

Compliance Modernization

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Health Canada's Inspection Review

- Launched to identify challenges and opportunities towards strengthening Health Canada's compliance and enforcement function
- Functional Review conducted in Fall 2014
- Organizational review Jan-Mar 2015
- Compliance and Enforcement Modernization Roadmap development Feb-May 2015

Why Change?

We must evolve to:

- Adapt to a dynamic, regulatory environment
- Keep pace with rapid scientific and commercial innovation in the global market place
- Respond to public demand for more transparency
- Invest in technology to help identify and respond to risks

Our evolving approach

Current C&E Model

- Predominantly domestically-focused C&E programs
- Cooperation with other regulators
- C&E priorities static, sometimes misaligned with emerging risks
- High reliance on voluntary compliance
- Minimal transparency on C&E decision making
- Stand-alone and generally outdated IT systems and tools, preventing optimal risk analysis

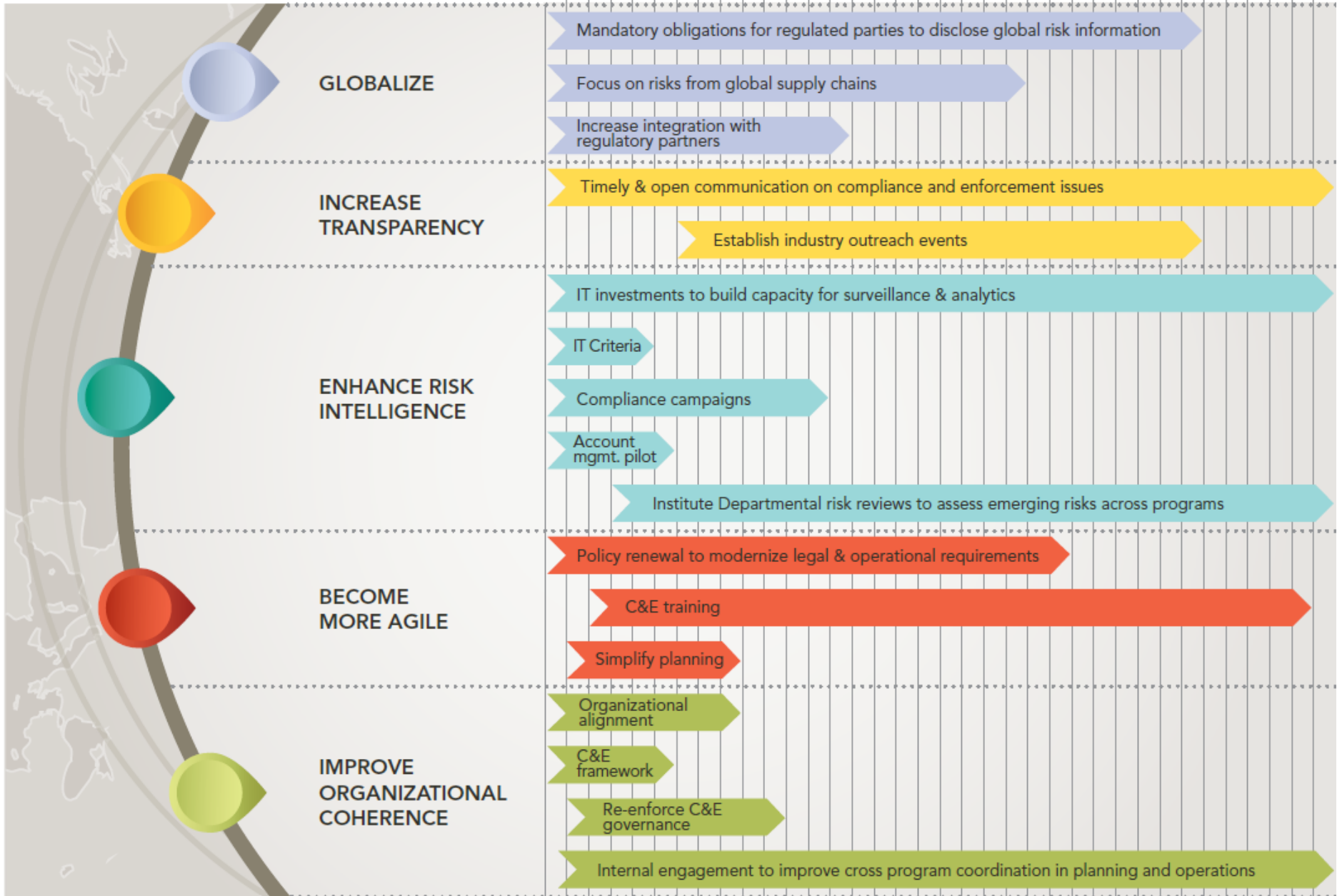
Where C&E needs to go

- Focused on risks presented by global supply chains
- Integration with other regulators
- C&E planning adaptive to a dynamic risk environment
- Use all compliance and enforcement tools to reduce harms
- Embed transparency in all C&E programs
- Integrated information based on international standards


C&E Modernization

- 5 themes covering 17 high-level actions, including transparency
- Blended approach with some program specific activities and some Department-wide
- Work underway on roles and responsibilities and risk intelligence
- Focused engagement critical to implementation

COMPLIANCE AND ENFORCEMENT MODERNIZATION ROADMAP



Transparency – drug inspection data base

 Government of Canada / Gouvernement du Canada








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Drug & health product inspections

Search results

Showing 1 to 10 of 4,415 entries | Show entries Filter items

Reference Number 	Establishment Name 	Site 	Inspection Start Date 	Rating 	Currently Licensed 	Terms and Conditions 
101029	Bayer Inc.	A	2015-11-03	Inspection in progress	Yes	Yes
101597	UCB Canada Inc.	A	2015-11-03	Inspection in progress	Yes	Yes
102212	Sterinova Inc.	A	2015-11-02	Inspection in progress	Yes	Yes
102269	Diamond Hoof Care Ltd.	A	2015-10-30	Inspection in progress	No	No
101076	McKesson Canada Corporation	I	2015-10-29	Inspection in progress	Yes	No
102189	Chifam Inc.	A	2015-10-29	Inspection in	Yes	No

Allows Canadians to find, in a searchable database, the latest results from the Government's drug and health product inspections.

Proactive Compliance Calendar

HEALTH CANADA COMPLIANCE CALENDAR FOR FY 2015–16 PROACTIVE COMPLIANCE CAMPAIGNS BY PROGRAM AREA

	CONSUMER PRODUCTS	PESTICIDES	HEALTH PRODUCTS	TOBACCO	CONTROLLED SUBSTANCES	RADIATION EMITTING
FOURTH QUARTER	<ul style="list-style-type: none">  Matches – verification of compliance with the flammability and labelling requirements of the <i>Hazardous Products (Matches) Regulations</i>.  Lighters – verification of compliance with the mechanical, labelling and record-keeping requirements of the <i>Lighters Regulations</i>.  Cribs, Cradles and Bassinets – focus on cribs and cradles for compliance with the mechanical and labelling requirements of the <i>Cribs, Cradles and Bassinets Regulations</i>.  Mandatory Incident Reporting under the CCPSA – develop educational videos for industry. 	<ul style="list-style-type: none">  Agriculture & Commercial Outreach – promoting the need to follow the label, including personal protective equipment & restrictive entry intervals. 	<ul style="list-style-type: none">  Nosodes – verify compliance with labelling changes for nosode products, a category of NHPs that have been promoted as a substitution for vaccinations. 	<ul style="list-style-type: none">  Cigar Inspections – based on amendments to the Tobacco Act, inspections at retail and importation levels. 	<ul style="list-style-type: none">  Marijuana Advertising Monitoring and Enforcement Team – Anticipated posting of advertising compliance actions taken to address illegal advertising of marijuana (e.g. warning letters). 	<ul style="list-style-type: none">  Tanning Equipment – border inspection in collaboration with CBSA to verify new tanning equipment labelling requirement.  Industrial X-Ray Equipment – regulatory review of industrial x-ray equipment.



Compliance Promotion

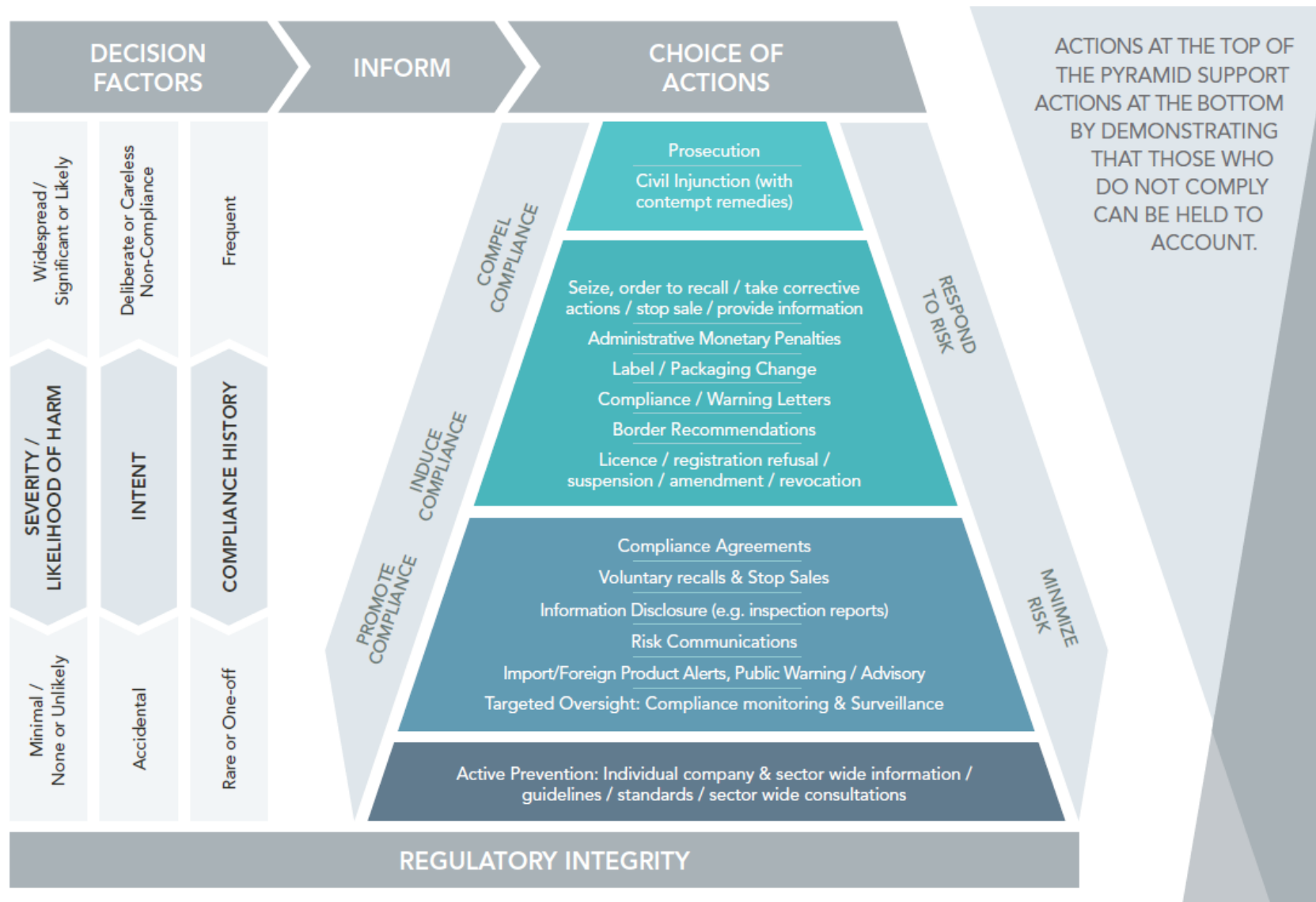
Compliance promotion is any activity that increases awareness, informs, motivates or changes behaviour, and encourages compliance with a regulatory requirement. This can include educational activities and making information available to both the regulated party and the public.



Compliance Monitoring

Refers to the oversight employed to determine if regulated parties are complying with the law. This can include surveillance, inspections and sampling.

Compliance Decision Model

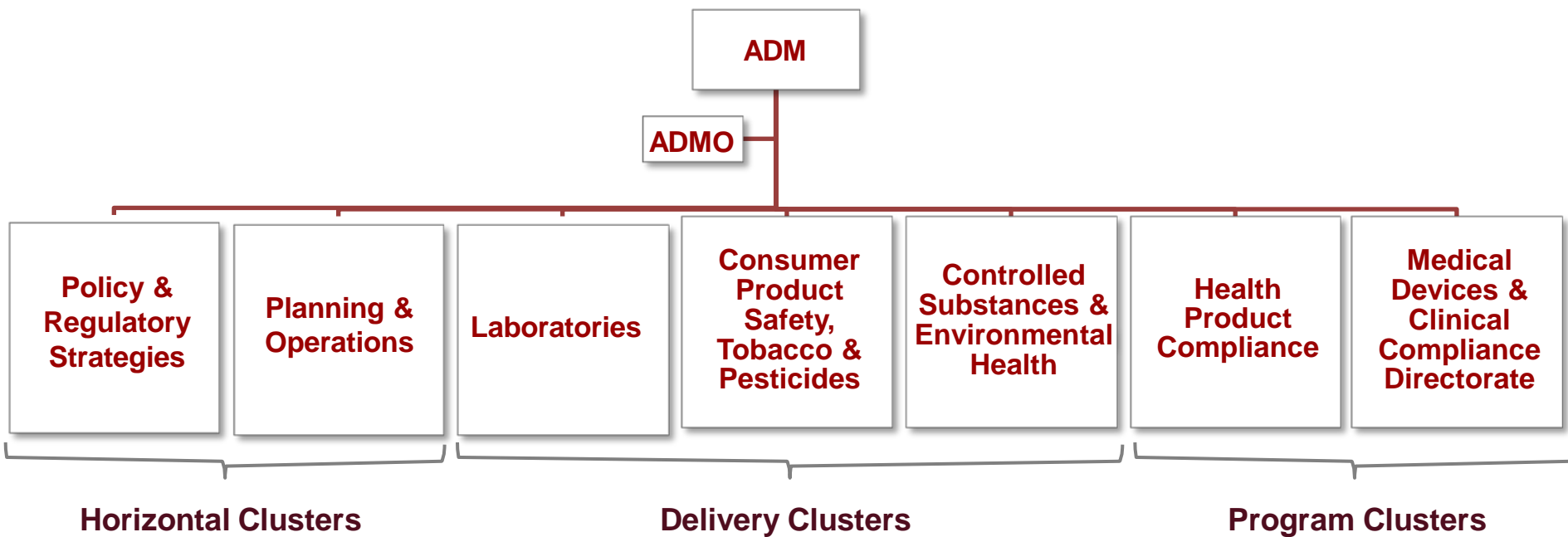


What Does Improving Organizational Focus Mean?

It means:

1. Establishing a single point of executive leadership and accountability for
 - a) What is delivered
 - b) How it is delivered
2. Simplifying the management of programs with national delivery
3. Reducing organizational complexity to help clarify roles and responsibilities with partner branches

ORGANIZATIONAL STRUCTURE



The story so far

Early Successes

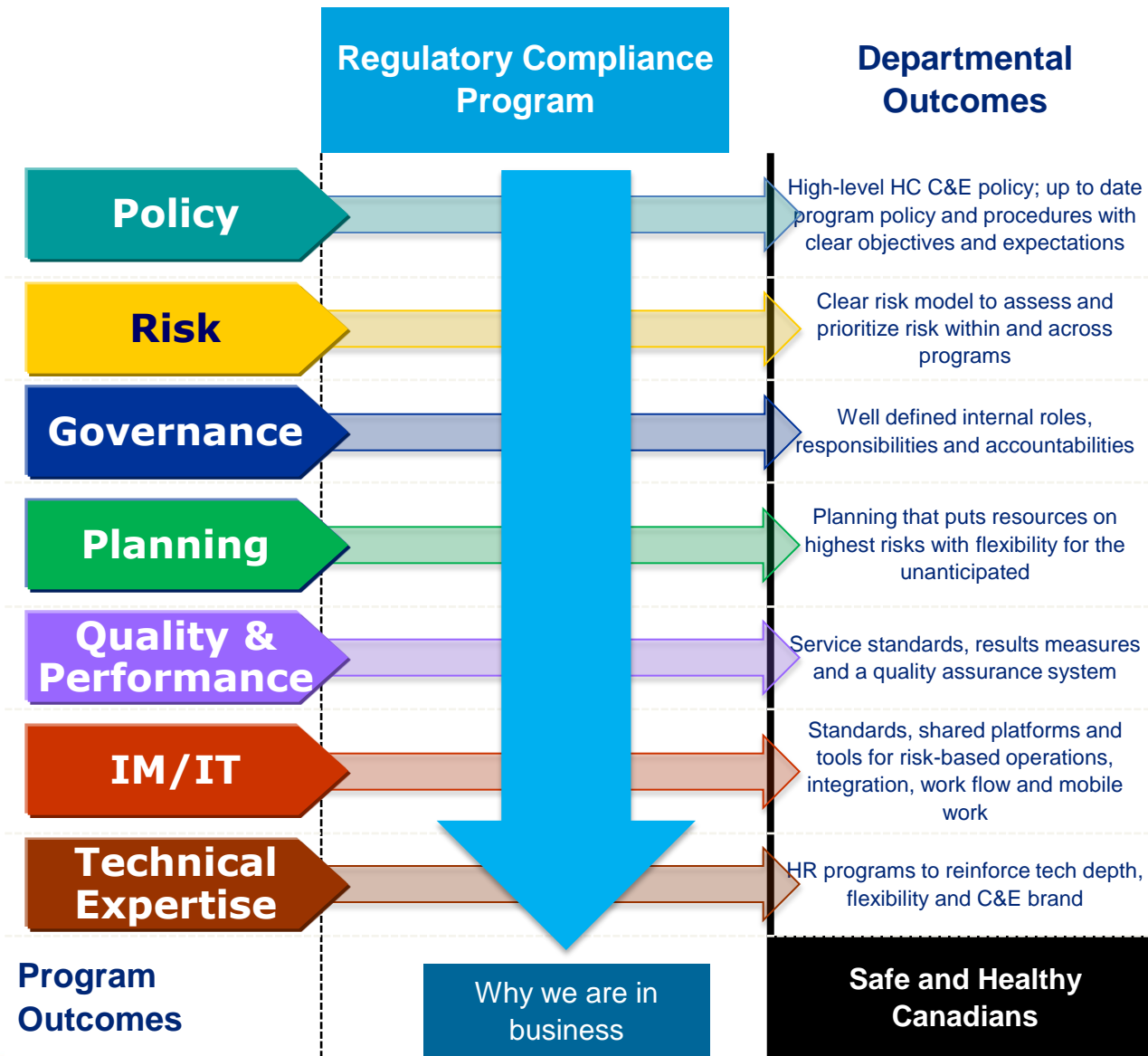
- Broad-based engagement
- Practical early wins
- Launch and learn
- Project management
- Governance - building a platform

Looking Forward

- Success metrics
- Engagement on implementation
- Agility + Coherence
- Early warning mulligan
- Change agenda management

Questions?

C&E Excellence Framework



Regulatory Operations and Regions Branch Roadmap

Vision:

Achieve regulatory excellence across the compliance and enforcement continuum

Compliance and Enforcement Transformation

Objective

To be risk based and responsive to: Global Supply Chain, Product Innovation, and Consumer Expectations



- Enhance risk intelligence for improved decision making and resource deployment
- Conduct and implement program and regulatory reform
- Increase transparency to inform Canadians and increase industry compliance
- Adopt a more proactive and assertive approach to non-compliance

Operational Excellence

Objective

To enable effective and efficient delivery of programs



- Deploy and leverage key technology enablers
- Review and improve operational rigour and consistency
- Demonstrate value and effectiveness
- Strengthen management processes

Strategic Partnerships

Objective

To maximize program results through purposeful and active engagement

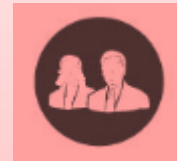


- Share and action risk-based intelligence
- Strengthen relationships through enhanced governance
- Lead and collaborate on best practices

People and Workplace

Objective

To achieve a respectful and high performing workplace



- Develop and support RORB employees
- Create opportunities for employees to participate in delivering our transformation agenda
- Champion mental health, diversity and OL strategies

Mission:

Lead compliance and enforcement and complementary scientific programs to inform and protect Canadians from health risks associated with products, substances and their environment