

ADVANCING CANADA-U.S. REGULATORY ALIGNMENT: A Canadian Agri-Food Sector Perspective

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EXECUTIVE SUMMARY

International regulatory cooperation has been receiving increasing attention as a way to facilitate trade among countries and to eliminate unnecessary regulatory requirements. In fact, the Organisation for Economic Co-operation and Development (OECD) considers it to be one of the best practice regulatory principles and a key element for regulatory quality.¹

Regulatory cooperation (also referred to as “regulatory alignment”) can be applied to specific areas of regulation where unnecessary and/or duplicative measures are found. When effectively implemented, it can benefit not only business-regulated parties but also consumers and regulators. Regulatory alignment has numerous advantages and opportunities, many of which have not yet been fully leveraged. For the most part, this alignment is still occurring in an individual, ad hoc manner, leaving room for the development of a systematic effort to achieve ongoing success.

Canada and the United States have a strong bilateral trade partnership. The two countries share deeply integrated manufacturing and consumer markets, and their citizens share common product preferences and levels of risk tolerance. Nevertheless, despite their integrated supply and value chains, Canada and the U.S. remain challenged by the existence of two highly independent regulatory systems, leading to an enormous amount of duplication and costly requirements that are deleterious to trade.

As a result, regardless of their sector, firms are forced to spend vast amounts of time and money gathering information, adjusting specifications, and performing conformity assessments for compliance in order to enter specific markets.² Governments tend to work in isolation when it comes to protecting their consumers, environment, and economy, which leads to international misalignment that could be avoided without compromising the quality of services and/or products or diminishing the protection provided by the regulatory system.

This report is timely due to the recent commitment to perform a comprehensive update to Canada’s regulatory environment made by the Finance Minister during the government’s 2018 Fall Economic Statement.³ Using two case studies, this report demonstrates how regulatory misalignment is affecting the competitiveness of the agri-food sector in Canada by exacerbating challenging factors such as high costs to firms, duplicative approval processes, and limited access to new technologies. We believe it is in Canada’s best national interests to strengthen its trade relationship with the U.S. by partnering with the U.S. to address existing regulatory misalignments and adopt measures to avoid creating new ones. We highlight some recommendations, aligned with good regulatory practices, that can be implemented by stakeholders, such as:

- trade should be considered in the policy-making process;
- industry stakeholders, regulators, and trade negotiators should have open discussions to improve regulatory cooperation;
- international and private standards should be included within national regulatory frameworks to facilitate trade, encourage investments, and boost innovation;

1 “Facilitating Trade through Regulatory Co-Operation,” *Organization for Economic Co-Operation and Development (OECD)*, 2018, <<http://www.oecd.org/tad/ntm/facilitating-trade-through-regulatory-cooperation.htm>> [accessed June 14, 2018].

2 *International Regulatory Co-Operation and Trade: Understanding the Trade Costs of Regulatory Divergence and the Remedies*, 2017, OECD Publishing <<http://dx.doi.org/10.1787/9789264275942-en>> [accessed June 15, 2018].

3 Jesse Snyder, “Ottawa Proposes Sweeping Review of Canada’s Regulatory Regime to Consider “Efficiency and Economic Growth”,” *National Post*, 2018 <<https://nationalpost.com/news/canada/ottawa-proposes-sweeping-review-of-canadas-regulatory-regime-to-consider-efficiency-and-economic-growth>> [accessed November 25, 2018].

- a cultural shift towards regulatory partnership between Canadian and U.S. regulatory departments should be promoted downstream to support the adoption of common regulatory programs when possible; and
- a pilot project of a joint food safety mechanism should be considered as part of the regulatory cooperation efforts.

While this report focuses on building stronger regulatory cooperation between Canada and the U.S. in the agri-food sector, its recommendations are applicable to many other sectors and can contribute to advancing the government's regulatory reform agenda to improve Canada's economic growth and innovation.

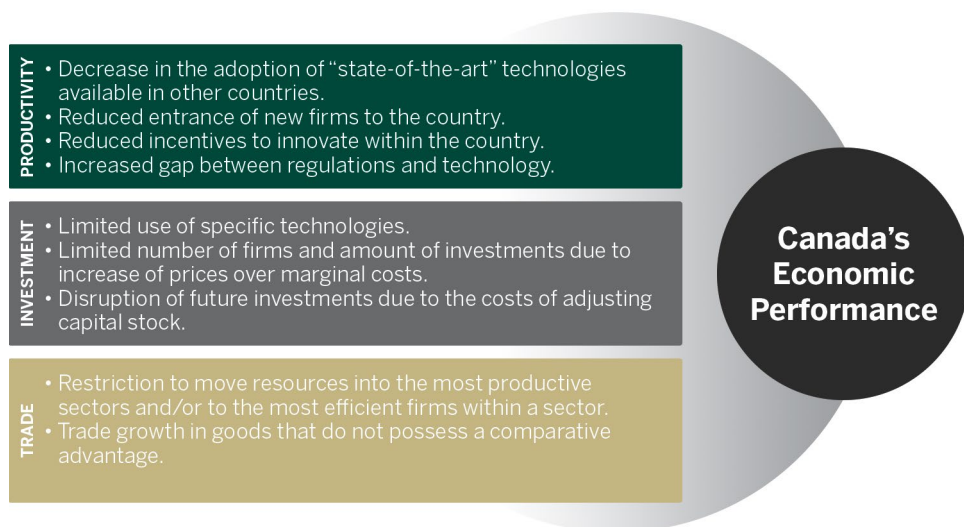
BACKGROUND

Regulatory Misalignment: A Costly Burden to Trade

Regulatory alignment and greater partnership between jurisdictions are complex aims to manage for several reasons: (1) they can be perceived as affecting sovereignty; (2) they involve costs that can be difficult to identify and quantify; (3) they require the participation of several levels of government and, in some cases, multiple agencies; and (4) they require regulatory departments to adopt new approaches and complex cultural changes. In addition, regulatory cooperation is positioned with a foot in two camps—one being trade negotiators and the other regulators. Despite the fact that regulatory misalignment is clearly an issue that necessitates collaboration between both of these camps, trade negotiators and regulators are still reluctant to embrace the issue as their own.

Further, Canada is generally acknowledged to be a country with overly complicated regulations in place. A 2018 report published by the Canadian Chamber of Commerce notes that “the elimination of trade barriers and unnecessary regulatory differences across Canada could add as much as CA\$130 billion⁴ to Canada’s GDP by freeing trade and commerce within our own internal markets.”⁵ According to a recent study published by the Canadian Federation of Independent Business, regulations from all levels cost Canadian small and medium businesses an estimated \$36 billion in 2017.⁶ There is no question that Canada’s regulatory system contributes to the well-being of its citizens and to the achievement of its social and economic goals. However, it is also true that some regulations reflect a bygone era that has been surpassed by technological and societal evolution. This misalignment has led to regulatory inefficiency with negative impacts on Canada’s economic performance, especially when compared to major trading partners like the U.S. (see Figure 1).⁷

FIGURE 1: POTENTIAL EFFECTS OF COMPLICATED AND OUTDATED REGULATIONS ON CANADA'S ECONOMIC PERFORMANCE



Source: Fidele Ndayisenga, Downs Andre, and Policy Research Initiative, “Economic Impacts of Regulatory Convergence Between Canada and the United States,” *Policy Research Initiative Working Paper Series*, 2005.

4 Note: To the best knowledge of the author, all figures are in Canadian dollars (CA\$) unless otherwise specified.

5 Canadian Chamber of Commerce, *10 Ways to Build a Canada That Wins*, 2018.

6 Queenie Wong, *The Cost of Government Regulation on Canadian Businesses*, 2018.

7 Fidele Ndayisenga, Downs Andre, and Policy Research Initiative, “Economic Impacts of Regulatory Convergence Between Canada and the United States,” *Policy Research Initiative Working Paper Series*, 2005.

In terms of trade policy, tariffs represent one of the greatest challenges that firms must take into consideration. Domestic regulations have always existed, and in theory, they are applied to foreign products on the basis of “national treatment.” Regulations were commonly seen as an instrument to safeguard jurisdictions, rather than as an impediment to trade.

Since the formation of the World Trade Organization (WTO), the WTO agreements on sanitary and phytosanitary (SPS) measures and technical barriers to trade (TBT) have contributed significantly to the removal of regulatory barriers. Between Canada and the U.S., some legacy regulatory differences have been resolved; however, there are still certain artifacts and remnants of regulatory systems that are considered highly protectionist in nature. A report released in 2016 by the Canadian Chamber of Commerce noted that non-tariff measures applied to foreign products can impose an average cost equivalent to a tariff of 45%, and can restrict trade almost twice as much as a tariff.⁸ Therefore, with globalization and trade comprising key elements of Canada’s economy (31% of GDP in exports of goods and services in 2017), it is time to shift the nationalistic mindset that generated these regulations and collaborate with other jurisdictions to reduce regulatory burdens and costs without risking national safety and security.⁹

Canada and the United States: A History of Collaboration

Canada and the U.S. have a long-standing history of collaboration, which has been strengthened mainly by their geographic proximity. Both countries share more than just a land border—they share air space, inland waters, and the environment as well, all of which involve common risks and problems that are better solved by working together. Close collaboration has been critical in addressing mutual issues and has bolstered the adoption of joint efforts to advance our economies and protect citizens and the environment for the common good. We have seen a variety of approaches implemented in different areas, ranging from informal dialogues and exchanges of information to mutual recognition agreements and the creation of formal partnerships (see Figure 2).

The two nations have also developed a deeply integrated economy and supply chain network, reflected in more than US\$2 billion worth of goods and services that are traded every day.¹⁰ Canada and the U.S. have the largest bilateral trading relationship worldwide, and the benefits of this bond are readily apparent in sectors such as the automotive and agri-food industries, which represent some of their most integrated supply chains.¹¹

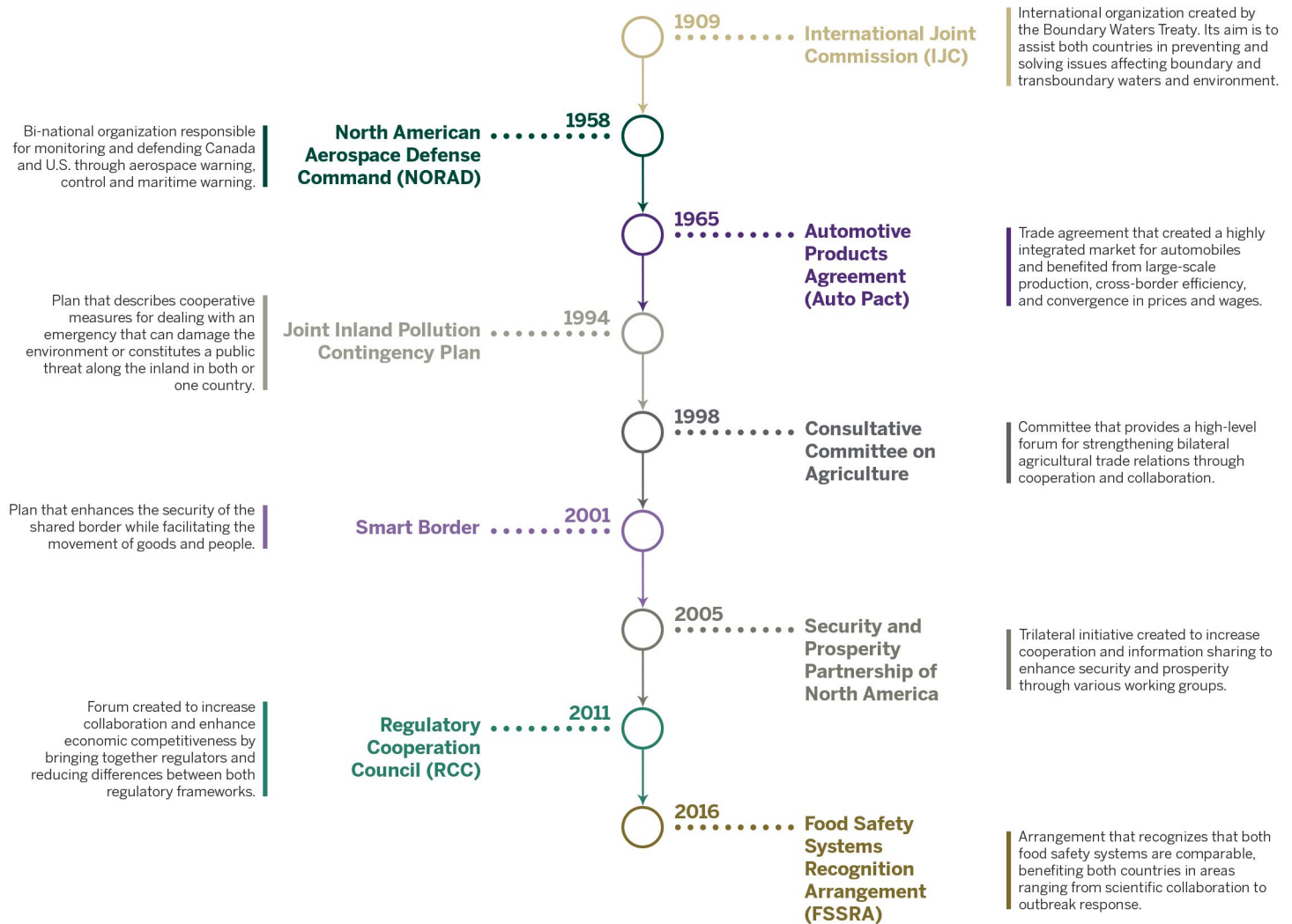
8 Canadian Chamber of Commerce, *Canada’s Next Top Trade Barrier: Taking International Regulatory Cooperation Seriously*, 2016.

9 “Annual Economic Indicators,” *Global Affairs Canada*, 2018 <http://www.international.gc.ca/economist-economiste/statistics-statistiques/data-indicators-indicateurs/Annual_Ec_Indicators.aspx> [accessed August 3, 2018].

10 “Fact Sheet: United States-Canada Relationship,” *U.S. Embassy & Consulates in Canada*, 2016, <<https://ca.usembassy.gov/fact-sheet-united-states-canada-relationship>> [accessed June 22, 2018].

11 “Canada – U.S. Trade Still a Powerful Driver for Automotive Sector,” *Export Development Canada*, 2017, <<https://edc.trade/canada-u-s-trade-still-powerful-driver-automotive-sector>> [accessed June 25, 2018].

FIGURE 2: CANADA-U.S. REGULATORY COOPERATION: EXAMPLES THROUGH HISTORY



Source: Global Affairs Canada, "Agriculture," 2016; Angeles M. Villareal and Jennifer E. Lake, *Security and Prosperity Partnership of North America: An Overview and Selected Issues*, 2009; "U.S. - Canada Smart Border/30 Point Action Plan Update," U.S. Department of State, 2002 [accessed September 25, 2018]; "The Canada-U.S. Defence Relationship," National Defence and the Canadian Armed Forces, 2015 [accessed September 10, 2018]; "EPA Collaboration with Canada," United States Environmental Protection Agency, 2018 [accessed September 10, 2018]; Bob Carberry and Mark Fisher, *Untapped Opportunities Advancing Regulatory Cooperation in the Great Lakes Region*, 2018; "Food Safety Systems Recognition Arrangement," Canadian Food Inspection Agency, 2016.

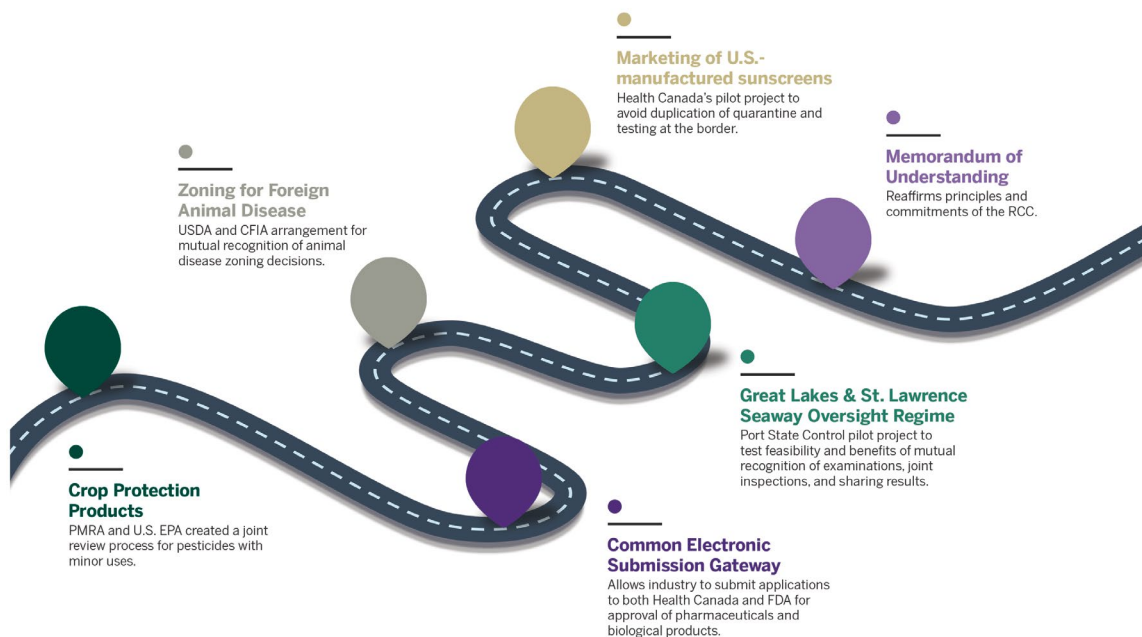
Supply chain integration has come a long way since the implementation of trade agreements provided the foundations for joint Canada-U.S. growth. Three such agreements reshaped the concept of trade: the Canada-United States Automotive Products Agreement (the "Auto Pact") in 1965, the Canada-United States Free Trade Agreement (CUSFTA) in 1987, and finally, the North American Free Trade Agreement (NAFTA), signed in 1994. Originally, these agreements effectively erased the border between Canada and the U.S. by reducing tariffs, allowing products to move freely between countries, and companies on both sides of the border to become truly multinational corporations. However, the reduction and/or elimination of tariffs exposed regulatory differences as greater barriers to trade. Accordingly, each jurisdiction established its own array of regulations to address new hazards, new risk assessments, new technologies, and new public expectations, forgetting that Canada and the U.S. had more similarities than differences, including the responsibility to safeguard their people, environments, and economies. Companies engaged in cross-border transactions started to face differences in product standards, regulatory requirements, and compliance assessment that—although they were intended to be protective measures—eventually began to affect trade flow across sectors.

NAFTA was viewed as a unique trade agreement that took into account more than just trade liberalization, and the proof of this was the creation of trilateral committees and working groups (CWGs). The purpose of the CGWs was to encourage the exchange of information and collaboration to solve minor disputes and create long-term benefits. These CWGs, mostly formed by technical and sectoral experts, were chaired by regulators but their agendas were seen as beyond the scope of their mandates and mainly driven by trade. Agendas at these groups were largely comprised of thorny, long-standing trade irritants, and were not focused on proactive measures. Thus, regulators assigned a lower priority to the efforts of these working groups, delivering modest progress at best on a limited number of issues, and suggesting that a more robust and differently structured regulatory cooperation effort was required.

In 2010, the Canadian and U.S. federal governments announced the creation of the Canada-United States Regulatory Cooperation Council (RCC). The objectives of this partnership were to pursue greater regulatory alignment, increase mutual recognition of regulatory practices, and establish smarter and less burdensome regulations. Initially, the RCC's efforts focused on four highly integrated key sectors that faced known regulatory barriers to trade: agriculture and food; transportation; health and personal care products; and workplace chemicals and the environment. Yet, the RCC quickly noticed that a sectoral approach was not practical since several regulatory agencies are involved within each sector. Therefore, the RCC Work Plan was reorganized to make accountabilities clear within each regulatory agency instead.

Since its creation, the RCC has yielded significant results, demonstrating that it is possible to resolve existing differences between Canadian and U.S. regulatory systems while jointly developing alternatives to ensure future alignment (see Figure 3).

FIGURE 3: CANADA-U.S. RCC ACHIEVEMENTS TO DATE



Notes: PMRA = Canada's Pest Management Regulatory Agency; EPA = U.S. Environmental Protection Agency; USDA = United States Department of Agriculture; CFIA = Canadian Food Inspection Agency; FDA = U.S. Food and Drug Administration.

Source: "Canada-United States Regulatory Cooperation Council Joint Forward Plan August 2014," Treasury Board of Canada Secretariat, 2016 [accessed August 22, 2018]; "Regulatory Cooperation a Vessel for Smoother Trade," Treasury Board of Canada Secretariat, 2017 [accessed September 10, 2018]; "Memorandum of Understanding between Canada and the United States to Advance the Regulatory Cooperation Council," Treasury Board of Canada Secretariat, 2018 [accessed September 10, 2018].

A Brief Description of the Current Agri-Food Regulatory Landscape in Canada

The agri-food sector is Canada's largest manufacturing sector, contributing more than \$110 billion to the country's GDP and creating \$47 billion worth of bilateral trade with the U.S. in 2016.¹² Thus, it is not surprising that in 2017, the Advisory Council on Economic Growth named agri-food as one of the key sectors that could drive economic growth.¹³ Canada is considered a trusted food supplier. It possesses a vast amount of natural resources and land, and it has an excellent record of successful innovation and technology. However, in order to become the "trusted global leader in safe, nutritious, and sustainable food in the 21st century," Canada needs to remove the obstacles that are preventing its agri-food industry from becoming truly competitive.¹⁴

The agri-food sector is a prime example of how a complex and outdated regulatory system can hinder competitiveness. In the 20th century, as nations were trying to establish good reputations for their products and secure export markets, they adopted differences in terms of package sizes, grades, product standards, and mandatory certifications. Although this process started over 50 years ago, these differences remain largely in place. As a result, the regulatory system has become one of the main impediments to investment and innovation within the sector. As technology and society evolves, regulations must be updated to be coherent with the global regulatory environment, and especially with major trading partners.

In light of this impediment, the federal government, through the Canadian Food Inspection Agency (CFIA) and Health Canada (HC), has made the first move and started to modernize and overhaul the regulatory system overseeing the agri-food sector. The revision focuses on legislation and regulations for food safety and animal and plant health. In addition, it complements the inspection modernization, the refocusing of the CFIA's activities, and increasing regulatory alignment with the U.S. through the RCC workplan.¹⁵ More recently, the Canadian federal budget for 2018/19 allocated \$11.5 million over the next three years to making the regulatory systems more agile, transparent, and responsive. One of the main approaches involves targeted regulatory reviews to address bottlenecks and irritants that are limiting innovation and competitiveness within the sector.¹⁶ A second initiative encourages engaging with national and international stakeholders, such as the U.S., to recognize areas where regulatory modernization is most needed; this can be accomplished by leveraging the work of the RCC. In fact, through the RCC, the CFIA, HC, and the U.S. FDA all signed the Food Safety Systems Recognition Arrangement (FSSRA). This arrangement officially recognizes that U.S. and Canadian food safety systems provide comparable public health outcomes. However, the food safety regulatory system overseeing meat, poultry, and processed egg is not considered in the arrangement due to the fact that the USDA was not a signatory.

The commitment to the FSSRA follows the Parliament of Canada's approval of the Safe Food for Canadians Act (SFCA) in 2012. In theory, the SFCA is considered the major regulatory transformation of the Canadian legislative framework overseeing food safety throughout the food supply chain. Yet in practice, to date, it has only been perceived as a consolidation of regulations without substantial changes. After a lengthy public consultation period, the main set of regulations, the Safe Food for Canadians Regulations (SFCR), was finally published in the Canada Gazette on June 13, 2018. These regulations will impact approximately 6,500 food and beverage processing establishments

¹² Global Affairs Canada, "Agri-Food Processing Sector," *Invest in Canada*, 2018; Pat Finnigan, *Report of the Standing Committee on Agriculture and Agri-Food*, 2017.

¹³ Advisory Council on Economic Growth, *Unleashing the Growth Potential of Key Sectors*, 2017.

¹⁴ Advisory Council on Economic Growth.

¹⁵ "Regulatory Modernization," *Canadian Food Inspection Agency*, 2015, <<http://www.inspection.gc.ca/about-the-cfia/strategic-priorities/regulatory-modernization/eng/1345492077853/1376482667229>> [accessed January 16, 2018].

¹⁶ "Budget 2018: Chapter 2 – Progress," *Government of Canada*, 2018, <<https://www.budget.gc.ca/2018/docs/plan/chap-02-en.html>> [accessed October 5, 2018].

within Canada.¹⁷ Collectively, the SFCA and the SFCR will allow Canada to theoretically align with the U.S. Food Safety Modernization Act (FSMA) implemented in 2011.

Regulatory modernization and alignment with trading partners is a work in progress. Particularly in the agri-food sector, it has been challenging to maintain continuous engagement between government agencies on both sides of the border. Consequently, efforts under the RCC have not yielded meaningful results, leaving several areas in this sector—such as alignment of standards and approval of new technologies—in need of attention in order to overcome challenges and foster growth and competitiveness.

17 “Overview of the Food and Beverage Processing Industry,” *Agriculture and Agri-Food Canada*, 2016, <<http://www.agr.gc.ca/eng/industry-markets-and-trade/market-information-by-sector/processed-food-and-beverages/overview-of-the-food-and-beverage-processing-industry/?id=1174563085690>> [accessed April 6, 2018].

CASE STUDY 1: 3M REVIEW AND APPROVAL SYSTEMS FOR NEW TECHNOLOGIES

Context

The safety of our food supply relies on the proper implementation of methods and procedures (e.g., Hazard Analysis and Critical Control Points (HACCP) and Good Manufacturing Practices (GMP)) to comply with regulations and ensure that food products are free from anything that could potentially harm consumers. Food businesses and testing laboratories depend on the availability of innovative technologies to help them be more efficient, productive, sustainable, and cost-effective, while also keeping pace with a dynamic global market and ensuring consumer safety.

Due to rapid advances in biotechnology, automation, and software development, numerous new methods for food analysis are developed and commercialized every year. However, before a new analytical technology can reach the market, it must undergo an exhaustive validation process to ensure it is reliable, accurate, and fit for purpose. Validation of new analytical methods has become a relevant aspect of their commercialization, especially when it comes to international trade. Well-known validation schemes are recognized and accepted worldwide by government agencies and food businesses, and thus, are widely used by method developers. As an example, ISO 1640 is the standard generally used by certification bodies in Europe to validate new microbiological methods.¹⁸ Meanwhile, in the U.S., the Association of Official Analytical Chemists (AOAC) offers two alternatives: the AOAC Research Institute Performance Tested MethodsSM (PTM) program or the AOAC INTERNATIONAL Official Method of AnalysisSM (OMA) program. Canada (along with a few other countries) is an exception in that it requires new analytical methods to be validated according to domestic protocols, regardless of their approval by any of the former international schemes.

The Bureau (the Bureau) of Microbiological Hazards under HC develops the food safety standards and policies required to minimize the risk of foodborne illnesses. In addition, the Bureau—through the Microbiological Methods Committee (MMC)—is responsible for validating, approving, and publishing in the Compendium of Analytical Methods (the Compendium) the microbiological methods that can be used to comply with the CFIA mandated testing. Whenever microbiological criteria exist, processing facilities must have their testing conducted in an accredited laboratory and the testing methods must be within the scope of their accreditation in order to fulfil regulatory requirements enforced by the CFIA. Therefore, food businesses are limited to use the methods found in the Compendium in order to identify and analyze the hazards that pose a risk of food contamination and to verify that food products meet the biological, chemical, and physical standards established by HC regulations.

Canada and the U.S. have in place a robust and reliable system of standards setting, inspection, and business practices that is well grounded in science. This system includes the criteria, processes, and tools used for food testing. Even though the 2011 Joint Action Plan and the 2014 Joint Forward Plan from the RCC included action items to achieve mutual reliance on food testing results, government agencies on both sides of the border continue to work independently to assess microbiological food safety risks and approve new technologies. Duplicative regulatory requirements, such as the approval of microbiological methods by the MMC, are restricting the use of innovative

18 ISO 16140-2:2016 *Microbiology of the Food Chain- Method Validation- Part 2: Protocol for the Validation of Alternative (Proprietary) Methods against a Reference Method* (Geneva, Switzerland: International Organization for Standardization, 2016); Vicky Jasson, Liesbeth Jacxsens, Pieterneel Luning, Andreja Rajkovic, and Mieke Uyttendaele, "Alternative Microbial Methods: An Overview and Selection Criteria," *Food Microbiology*, 27.6 (2010), 710–30.

technologies and/or new products, and thus, negatively affecting the Canadian agri-food sector's competitiveness relative to the U.S. Whether this lack of alignment stems from issues of risk perception or political choices regarding the willingness to adopt new technologies, it is creating administrative burdens, duplication of efforts, and unnecessary cost increases for businesses and consumers.

Company Profile

The 3M Company (3M) is a global science-based conglomerate with a wide variety of products ranging from office to health care products. Its operations have expanded to more than 70 countries and its products are sold in nearly 200 countries.

In 2017, 3M's global sales totalled around US\$32 billion.¹⁹ Interestingly, 3M invests close to 6% of its revenue each year in research and development in order to develop "technologies that advance every company, products that enhance every home, and innovation that improves every life."²⁰ The company's business is divided into five major business sectors: consumer, industrial, electronics and energy, safety and graphics, and health care.

Within the health care industry, 3M is recognized as a leading global manufacturer of a vast portfolio of solutions that can be used by the food and beverage industry for sampling, identification, testing, and monitoring. 3M Food Safety products are sold in over 60 countries where the company works together with its customers to achieve the highest level of quality and safety for consumers.

Commercializing New Technologies in Canada: Challenges and Opportunities

When 3M develops a new microbiological detection method that offers improvements in the level of detection, accuracy, time to result, and productivity, it submits the method to third-party accreditation bodies that are recognized by most countries around the world, including the U.S. Many 3M Food Safety microbiological methods have AFNOR Certification (ISO 1640), which complies with European regulations and/or AOAC approval, which is accepted by U.S. authorities. However, in Canada, neither the certification nor the tests and validation data used for those submissions are accepted by HC, which has its own protocol for validation of alternative microbiological methods that differs from international schemes on technicalities (e.g., definition of fractional positives, classification of food matrices, and statistical analysis). Consequently, 3M is obliged to generate a second set of test data, prepare a new validation dossier, and start a new submission specifically for the Canadian market.

In December 2011, 3M introduced the first generation of the Molecular Detection System (MDS), a unique, fast, and accurate technology for pathogen testing. The method became available worldwide for detecting three of the most common pathogens (*Listeria* spp., *Salmonella*, and *Escherichia coli* O157), with a later launch of the *Listeria monocytogenes* assay in early 2012.²¹ By 2014, the four assays had received PTM certification from AOAC. In Canada, however, it took at least one additional year to get the methods approved and published by HC in the Compendium as "Laboratory Procedures for the Microbiological Analysis of Food" (MFLP) (see Table 1).

19 3M Reports Fourth-Quarter 2017 Results; Raises 2018 Earnings Outlook, 2018.

20 "3M Research & Development," 3M, 2018, <https://www.3m.com/3M/en_US/company-us/about-3m/research-development> [accessed July 12, 2018].

21 "3M Food Safety Unveils Innovative Molecular Detection System for Dangerous Foodborne Pathogens," *Business Wire*, 2011.

TABLE 1: COMPARISON OF APPROVAL DATES FOR THE FIRST-GENERATION 3M MOLECULAR DETECTION SYSTEM

Assay	PTM AOAC Certification Date	Compendium Issued Date
<i>Listeria</i> spp.	August 2012	November 2013
<i>Salmonella</i>	April 2012	July 2013
<i>Escherichia coli</i> O157	July 2012	November 2016
<i>Listeria monocytogenes</i>	May 2014	April 2017

Source: PTM Validated Methods - AOACRI, AOAC Research Institute [accessed, March 26, 2018]; “Laboratory Procedures for the Microbiological Analysis of Foods,” Compendium of Analytical Methods, Health Canada [accessed June 7, 2018].

In 2015, 3M decided to launch the second generation of the MDS, which claims to reduce technician time by 30%, among other benefits (see Figure 4), when compared to the previous generation. These new assays (*Listeria* spp., *Salmonella*, *Escherichia coli* O157, and *Listeria monocytogenes*) have been granted “First Action” status through the OMA program by AOAC INTERNATIONAL, and have already been benefiting food and beverage businesses in the U.S. for over a year. Meanwhile, in Canada, only the *Listeria* spp. assay has been approved and published as an MFLP in the Compendium.

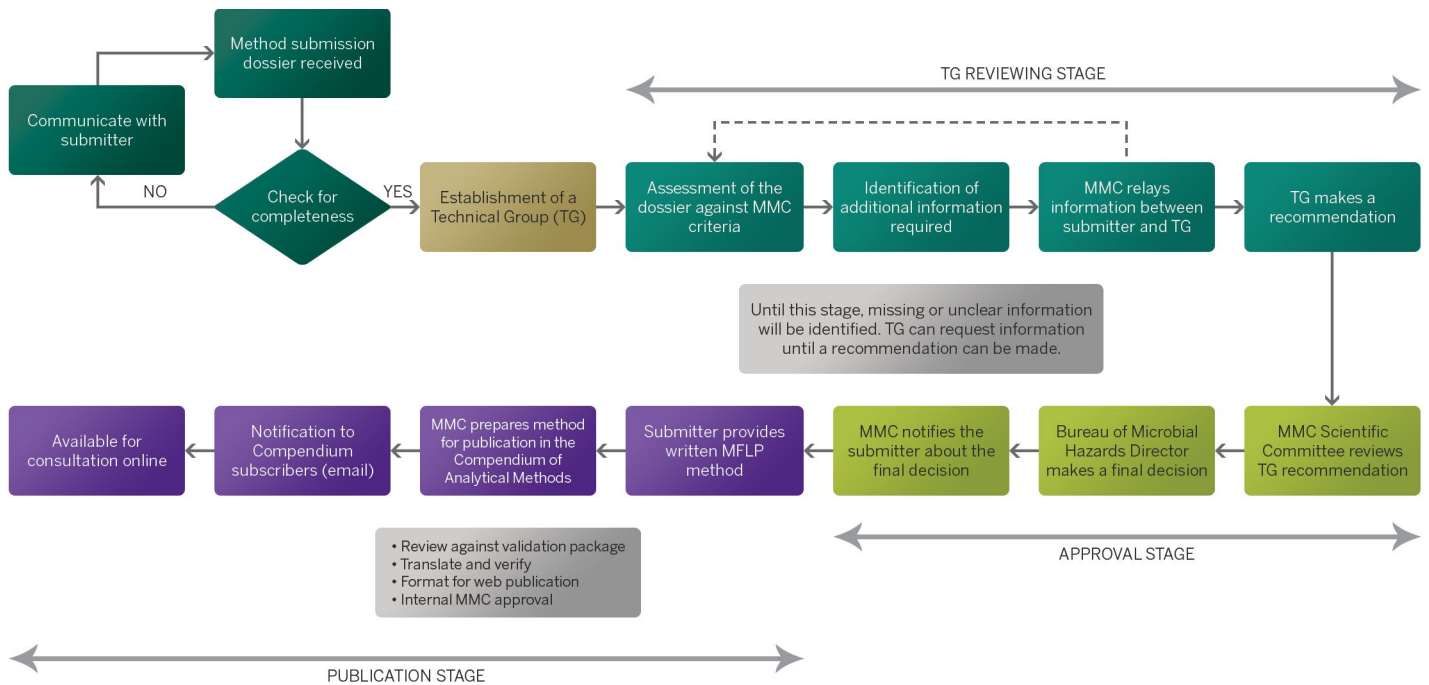
FIGURE 4: ADVANTAGES OF THE SECOND-GENERATION 3M MOLECULAR DETECTION SYSTEM OVER THE FIRST GENERATION

- Fewer handling steps, which reduces errors and contamination.
- Faster turnaround:
 - *Salmonella* and *E. coli* O157 assays gain a 15-minute reduction on instrument time compared to the first generation.
 - *Listeria monocytogenes* assay only needs 24 hours of sample incubation regardless of the type of food, compared to a matrix-dependent 24–48 hours incubation with the first-generation MDS.
- Higher performance.

Source: 3M, personal communication, May 8, 2018.

From the moment that a complete dossier is submitted to the MMC, it can take 18–30 months before it is officially published in the Compendium (see Figure 5). Notably, this process does not include the time required to generate the test data and prepare the dossier prior to submission.

FIGURE 5: APPROVAL PROCESS OF NEW MICROBIOLOGICAL METHODS BY THE MMC IN CANADA



Source: Leanne DeWinter, Microbiological Methods Committee, Bureau of Microbial Hazards, Health Canada, “Approval of Food Microbiological Methods in Canada,” 2014.

The MMC reviews the data and proposed method in great detail, meaning that it often comes back with questions and a request for additional information. This process can be slow and unpredictable due to an increase in the number of approval submission. Moreover, members of the MMC are officials from the CFIA and HC who might lack the time necessary to ensure a timely revision of all methods submitted. Once the method is approved, there is another long wait period, during which the method is prepared and approved by all parties for its final publication in the Compendium.

The process of validating, approving, and publishing a new microbiological method in Canada is not only long but also costly. To gain approval and commercialize a new pathogen detection method for the four organisms mandated by HC (i.e., *Listeria* spp., *Listeria monocytogenes*, *Salmonella*, and *Escherichia coli* O157), 3M estimates that it will cost the method developer approximately \$500,000 in out of pocket costs and approximately \$5.5 million dollars in net present value.²² These estimates are based on a cost comparison between two scenarios where an innovative method is being commercialized—one in Canada versus one elsewhere in the world (see Table 2).

22 3M, personal communication, March 7, 2018.

The pathogen testing market is growing globally, due in part to the implementation of stricter regulations such as the SFCA and the FSMA. Regulatory modernization is expected to make food manufacturers implement strong preventive systems, which include food safety controls across the whole supply chain. In addition, shifting to an outcome-based approach is projected to increase opportunities for innovation for food businesses, and give them more flexibility to introduce new technologies, processes, and procedures while achieving food safety requirements.²³ This growth represents a great opportunity for the pathogen testing market in Canada, considering that market grew 7.7% from 2013 to 2016, going from 224 million tests (23% of microbiology test volume) to more than 280 million tests (24.4%). In terms of total market value, pathogen testing accounts for 51%—or US\$1.8 billion—of the global market value of microbiology testing.²⁴

TABLE 2: ESTIMATED COST AND OPPORTUNITY COST: TWO SCENARIOS FOR METHOD AVAILABILITY

Cost of Approving a Method by Health Canada

	Range (CA\$)		
	Low	High	Average
Cost to generate test data as per HC at an accredited lab per organism	\$80,000	\$120,000	\$100,000
Cost of assays for those tests	\$8,000	\$10,000	\$9,000
Technical resource time	\$12,000	\$16,000	\$14,000
Subtotal per organism	\$100,000	\$146,000	\$123,000
Total cost for 4 organisms			\$492,000

NPV Analysis Comparing Two Scenarios*

*Note: data used is simulated and does not represent 3M actual data

Discount rate	10%		
NPV Scenario 1	\$6,743,907		
NPV Scenario 2	\$1,047,457		
NPV Delta	\$(5,696,451)		
Estimated pathogen testing supplies market	\$20,000,000	\$22,000,000	\$21,000,000

23 “Backgrounder: Proposed Safe Food for Canadians Regulations,” *Canadian Food Inspection Agency*, 2018, <<http://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/regulatory-initiatives/sfca/proposed-sfcr/tools-resources-and-guidance/backgrounder/eng/1484935542023/1484935542619>> [accessed April 5, 2018]; Canadian Food Inspection Agency, *Safe Food for Canadians Regulations*, Canada Gazette, 2017.

24 Bob Ferguson, “A Look at the Microbiology Testing Market,” *Food Safety Magazine*, 2017.

Scenario 1: Method commercially available in year 1

	Y0	Y1	Y2	Y3	Y4	Y5	Y6
Estimated share of new method		3%	10%	25%	30%	35%	35%
Estimated revenue		\$630,000	\$2,100,000	\$5,250,000	\$6,300,000	\$7,350,000	\$7,350,000
Estimated net cashflow		\$220,500	\$735,000	\$1,837,500	2,205,000	\$2,572,500	\$2,572,500

Scenario 2: Method commercially available in year 3 (After HC approval timeline)

	Y0	Y1	Y2	Y3	Y4	Y5	Y6
Estimated share of new method		0%	0%	0%	3%	10%	25%
Estimated revenue					\$630,000	\$2,100,000	\$5,250,000
Estimated net cashflow	\$(492,000)				\$220,500	\$735,000	\$1,837,500

Source: 3M, personal communication, March 7, 2018.

It must be noted that many of the agri-food products processed in the U.S. and imported into Canada are tested using methods approved in the U.S., but potentially not approved in Canada yet. Thus, the early access to innovative methods is providing an advantage to American food processors and could make the U.S. a more attractive market for method developers than the Canadian food manufacturing sector.

Initiatives to align regulations are in progress (e.g., the SFCR), and once these are fully enforced, they are expected to significantly reduce administrative complexity and duplication for government agencies and food businesses. Further, the MMC approval process has undergone a recent review intended to improve its efficiency and predictability.²⁵ Although updates to guidance documents, templates, and requirements that facilitate the submission process for stakeholders are expected, it is uncertain when they will be released and implemented. In the meantime, duplicative efforts and costs required to gain approval in Canada are discouraging developers and suppliers from investing and entering the Canadian market, while also preventing Canadian food processors and laboratories from accessing the latest technologies enjoyed in the U.S.

²⁵ MMC email communication, "Note to the Industry/ MMC Process Improvement," August 15, 2018.

CASE STUDY 2: MAPLE LEAF FOODS AND ACCESS TO NEW TESTING METHODS

Context

In a global food supply chain, where products have a short shelf life, food companies rely on rapid and efficient detection methods, not only for regulatory compliance, but also to minimize the risk to their brands and, of course, to consumers. In addition, companies require that testing methods be cost-effective without compromising the safety of their products.

The microbial testing market has evolved from conventional culture methods that can take days to obtain results to more innovative platforms that require just hours to determine if a pathogen is present. Besides offering increased efficiency and potential economic advantages, newer technologies are becoming more sensitive and specific as well, which means that pathogens can be detected at lower numbers and with a higher degree of confidence. Furthermore, testing companies are venturing on trends that favour greater flexibility and adaptive solutions, allowing laboratories to run multiplex assays without extra labour time. The food testing industry continues to grow, providing a vast array of testing alternatives for food businesses and laboratories to choose from based on their own requirements.

Food safety regulations require food businesses to test their products, equipment, and/or environment for the presence of pathogenic bacteria. In Canada, in high-priority cases such as *Listeria monocytogenes* and *E. coli* O157, alternatives for testing methods are restricted to those approved by the MMC to comply with the CFIA mandates. The options published in the Compendium are limited to less than 50% of those methods approved by AOAC (i.e. those available for U.S. food businesses) (see Table 3). This limitation means that food businesses and laboratories in Canada might need to choose methods that are less efficient and cost-effective when compared to alternatives available in the U.S. testing market.

TABLE 3: COMPARISON OF NUMBER OF APPROVED METHODS BY AOAC AND HC FOR THREE OF THE MOST COMMON PATHOGEN ASSAYS

Assay	AOAC approved methods		HC MFLP approved methods
	PTM	OMA	
<i>Escherichia coli</i> O157	34	5	12
<i>Listeria</i> spp.	42	11	14
<i>Listeria monocytogenes</i>	24	9	13

Notes: *E. coli* O157: all methods included can be used for testing meat and meat products. *Listeria* spp. and *L. monocytogenes*: all methods included can be used for testing meat and meat products and environmental surfaces.

Source: PTM Validated Methods - AOACRI, AOAC Research Institute [accessed, June 7, 2018]; Official Methods of Analysis, AOAC International, [accessed June 7, 2018]; "Laboratory Procedures for the Microbiological Analysis of Foods," Compendium of Analytical Methods, Health Canada [accessed June 7, 2018]

Company Profile

Maple Leaf Foods (MLF) is one of Canada's oldest and largest food processing companies with reported sales over \$3 billion in 2017, 11,500 employees, and more than 20 facilities across the country.²⁶ The company produces packaged meats for consumers in Canada, the United States, and Asia. Some of its most popular brands include Maple Leaf, Maple Leaf Prime, Maple Leaf Natural Selections, Schneider's, Schneider's Country Naturals, and Mina.²⁷

MLF has benefited from the highly integrated meat supply chain that Canada and the U.S. have developed. Every day, both finished products (e.g., wieners, sliced and whole piece deli meats, prepared meats, etc.) and intermediate products (e.g., fresh and frozen raw pork, chicken, and beef) produced in Canada are exported across the border for further processing in the U.S., and vice versa. In 2012, MLF sent over 650 shipments of meat across the border each month, worth \$240 million in total.²⁸

Looking to the future, and recognizing that food systems are gradually shifting to more sustainable, healthy, and humane alternatives, MLF plans to continue expanding and diversifying its business in both Canada and the U.S. To this end, the company has recently acquired two U.S. companies that have positioned MLF as the U.S. leader in the retail market for protein alternatives.²⁹ Meanwhile, in Canada, MLF has just acquired a privately held, market-leading company that raises organic, antibiotic-free chicken.³⁰ Moreover, in 2018, MLF launched the most extensive food rebranding in the history of the company, which included switching 44 meat product formulations to contain only natural, basic ingredients.³¹ With these acquisitions and product transformations, MLF seeks to demonstrate its commitment to become "the most sustainable protein company on Earth" and to "raise the good in food."³²

Access to New Technologies: Challenges and Opportunities

MLF has its own corporate laboratories, located in Aberfoyle and Toronto, that are responsible for all of the company's sample processing and testing. Federally registered food facilities require two elements to comply with the CFIA testing mandates: (1) laboratories must be certified by an accreditation body (e.g., the Canadian Association for Laboratory Accreditation (CALA) or the Standards Council of Canada (SCC)) before they can start implementing a testing method, and (2) testing methods implemented in the laboratory must be approved by HC when necessary (e.g., in the case of major food pathogens).

Accreditation of a laboratory can take up to six months for each new method that needs to be implemented, and costs can be substantial. For example, the accreditation cost for the lab in Aberfoyle is \$9,895 per year, and the cost for the Toronto laboratory is \$5,397 per year.³³ Further, adding a new method to the scope of a facility's accreditation costs the company approximately \$775 each time. However, if a significant addition (e.g., a new test format) must be included, it costs the company \$775 plus the costs for an auditor to travel to the facility to audit the new method—an estimated \$1,000 per day.³⁴

26 Maple Leaf Foods, *To Be The Most Sustainable Protein Company on Earth: 2017 Annual Report*, 2017.

27 Maple Leaf Foods, op. cit.

28 Maple Leaf Foods, personal communication, January 22, 2018.

29 Hollie Shaw, "Maple Leaf Foods Goes All-Natural in Entire Line of Processed Meats," *Financial Post*, May 15, 2018.

30 "Maple Leaf Foods to Acquire Select Poultry Assets of Cericola Farms," *Cision*, 2018, <<https://www.newswire.ca/news-releases/maple-leaf-foods-to-acquire-select-poultry-assets-of-cericola-farms-686801761.html>> [accessed July 20, 2018].

31 Shaw, op. cit.

32 Maple Leaf Foods, *2017 Annual Report*, op. cit.

33 Costs between laboratories vary depending on the number of methods included in the scope of accreditation.

34 Maple Leaf Foods, personal communication, April 4, 2018.

At MLF laboratories, approximately 1,192 major pathogen tests are run every week (57,216 annually).³⁵ For pathogens such as *Salmonella* spp., *E. coli* O157:H7, and *Listeria monocytogenes* labs use polymerase chain reaction (PCR) methods; for *Listeria* spp. testing, they use a more sophisticated combination of technologies (isothermal PCR and bioluminescence detection), which is produced by 3M. Although both techniques only need approximately an hour of instrument time to yield a result, the 3M MDS has the advantage of a less complex sample preparation when compared to a standard PCR. The newest version of the 3M MDS (i.e., second generation), which has only been approved in Canada for *Listeria* spp., has been shown to be more efficient with regards to turnaround time; for instance, the method currently used by MLF to detect *Salmonella* requires approximately 32.2 more minutes of active technician time plus 44 extra minutes of incubation and instrument run time for analyzing the same number of samples as the second-generation 3M MDS method (96 samples).³⁶ These sums total 183 extra labour hours and translate to extra costs of about \$4,572 per year based on the number of *Samonella* spp. tests run by MLF in 2017.³⁷

Currently, MLF performs a different method and protocol for each pathogen that analyze a maximum of 96 samples per run. Even if fewer than 96 samples need to be analyzed, a complete run has to be performed regardless. Thus, another effective cost-saving strategy involves having the flexibility to run all pathogen assays simultaneously following the same protocol to maximize output, which is an advantage of the second-generation MDS. Assuming that all of the second-generation 3M MDS pathogen assays were approved in Canada, MLF laboratories would be able to run the instrument at full capacity (96 samples) regardless of the pathogen assay, saving an estimated 268 hours of labour time (equivalent to \$6,696 per year) due to incomplete runs.³⁸

The direct costs of laboratory accreditation and extra labour time presented here may seem negligible for a company as large as MLF. However, other indirect costs and opportunities should also be considered, such as the benefits of redirecting saved labour hours to pursue other activities like training and reskilling personnel. In addition, although “time is money,” food businesses must consider accuracy and reliability of results in the equation. Manufacturing food products that are perishable in nature requires timely, accurate, and reliable testing results before products are released into the market. If a test needs to be rerun due to an invalid result or lack of accuracy, not only it will require extra work but it can also delay a product release, shorten product shelf life, and/or, worst of all, compromise the safety of consumers. For this reason, companies like MLF must weigh the alternatives in the Compendium and choose methods that provide the most accurate results, even if they might not be the most efficient to run.

It is not common practice for firms to quantify how much they can lose due to delays in product release or loss of product shelf life, nor do firms routinely quantify the benefits that new technologies could bring and their potential impact on current laboratory practices. Rather than investing in assumptions, these companies only look into what is available for regulatory compliance (because, as noted, time is money). What food companies *do* know is how much they can lose due to food contamination. Recalls cost companies millions of dollars in lost revenues, fines, lawsuits, legal fees, and loss of trust, and carry costs incurred for the government as well. Access to leading-edge technologies and products can play a key role in preventing these disastrous events and building a world-class safe food supply chain, which is the main goal of food businesses and government alike.

35 Based on 2017 data provided by MLF laboratories.

36 “Comparison of Four Rapid Pathogen Detection Platforms and the Impact on Technician Labor Time and Time to Result,” 3M, 2016.

37 Based on a minimum wage of \$25 per hour for chemical/ biochemical laboratory technicians (“Labour Market Information Job Bank,” *Government of Canada*, 2018, <<https://www.jobbank.gc.ca/explorecareers?select=ec-wages>> [accessed July 25, 2018].); Maple Leaf Foods, personal communication, July 26, 2018.

38 Estimates based on the number of samples run for major pathogens by MLF laboratories in 2017.

CONCLUSION

Canada and the U.S. share nearly identical levels of risk tolerance and preferences for commercial products. Moreover, their safety levels are so similar that in 2016, as part of the RCC Work Plan, the CFIA, HC, and the U.S. FDA signed the Canada-U.S. FSSRA. In theory, this agreement officially recognized that both countries' food safety systems provide comparable public health outcomes. In practice, implementation of these "recognized" regulations and standards has not resulted in the tangible results that greater cooperation between these agencies should bring—partly because the USDA was not a signatory of this arrangement. Accordingly, differences between the USDA and FDA systems could complicate cross-border regulatory collaboration regarding food safety, and ultimately prevent the elimination of product reinspections, audits of processing plants by the other jurisdiction, certifications and duplicative laboratory testing in much of the agri-food sector. Product approvals and foreign country/product inspections are still being done separately by the two jurisdictions.

There is no doubt that the biggest challenge to regulatory cooperation centres on the activities and actors involved in implementing certain regulations and standards, rather than the regulations and standards themselves. Differences in lower-level activities are the ones that are costing food companies time and money. Yet, these activities often seem to be overlooked by regulators due to the lack of quantifiable evidence demonstrating the economic and administrative burden they represent to food businesses. Therefore, the two cases presented in this report are intended to provide clear evidence of how food businesses still deal with unnecessary differences and suffer the consequences of duplicative requirements. However, more evidence from food businesses is needed to further the discussion and raise greater awareness about the real issues underlying regulatory misalignment. We hope that this report encourages more industry participation while providing regulators with some key recommendations to improve regulatory cooperation in the agri-food sector.

RECOMMENDATIONS

Trade should be considered in the policy-making process.

In 2012, the OECD countries adopted the *Recommendation of the Council on Regulatory Policy and Governance*, which recognizes “the need to establish institutions, governance, and processes to ensure that regulations are fit for purpose and do not impose unnecessary costs on society.”³⁹

Supply chains are no longer country specific. Instead, products are manufactured and shipped across the world. As such, trade should be considered (1) as an integral part of the commercial environment that is affected by the regulatory system, and (2) as an inherent activity during policy-making and when adopting new regulations that address health, safety, and the quality of consumer products. Because of trade, consumers in Canada and the U.S. are able to access a wide range of safe and high-quality agri-food products. It makes sense that trade practices be in line with regulations and their implementation on both sides of the border as a way of ensuring consumers’ safety, regardless of the product’s origin. Thus, it is encouraging to see that the Canadian government has provided \$10 million, over three years, to help federal departments and agencies incorporate economic and competitiveness considerations when developing and implementing regulations.⁴⁰

Industry stakeholders, regulators, and trade negotiators should have open discussions to improve regulatory cooperation.

It is crucial that industry stakeholders, regulators, and trade negotiators exchange information to advance the agenda on regulatory cooperation between Canada and the U.S. First, regulators and trade negotiators within each jurisdiction should communicate and work in close collaboration to avoid the emergence of new regulatory misalignments and to deal with existing ones. These conversations will require sound evidence and a deep understanding of how misalignments are affecting the economic competitiveness of the agri-food sector to support the decision-making process.

As shown in the case studies in this report, regulatory misalignment often occurs during implementation and at a technical level, so there is still little research or publicly available information that truly captures the effect of regulatory differences on increasing costs, trade restrictions, and consumer demands. In order to overcome this lack, industry stakeholders need to share their experiences more openly with government regulators and trade negotiators to improve evidence-based policy-making.

Creating an enabling environment for both industry and government to engage in conversations can be challenging. However, alternative forums such as discussion sessions, round table conferences, and/or workshops can be led by independent thought leader organizations. Emerging ideas and insights are easier to share in a neutral field. Moreover, adopting a bottom-up approach, where stakeholders are the ones informing regulators and trade negotiators, can help the latter prioritize their efforts and achieve the desired outcome (i.e., a safe food supply chain) in the most cost-effective way. This recommendation aligns with the recent proposal to launch a Centre for Regulatory Innovation announced by the federal government with \$11.4 million over five years, and \$3.2 million per year ongoing.⁴¹

39 *International Regulatory Co-Operation and Trade*, op. cit.

40 “Fall Economic Statement 2018: Chapter 3 - Confidence in Canada’s Economic Future,” *Government of Canada*, 2018 <<https://budget.gc.ca/fes-eea/2018/docs/statement-enonce/chap03-en.html>> [accessed November 25, 2018].

41 “Fall Economic Statement 2018: Chapter 3 - Confidence in Canada’s Economic Future,” op. cit.

International and private standards should be included within national regulatory frameworks to facilitate trade, encourage investments, and boost innovation.

Alignment with international standards has always been the ideal scenario. Substantial effort has been made at the international level to achieve a higher degree of collaboration among countries, but most of the work required to improve a global regulatory framework remains at the national level.⁴² It is well known that national regulations and institutions are subject to political pressure that can restrict the degree of international coordination achieved. Thus, one of the main challenges for every country is to determine the appropriate balance between domestic interests and international standards and certifications that are adopted.

In the agri-food sector, new technologies and methods available globally are thoroughly assessed and approved by third-party certification bodies that ensure the appropriate performance of the new products. Where reliable evidence exists to support the adoption of new technologies and products, it should not be necessary for product developers to incur extra conformity assessment costs or adjustment costs.

New technologies and innovations are key elements that should be used to make Canada a world-class leader in high-value food products and exports. Canada must update its regulatory system to allow for innovation and business growth while maintaining a high level of safety and quality of products. Private standards should be seen as a mean to achieve or complement regulatory compliance, rather than as a substitute for regulatory oversight. Due to the fact that private standards are mostly developed and updated by the industry, their recognition by regulatory authorities can help firms manage resources more efficiently (without needing to increase national capacity), keep up to date with the current needs of the industry, and minimize redundancies.

For example, the SCC has approved private standards such as ISO 9000, ISO 9001, and ISO 14001 as National Standards of Canada.⁴³ These standards are intended to help businesses be more efficient, meet environmental obligations, and ensure that their products meet customer expectations. Canadian certification bodies accredited by the SCC can assess and certify businesses following ISO standards, which are recognized globally. In fact, as part of the Fall Economic Statement, the government has announced that Canadian regulators will be able “to pursue mutual recognition of international regulatory decisions and approvals when a product has been certified and deemed safe by a comparable international regulator.”⁴⁴

A cultural shift towards regulatory partnership between Canadian and U.S. regulatory departments should be promoted downstream to support the adoption of common regulatory programs when possible.

As mentioned above, most regulatory misalignments do not occur at the top of the regulatory framework (i.e., acts and regulations), but at the operational level, when they are enforced. Even though an agreement has been signed by the U.S. FDA, the CFIA, and HC (i.e., FSSRA), the industry is still facing duplicative requirements, procedures, and routine activities when trading.

Having a recognition arrangement implies that there is a high level of trust among the parties that signed the arrangement; however, this trust needs to be transferred downstream. In other words, a change in culture and behaviour has to occur not only among top regulators, but also at the level of implementation.

42 Tim Josling, Donna Roberts and David Orden, “Food Regulation and Trade: Toward a Safe and Open Global System— An Overview and Synopsis,” in *American Agricultural Economics Association Annual Meeting* (Denver, Colorado, 2004).

43 “Popular ISO Standards Adopted as National Standards of Canada,” *Standards Council of Canada*, 2016 <<https://www.scc.ca/en/news-events/news/2016/popular-iso-standards-adopted-national-standards-canada>> [accessed June 19, 2018]. ISO 9001 and ISO 14001 as National Standards of Canada (NSC)

44 “Fall Economic Statement 2018: Chapter 3 - Confidence in Canada’s Economic Future,” op. cit.

Regulators must lead by example and show a willingness to try things in a different way. They should also raise awareness among their staff on the benefits that adopting common regulatory programs can bring to the industry and to their daily work. Technical officials from HC, the CFIA, and the U.S. FDA need to work together to develop training and/or reskilling programs for their staff based on the specific common regulatory programs; this is relevant because adopting common regulatory programs, when they make sense, and similarly mandated agencies on both sides of the border following the same procedures (e.g., the inspection processes, the same frequencies for testing, etc.) requires cross-recognized staff so that verification procedures and inspections are not redundant.

A pilot project of a joint food safety mechanism should be considered as part of the regulatory cooperation efforts.

Establishing joint mechanisms has been suggested by stakeholders on both sides of the border and with different perspectives in mind.⁴⁵ In addition, a December 2012 progress report to leaders from the RCC suggested that bringing jointly approved products to Canadian and U.S. consumers at the same time might be a decision that could help avoid unnecessary costs.⁴⁶ To date, HC and the U.S. FDA have been successfully working together under the RCC to develop a bilateral system for joint crop protection product reviews. Meanwhile, in the agri-food sector, the 2014 Joint Forward Plan proposed the development of a Canada- U.S. FDA Joint Committee on Food Safety to jointly develop criteria, processes, and tools to facilitate mutual reliance on food testing results.⁴⁷

Our recommendations entail leveraging the existing efforts under the RCC to ultimately establish an independent joint mechanism that institutionalizes the commitment to overview risk assessments, product approvals, and standards for both countries. Establishing such a mechanism under the RCC, led by the four main regulatory agencies involved in the agri-food sector (HC, CFIA, USDA, and U.S. FDA), could provide enormous benefits to Canada and the U.S., such as (1) dealing with new technologies and processes in a synchronized way from their inception, thereby avoiding duplication of efforts down the line; (2) reaffirming the commitment of regulators at the highest level towards developing joint work plans for emergent and current issues; (3) ensuring a consistent approval and risk assessment process that can be used along the highly integrated food supply chain regardless of where the product is produced or marketed; (4) combining the expertise from both jurisdictions to produce common evidence-based risk assessments and product approvals that can inform regulators during policy- and decision-making processes; and (5) bringing products to both markets at the same time, reducing costs for companies and consumers.

Given the benefits outlined above, it is clear that institutionalizing a joint mechanism could represent the next level of regulatory cooperation within the agri-food sector. Analysts must develop a detailed project proposal that can be distributed among key stakeholders, and then focus their efforts on executing the concept. The proposal will need to (1) identify the leading regulators to engage and the roles they will play within the new institution; (2) develop the objectives, responsibilities, and desired outcomes of the joint mechanism; and (3) describe a prototype of the approval and risk assessment process to be followed under this new joint mechanism (e.g., the creation of committees, stakeholder engagement, issue prioritization, timelines, etc.). Once a joint mechanism is institutionalized (and its benefits become tangible for government and business stakeholders), it has the potential to be implemented within other sectors as well. We expect this new approach to furthering regulatory cooperation and addressing regulatory misalignment to become a pilot project of the RCC Work Plan.

45 Meridian Institute, *Recommendations to Modernize the Meat and Poultry Oversight System in the United States*; Rory Mcalpine and Mike Robach, *Risk and Reward: Food Safety and NAFTA 2.0*, 2017.

46 *Canada-United States Regulatory Cooperation Council Progress Report to Leaders*, 2012.

47 "Canada-United States Regulatory Cooperation Council Joint Forward Plan August 2014," *Treasury Board of Canada Secretariat*, 2016, <<https://www.canada.ca/en/treasury-board-secretariat/corporate/transparency/acts-regulations/canada-us-regulatory-cooperation-council/joint-forward-plan-august-2014.html>> [accessed August 22, 2018].

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