Health Canada:
Framework for **Science** and **Research** **Excellence**

Health Canada   Santé Canada

Canada

Health Canada:
Framework for Science and Research Excellence

Health Canada is committed to strengthening science in government decision-making and supporting its scientists' critical work. In order for this to happen, Departmental scientists and researchers must have the tools and opportunities they need to pursue some of the most pressing questions we face, to make government science fully available to the public and to speak freely about their work.

Within Health Canada (HC), regulatory branches rely heavily on science to deliver on a mandate to help Canadians maintain and improve their health. Regulatory branches oversee Canada's health care system as well as safety of the food, health products and controlled substances supply. Our activities also include the promotion of a healthy and safe environment for living, working and recreation, by supporting climate change adaptation and reducing the harm caused by environmental contaminants and unsafe consumer and industrial products.

Scientists and researchers across HC undertake cutting-edge science and research and rely on the most up-to-date scientific information to inform decisions that impact the health and safety of Canadians. Our scientists deliver our mandate by carrying out a range of activities that include but are not limited to research, risk assessment, evaluation, surveillance, monitoring and testing. This work provides a strong evidence base that supports policies, programs, regulations, as well as risk and emergency management.

A Changing Context

The context that surrounds our science and research enterprise is constantly changing. Our science requires ongoing introspection, innovation, and investment to keep pace with a rapidly evolving domestic and global environment.

▶ Our government is committed to openness and transparency, with priority given to supporting our scientists, increasing stakeholder and public engagement, ensuring knowledge translation of research outcomes and promoting open access of our scientific publications, wherever possible.

▶ As responsible stewards of health data, we are embracing and investing in digital data sharing and management platforms, cooperative arrangements and big data practices.

▶ Health Canada is committed to being in good relation with Indigenous peoples. To this end, we continuously seek opportunities for reciprocal exchange of knowledge, identification of research priorities and collaborative approaches to science as a way to strengthen policy and regulatory decision-making.

▶ We increasingly rely on collaborations and partnerships to leverage expertise, help shape and influence domestic and international efforts, and support advancement of mutual interests.

▶ We are adapting our research designs and evaluations to better integrate sex, gender, race, diversity and Indigenous considerations through an intersectional lens.

- We are looking to the future to leverage innovative new approaches to advance our work while at the same time preparing ourselves to be able to assess and manage new products and technologies to which Canadians are exposed.

- Our communications with Canadians on science issues are placing more emphasis on accessibility, diversity, science literacy and timeliness by embracing social media, web, digital storytelling and other engagement tools so we can listen and adapt our course and messaging as necessary.

Overall, our priorities are increasingly global and our problems, more complex. Our policy experts are working with our scientists and evaluators to adapt our regulatory frameworks to changing environments and emerging technological and health innovations.

We continue to invest in a modern, highly skilled workforce that ranks our scientists among the best in the world.

A Framework for Science and Research Excellence

Staying at the top of our game takes work. To this end, HC has developed a Framework for Science and Research Excellence, herein referred to as the "Framework", to help guide our focus towards key elements of the science and research enterprise. This includes strengthening our foundations in areas like research ethics, sex, gender, race and diversity considerations, scientific integrity, Indigenous knowledge and investing in our scientists and researchers. It also includes foundational enablers which help position our science and scientists for success, including, but not limited to, library services, information technology (IT) and lab infrastructure, human resources (HR) support for science, and science security. Building upon the foundational elements, the framework recognizes the essential roles of enhanced communications and collaborations to deliver on our mandate and secure the trust and confidence of Canadians. Finally, sitting atop the Framework are elements related to nurturing and harnessing innovation, as well as learning through real-world experience and implementation science.

The Framework seeks to provide a clear, structured approach for thinking and talking about science and taking action on it in the Department. It will build on existing internal best practices and efforts to deliver on the above challenges. It will support a shared vision, as well as a common language and approach for horizontal science and research collaboration, internally within HC, and be flexible to meet the diverse needs of Branches.

Innovation & Real-World Learning

Communication and Collaboration

Foundational Elements and Enablers

Advancing the Framework

Health Canada's Framework must be relevant, timely and adaptive in order to meet the evolving needs of our science mandate. Its responsiveness will rely on ongoing input and perspectives from our scientist communities; views critical to ensuring the Framework appropriately captures our needs and describes a common vision for a healthy, innovative, highly-effective and internationally-respected scientific capacity. To this end, an integrated network of scientists and researchers (Health Canada's Science and Research Integration Network (SciRIN)) will ensure the views of the community are reflected, while lending voices and perspectives to inform decision-making on science interests.

Efforts to advance Framework elements will not be carried out in isolation. Implementation is a shared responsibility on the part of all Branches in the context of their own mandated activities. Work planning and prioritization will recognize and advance alongside ongoing initiatives, best practices and successful efforts, while prioritizing and strengthening areas of emerging concern in need of attention. Outcomes will take a number of forms including but not limited to guidance, procedural changes, strategic input, communications and explanatory instruments, with indicators for success developed and measured on an ongoing basis both at Branch and Departmental levels.

Ultimately Health Canada's Framework will help the Department steer a course for continued growth in science and research excellence, supporting the Department and the Government of Canada in our objective to serve Canadians well into the future.

Foundational Elements and Enablers

Foundational elements refer to core practices, standards and expectations considered essential for upholding the quality and rigor of Health Canada's world-class science and research. These include:

Anti-racism in science: Achieving racial equity in science involves the continuous work of actively opposing racism by methodically identifying, assessing, preventing, reducing and eliminating racial biases in the design, conduct, communication, management, review and use of research, science or related activities. HC aims to combat racial bias in science by actively seeking and generating disaggregated data and using these data as appropriate to take into account racial differences to support the relevancy of science and science policy decision-making and analysis for everyone living in Canada.

Data management and data sharing: HC's scientists and researchers not only generate vast amounts of data they also rely on third-party data to effectively deliver on the Department's mandate. HC's Data Strategy vision is to effectively use data as an asset to provide credible information, reliable advice and quality services. The commitment includes promoting science that it "Open by Design" and data that are "FAIR", i.e. Findable, Accessible, Interoperable and Reusable (Roadmap for Open Science) and comprehensively incorporate diversity and inclusion.

External science advice: HC upholds, promotes, and encourages the use of external science sources to acquire expert advice from individuals who have valuable knowledge or experience to inform the government's decision-making processes in an evidence-based manner. Various program areas within the Department currently use external experts, have in place a scientific advisory committee, or are considering implementing a form of receiving external advice.

Indigenous knowledge: "Indigenous knowledge has made, and continues to make, valuable contributions to environmental, regulatory, and other processes across the country."[11] HC encourages a science culture that seeks opportunities to learn from Indigenous people and exchange knowledge through two-eyed seeing and collaborative approaches to science. This is carried out in order to strengthen policy and regulatory decision-making processes and build trusting relationships with Indigenous Peoples in Canada.

Research ethics: Research by HC and/ or with external researchers involving human participants must meet the highest ethical standards to protect research participants in accordance with the core principles of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2).

Science governance: Science governance can start from individual employees leading a component of a research activity through to large-scale oversight and prioritization at the organizational level. Open and transparent decision-making around science at the senior management level is critical to ensure accountability of the organization for advancing science and research priorities at HC.

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[1]   Discussion paper: Indigenous Knowledge Policy Framework for Proposed Project Reviews and Regulatory Decisions. Government of Canada. www.canada.ca/content/dam/themes/environment/conservation/environmental-reviews/ik-discussion-paper-en.pdf

Science-policy integration: HC relies heavily on science to deliver on a mandate to help Canadians maintain and improve their health. Science and policy are two distinct disciplines that play a critical role in carrying out HC's mandate. HC relies on both communities to integrate scientific evidence in decision-making with a view towards strengthening HC policies, programs and legislation and in turn lead to positive outcomes for Canadians.

Science security: HC approaches its science within a culture of security and biosecurity that enables scientists to collaborate effectively with external organizations, while protecting valuable assets. Security encompasses aspects relating to threats relating to personnel, physical environment, IT/Cyber and collaboration vulnerabilities and intellectual property theft in accordance with the Treasury Board Secretariat's Policy on Government Security.

Scientific integrity: Under the HC-Public Health Agency of Canada (PHAC) Scientific Integrity Policy, scientific integrity is defined as "the condition resulting from adherence to concepts of transparency, openness, high quality work, avoidance of conflict of interest and ensuring high standards of impartiality and research ethics." HC fosters a culture that supports, promotes, and upholds scientific integrity as part of its scientific excellence.

Sex and gender-based analyses Plus: Biology, gender, economic and social factors contribute to differences in health risks, health services use, health system interaction, and health outcomes. The Health Portfolio Sex- and Gender-Based Analysis Plus Policy and the Health Canada SGBA Plus Action Plan 2022–2026 aim to strengthen the systematic integration of sex, gender and diversity considerations, through an intersectional approach, into all of HC's research, legislation, policies, regulations, programs, and services to advance equity, diversity and inclusion.

Foundational enablers refers to services required to support world-class infrastructure and a next generation scientific workforce. HC understands the importance of investing in the next generation of scientific professionals. The need to attract, retain and prepare to receive the next generation of scientists and researchers is part of HC's long-term investment.

Career progression and development: Opportunities for career advancement and career development should be available to all scientists and researchers wanting to progress. Employees need to understand what new leadership skills and training are required and available to move forward in their career, while maintaining a focus on their scientific expertise and interests. Likewise, HC must pursue a longer term vision including strategies to support career progression and retention within organizational boundaries.

Human resources support for science: HC Human Resources recognizes the unique considerations and needs of scientists and science programs within the Branches, including but not limited to the need to attract, hire and retain employees with specialized skills, the development of science management and science leadership competencies and supportive mechanisms for science collaborations. Accordingly, HC dedicates capacity to identify, explore and manage HR issues and opportunities with a view towards strengthening HR for science.

Labs, equipment and informatics: Modernization of laboratories, equipment and informatics is vital to keep pace with the advancement in technology in order for HC to meet its mandate and deliver services to all Canadians. In particular, replacement of broken or obsolete equipment, including upgrading of equipment software for informatics analysis is a critical priority for the department. HC's scientists and researchers rely on stable and modern equipment to be able to do their job efficiently and effectively.

Library services: The Health Library provides reference and research services and information resources that support the policy, research and regulatory activities of HC and the Public Health Agency of Canada. The research services provided by the librarians, enables scientists, researchers and policy makers to make well informed and timely decisions that aim to enhance and improve the health of all Canadians.

Communication and Collaboration

Effective communication of our science and strategic collaborations with partners, domestic and abroad, help to strengthen the rigor of our work and increase the public's confidence in federal science. It furthermore helps the population to better understand the role and importance of science in our decision-making and increases levels of science literacy amongst Canadians. Such efforts are essential to addressing the increasing and worrying prevalence of mis- and dis-information widely accessible to Canadians across media outlets.

Communication

Open and transparent science: HC is committed to greater openness in its science and research activities and results to accelerate discovery and implementation. Under the Office of the Chief Science Advisor's Roadmap for Open Science, federal science departments and agencies are advancing efforts to ensure that research summaries, articles and publications authored by federal scientists will be available open access. In addition to improving transparency, this will help us maximize HC's scientific contribution in the global sphere, support collaborative partnerships, and further raise the profile of our science and research activities.

Science communication: As forms of communication evolve, and as scientists are encouraged to communicate their work, HC seeks to support and enable its scientists in embracing and adopting

various communication formats including social media, blogs, podcasts, digital storytelling and more, alongside the more traditional forms of television, radio and print. The use of a variety of media tools enables the tailoring of messages to different audiences resulting in more effective outreach and engagement.

Science literacy: Science literacy is the ability to engage with science-related issues, and to understand basic scientific concepts and processes. HC has a role to play in communicating its science activities both internally to policy-makers as well as to the public in a way that resonates and builds trust.

Collaboration

Collaboration on horizontal science issues across branches, the Health Portfolio and within/outside government, domestically and internationally: HC works closely with domestic and international partners to deliver its programs and services and carry out cutting edge research in support of mandated activities. In addition to federal partners, it receives expert advice and consults stakeholders outside of government to enable more comprehensive and evidence-based decision-making. HC furthermore engages international partners to help strengthen domestic and global responses to health issues, by exchanging information, identifying challenges and sharing best practices.

Innovation and Real-World Learning

Innovation

The rate in which the world is evolving will require the government to respond with innovative ideas and tools. HC needs to maintain its resilience and ongoing pursuit of excellence by creating an environment that supports scientists, researchers, evaluators and inspectors to explore new approaches, build intellectual property and achieve results through novel means.

Artificial intelligence: Artificial intelligence (AI) is information technology that performs tasks that would ordinarily require biological brainpower to accomplish, such as making sense of spoken language, learning behaviors or solving problems[2]. While recognizing the limitations and risks of AI application, and following the Government of Canada's guiding principles and directives, Health Canada is exploring opportunities to integrate AI nto program processes, in order to improve services to Canadians.

Citizen science: Citizen Science (CS), sometimes called participatory research, community science or collaborative science, is an 'umbrella' term describing a variety of ways in which members of the public can participate in science. HC is exploring measures to facilitate the uptake of this powerful form of research and leverage world-wide momentum.

Evolving practices for stakeholder engagement: HC engages stakeholders on a variety of issues from pesticide regulatory decisions to the development of regulations, to domestic and international collaborations. HC's practices in engaging with stakeholders will continue to adapt as the public's awareness and appetite for science evolves.

Innovation sandboxes: Globalization creates the need for government to be agile and respond to novel products beyond traditional approaches. Regulatory sandboxes allow for live, time-bound testing of innovations under a regulator's oversight. They create space for industry to test, get regulatory advice, and seek support for innovative ideas and products that demonstrate the potential to provide benefits to Canadians and reduce regulatory burden.

Science and regulatory preparedness: HC must constantly be at the ready to respond to advancements in science and technology and emerging developments. With a growing number of disruptive technologies, we need to prepare our regulatory system to allow novel products (therapeutic, consumer, pesticides, food etc.) to get to market quickly to enable economic growth, while at the same time, protecting Canadians and our natural environment from potential negative impacts.

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[2] www.tbs-sct.canada.ca/pol/doc-eng.aspx?id=32592#appA

Real-World Learning

The knowledge gained and exchanged from real-world experiences enable staff to grow and gather insights to apply to the work they do, which benefits teams, projects, and the advancement of the organization as a whole. Real-world evidence continuously provides new information about the safety, efficacy and/or impact of a product or course of action respectively. This is in contrast to the initial data generated in a controlled environment, either in a clinical setting, with a limited population group or animal.

Implementation and behavioral science: Implementation science is "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services."[3] Understanding what works for whom, in which context, and why, will strengthen HC's ability to implement robust and comprehensive services, programs and policies for all Canadians.

Real-world learning: Iterative and timely analysis and evaluation to inform effective process, policy and practice: Continuous evaluation and improvement of current products, policies or programs based on real-world experience, allows for timely analysis and enhanced product effectiveness and/or safety. It also helps decision-makers identify risk mitigation measures that could include changes in process, policy and/or practices, which are essential for HC to remain current and relevant.

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[3]   Bauer, M., Damschroder, L., Hagedorn, H., Smith, J., Kilbourne, A. An introduction to implementation science for the non-specialist. www.ncbi.nlm.nih.gov/pmc/articles/PMC4573926/

Foundational Elements

- Anti-racism in science
- Data management and data sharing
- External science advice
- Indigenous knowledge
- Research ethics
- Science governance
- Science-policy integration
- Science security
- Scientific integrity
- Sex and gender-based analyses Plus

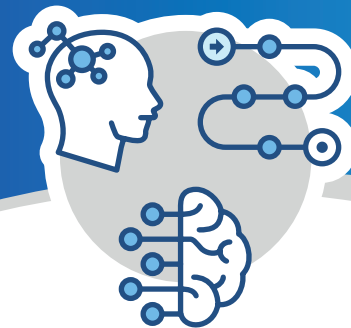### Foundational enablers

- Career progression and development
- Human resources support for science
- Labs, equipment and informatics
- Library services

Communication and Collaboration

- Open and transparent science
- Science communication
- Science literacy
- Science collaboration

Innovation and Real-World Learning

- Artificial intelligence
- Citizen science
- Evolving practices for stakeholder engagement
- Innovation sandboxes
- Science and regulatory preparedness
- Implementation and behavioral science
- Real-world learning