an equal opportunity to highlight their unique talents."31



## People and culture

Regulators can deploy a number of strategies to foster the attitudes and capacity needed to create and implement modern, responsive regulatory frameworks and operations. Many are applicable across a wide range of organizations; however, they often have a unique configuration or significance in regulatory contexts where there is a particular need to moderate risk aversion and reinforce adaptability.

Organizational change begins with attracting and retaining the right **sort of talent**, balancing a traditional focus on technical expertise with comparable attention to **diversity** and creativity. At the recruitment stage, this may mean advertising for a different mix of skills, reaching out to different education institutions and

programs, using new methods to remove unintended bias from the assessment process and evaluate fit, and pooling advertising and evaluation efforts where several regulators have similar talent needs. At the development and retention stage, it requires articulating a compelling narrative about organizational purpose, setting a clear tone and expectations around collaboration and innovation, automating relatively routine tasks so that staff can focus on more interesting work, and creating appealing learning and career paths (including opportunities for assignments outside of home organizations). It's also about giving employees time and support to propose and experiment with novel approaches, communicating boundaries for acceptable risk-taking, and having people's backs if (as is inherent in risk-taking) not everything goes exactly as hoped.

Regulators can use a variety of approaches to ensure the **transmission** to newer employees of the expertise and insights (though not always the attitudes) of highly experienced staff. Such approaches move beyond reliance on a sort of osmosis among colleagues and include shadowing, individual and group mentorship, and video-based documentation and dissemination of "war stories" and lessons learned from longterm personnel.

Alongside efforts to build the right mix of skills and knowledge, regulators can move from rigid work structures based on detailed job descriptions and static organizational units to more supple, competency- and project-based **approaches** in which different clusters of employees are brought together for limited periods of time to tackle specific subjects or issues. This is not a binary choice: more established and more dynamic approaches to the execution of work can and do co-exist with and complement one another, but regulators would do well to emphasize the latter, given the sorts of challenges they're facing.

leverage remote and hybrid work arrangements. What began for most organizations as an essential but temporary shift when the pandemic hit is now recognized as durable and, in some respects, salutary. Allowing employees to work where they prefer and use digital tools to collaborate can reduce real estate and other overhead costs, enhance agility, drive technology adoption and the use of data, reduce individual stress, expand and diversify the talent pool, and facilitate more flexible organizational cultures. It's also consistent with shifts in how regulatory mandates are delivered; for example, toward fewer paper-based processes and on-site inspections and more digitalization and data analysis. That said, we've all seen that remote and hybrid work can also inhibit organic, spontaneous connection and creativity. They should therefore be deliberately combined with other elements (such as informal online brainstorming sessions and regular inperson gatherings) in ongoing, iterative efforts to find an appropriate balance as circumstances evolve.

In Deloitte's global survey,

## 74%

of respondents said that remote/virtual work practices currently have a positive impact on well-being.<sup>32</sup>

## **52%**

of public sector employees agreed that the changes their organization put into place during the COVID-19 pandemic empowered workers to more successfully integrate the demands of their personal and professional lives.<sup>33</sup>



## Finally, regulators can fully

# Moving forward

The coming period could see once-in-a-generation change in the regulatory function. As the pressure of daunting challenges meets the opportunities created by emerging practices, tools, and strategies, transformation becomes possible. At the other side of that transformation lie regulators able to deliver results and fulfil a wide array of expectations more effectively, nimbly, and efficiently.

The potential is exciting. But for it to be realized, the leaders of regulatory organizations will have to bring clarity of vision, an openness to listening and learning, and exceptional tenacity to the job of taking their teams forward.

Where they're successful, their legacy will be one of renewal and revitalization. And the benefits will accrue not just to their employees, but to the sectors they oversee, the stakeholders who are interested in their mandates, and all Canadians in the form of stronger protections, a healthier environment, and a more vibrant economy.



# Endnotes

- 1. "OECD Best Practice Principles for Regulatory Policy -The Governance of Regulators". Organisation for Economic Co-Operation and Development. Retrieved January 12, 2022.
- 2. Total number of regulators, core govt. entities, independent regulators and self-governing professional bodies obtained via Deloitte's internal research.
- 3. "The Global Competitiveness Report 2018". World Economic Forum. Retrieved January 12, 2022.
- 4. "Survey of Regulatory Compliance Costs, 2016". Statistics Canada. Posted March 19, 2019.
- 5. "Trust in Government OECD". Organisation for Economic Co-Operation and Development. Retrieved January 12, 2022.
- 6. Anne Applebaum, *Twilight of Democracy*. Signal/McClelland & Stewart: 2020, pg. 59.9. Department of Justice Canada. Retrieved January 12, 2022.
- 7. "The world is ready for climate action". Deloitte. Retrieved January 12, 2022.
- 8. "Edelman Trust Barometer 2020 Global Report". Edelman. Retrieved January 12, 2022.
- 9. "Principles respecting the government of Canada's relationship with Indigenous Peoples". Government of Canada -Department of Justice. Modified September 01, 2021
- 10. "How to meet the crypto regulatory challenge". World Economic Forum. Posted September 02 2021.
- 11. "The digital transformation and Canada's economic resilience". Bank of Canada. Retrieved January 12, 2022.
- 12. Ibid.
- 13. "Canada's Al imperative Start, scale, succeed". Deloitte. Retrieved January 12, 2022.
- 14. "How much data is generated each day?". World Economic Forum. Posted April 17, 2019.
- 15. "Technology Futures: Projecting the Possible, Navigating What's Next". World Economic Forum in Collaboration with Deloitte. Posted April 2021.
- 16. "The Next Digital Economy". Policy Horizons Canada. Posted June 20, 2019.
- 17. "Gathering velocity". Deloitte Global TMT Predictions 2021. Retrieved January 12, 2022.
- 18. Ibid.

- 19. Total federal and provincial debt obtained via Deloitte's analysis of federal and provincial budgets, combined with internal projections.
- 20. "Regulatory Excellence: Lessons from Theory and Practice". Penn Program on Regulation's Best-in-Class Regulator Initiative. Posted June 2015.
- 21. "Developing data driven regulation for the digital ecosystem in France: Case study on the Electronic Communications, Postal and Print Media Distribution Regulatory Authority (ARCEP)". Organisation for Economic Co-Operation and Development. Retrieved January 12, 2022.
- 22. "Conditional marketing authorisation European Medicines Agency". European Medicines Agency. Posted September 17, 2018.
- 23. "Regulatory sandbox". FCA. Posted May 4, 2016.
- 24. "Determination No. A-2022-10". Canada Transportation Agency. CTA. Posted February 1, 2022.
- 25. "What is Better Rules?". Digital. Govt. NZ. Posted December 20, 2019.
- 26. "Compliance and Enforcement Policy". Government of Canada, Canadian Food Inspection Agency. Posted April 21, 2015.
- 27. "Supervising electricity and mining companies with drones and virtual reality in Peru: Case study on the Energy and Mining Regulator". Organisation for Economic Co-Operation and Development. Retrieved January 12, 2022.
- 28. "Digital Health Software Precertification (Pre-Cert) Program". U.S. Food and Drug Administration. Posted May 6, 2021.
- 29. "New digital fine-toothed comb from Denmark is about to make more than 300 million European consumers safer". Danish Safety Agency. Posted December 01, 2021.
- 30. "Workplace Inspection Campaign Launching In COVID-19 Hotspots". Ontario Ministry of Labour - Training and Skills Development. Posted April 08, 2021.
- 31. "Public Service Commission of Canada Audit Report on Employment - News Release". Public Service Commission of Canada. Retrieved January 12, 2022.
- 32. "The worker-employer relationship disrupted". Deloitte Posted July 21, 2021.
- 33. Ibid.

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