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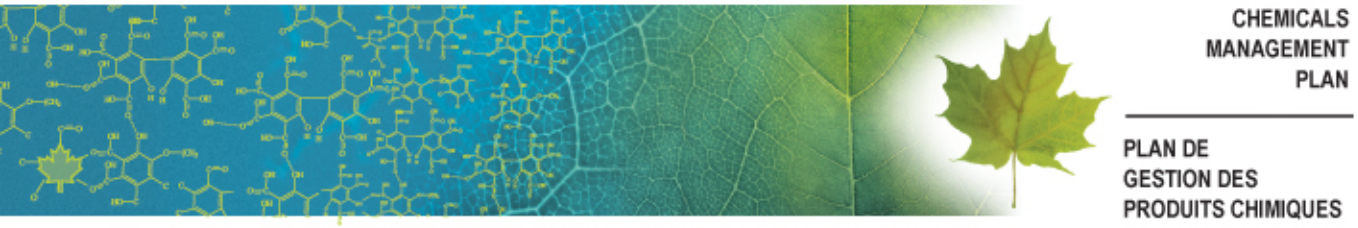
Overview of Approaches to Risk Management Decision-Making under the CMP

Health Canada – PAHO Workshop

Lima, Peru

November 8-10, 2016



CHEMICALS MANAGEMENT PLAN

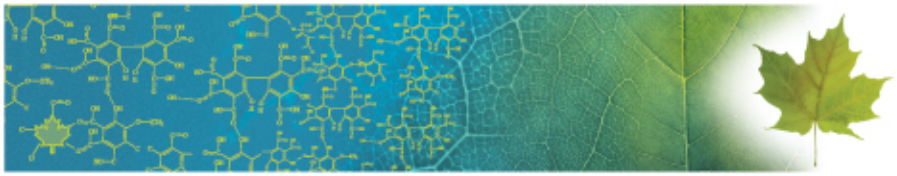
PLAN DE GESTION DES PRODUITS CHIMIQUES

Canada

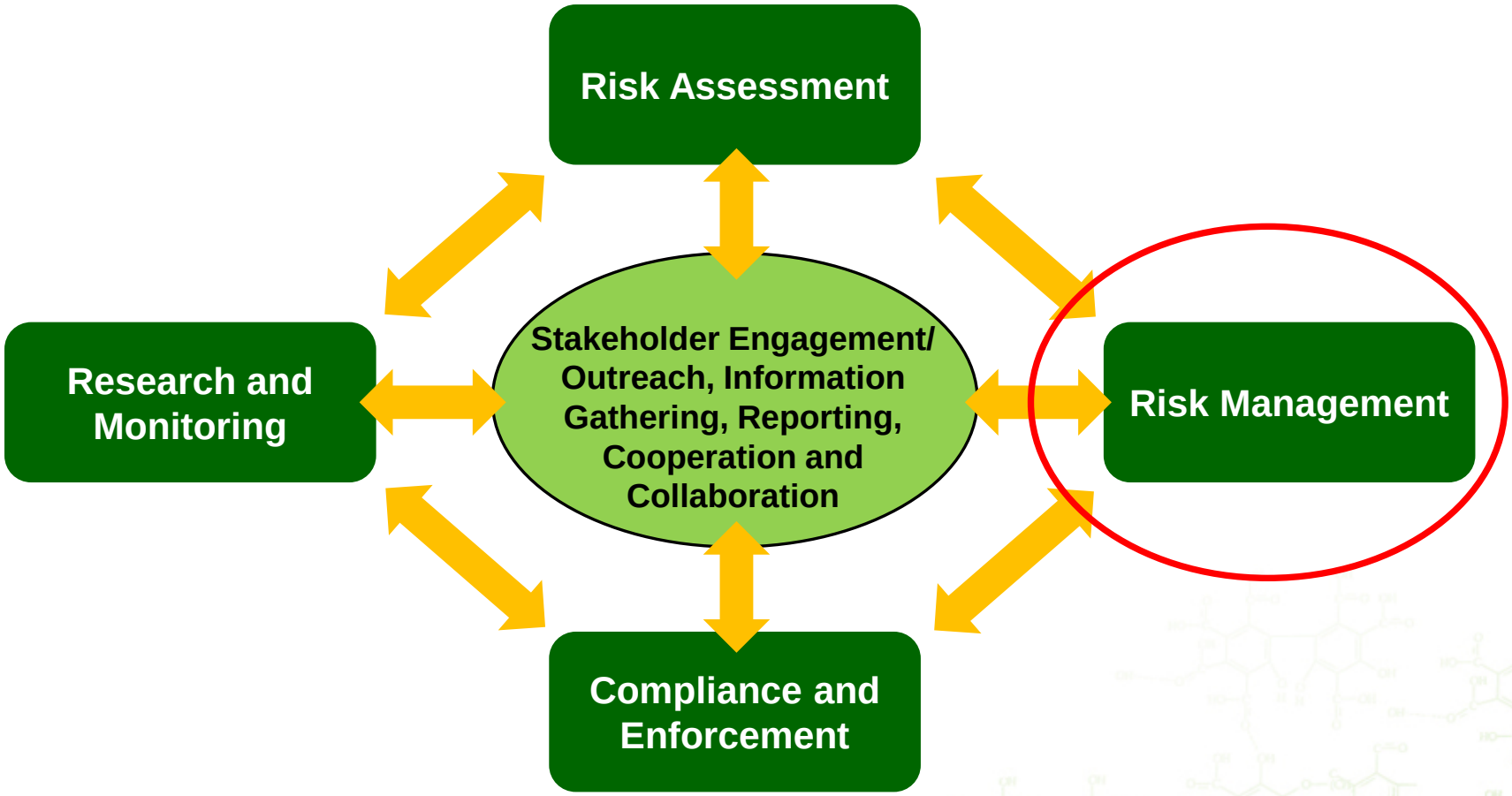
Objective

To provide an overview of the process for developing risk management (RM) instruments and factors influencing decision making

- Topics covered will include:
  - **Overview of the *Chemicals Management Cycle***
  - ***Description of the risk management process***
  - **Case study: *TDIs***
  - **Considerations and lessons learned**



Chemicals Management Cycle for CEPA Toxics

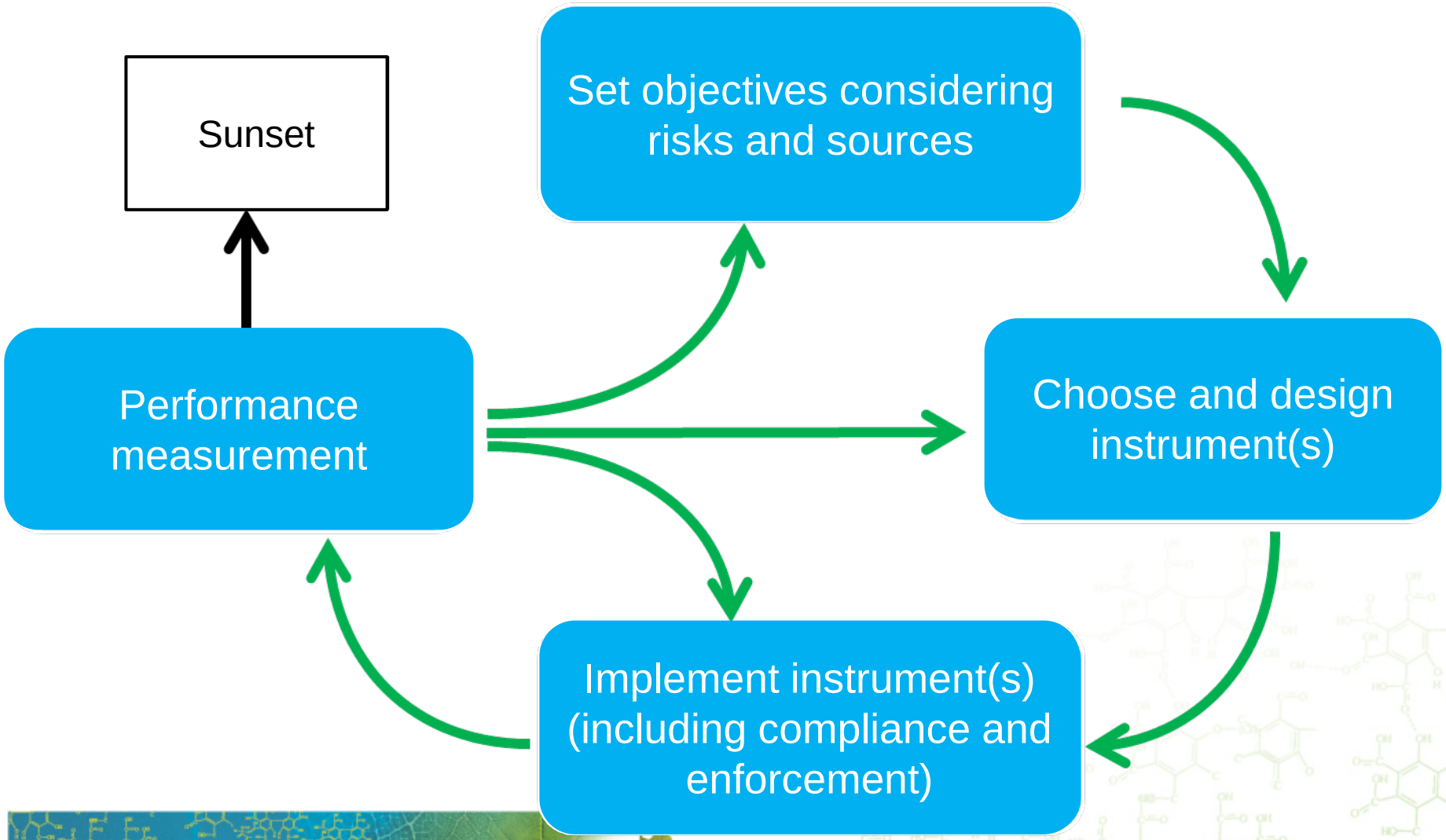


Risk Management

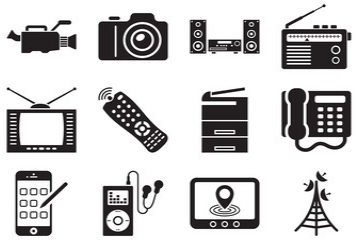
What is Risk Management (RM) for CEPA toxics?

- A **systematic** approach to identify and establish preventative or control actions to reduce or eliminate risks to human health and the environment posed by uses and/or releases
- It requires understanding the **lifecycle** of the substance in Canada
- Implementation of risk management includes compliance and enforcement
- RM is a **cyclical process** and does not “end” with the implementation of an instrument. Monitoring and performance measurement are used to assess ongoing relevance, success and effectiveness

RM Cycle


Sunset
Set objectives considering risks and sources
Performance measurement
Choose and design instrument(s)
Implement instrument(s) (including compliance and enforcement)

Sources of Environmental Release



Product Import, Export and Use

Transportation within Canada and across Canadian borders

Product Manufacturing / Assembly

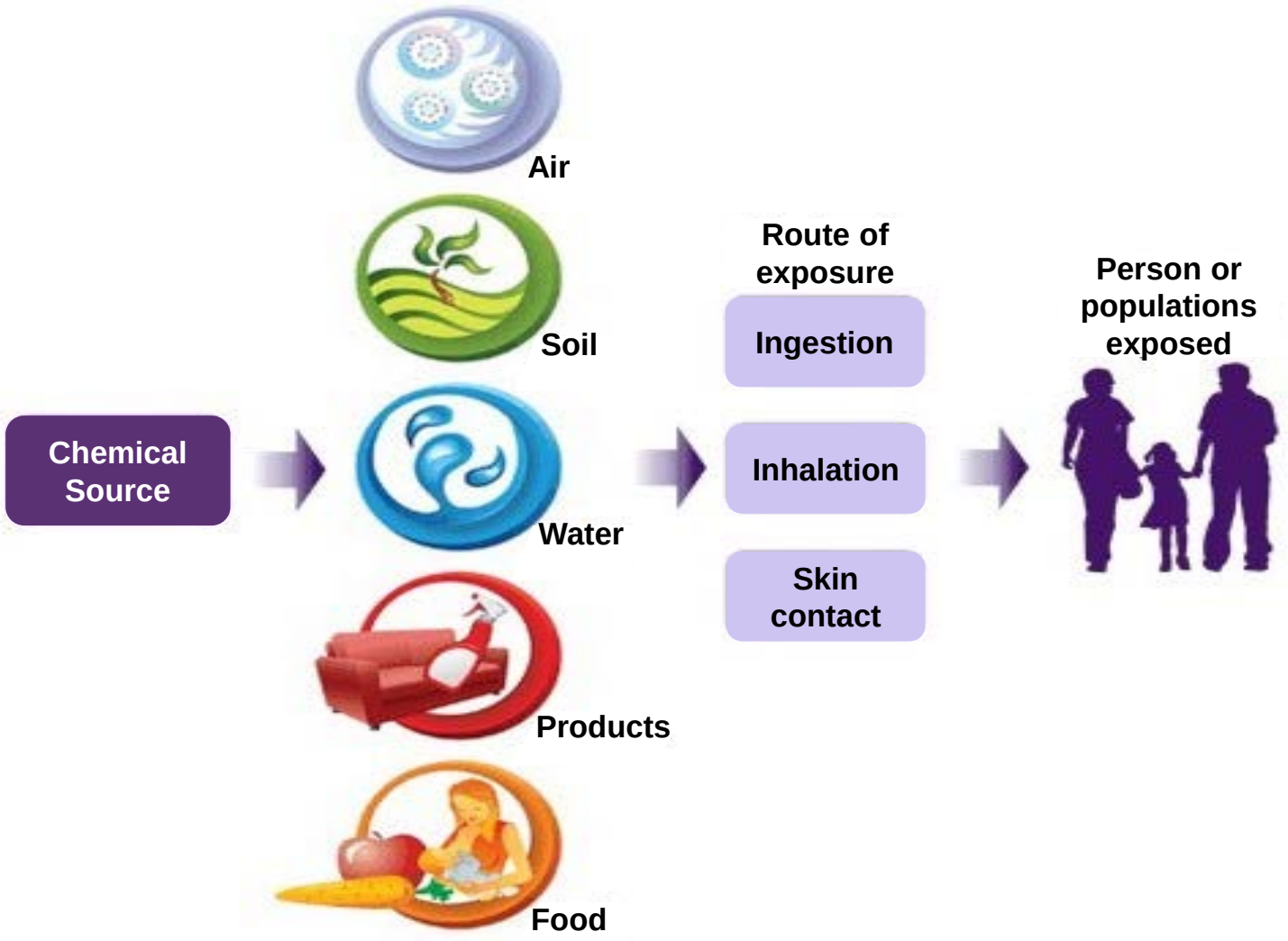
Releases to air, water, soil

Disposal / recycling

Chemical Manufacturing

Resource Extraction

Sources of Human Exposure



Initiating RM

Prior to proposing risk management actions, the following objectives are defined:

Environmental / Human Health Objective(s)

- Overall objectives to control, reduce, eliminate or prevent risks to the environment and/or human health based on affected media / exposure identified in the Risk Assessment phase

Risk Management Objective(s)

- Quantitative or qualitative target expected to be achieved by implementation of RM measures
- Different Risk Management Objectives (RMO) can be set for for different sources of release and exposure

Selecting a Risk Management Tool

A standardised framework is used for selecting the most appropriate tool(s) for risk management objectives. The following six main criteria are used:

- **Effectiveness:** degree to which the instrument can achieve the RM Objective in a timely manner
- **Economic Efficiency:** achieve the RM Objective while maximizing the overall benefits and minimizing costs to all stakeholders
- **Distributional Impact** of the instruments in terms of equity in the distribution of costs and benefits between sectors and regions
- **Stakeholder Support:** industry, provincial, territorial and municipal governments, ENGOs, Canadian public, etc.
- **Compatibility** with existing or proposed control measures in other jurisdictions
- **International Obligations:** alignment with Canada's international environmental, trade and/or investment obligations

Best Placed Act

- RM instrument under CMP can be developed under different Acts:
  - *Canadian Environmental Protection Act, 1999 (CEPA)*
  - *Food and Drugs Act (F&DA)*
  - *Pest Control Products Act (PCPA)*
  - *Canada Consumer Product Safety Act (CCPSA,* formerly *Hazardous Products Act)*
  - *Fisheries Act*
- Using the above Acts enables the use of existing government programs and areas of expertise and provides continuity in maintaining relationships with stakeholders.

Instruments Under CEPA Include

Instrument	Examples
Regulations	• Prohibition of Certain Toxic Substances Regulations, 2012 • Products Containing Mercury Regulations
Significant New Activity	• Pigment Red 3, TCEP
Pollution Prevention Planning Notices	• Synthetic Rubber Manufacturing Sector – Isoprene • Siloxane D4 in Industrial Effluents • Polyurethane and Other Foam Sector
Codes of Practice	• Code of Practice for 2-Butanone, oxime (Butanone oxime) Associated with the Interior Application of Consumer Alkyd Paint and Coating Products
Release Guidelines	• Guidelines for the Reduction of Dyes Released from Pulp and Paper Mills

Instruments Under Other Acts Includes

Act	Instrument/ RM Tool	Examples
Canada Consumer Product Safety Act	Schedule II prohibition on consumer products	• Polycarbonate baby bottles that contain BPA • Products that are made, in whole or in part, of polyurethane foam that contains TCEP and that are intended for a child under three years of age
Food & Drugs Act	Code of Practice	Codex Code of Practice for Reduction of Acrylamide in Foods
	Cosmetics Hot List	Naphthalene, Michler's Ketone
	Other	Consumption advice for Canadians to reduce acrylamide exposure
		Amendments to Food Packaging Submission Review Policy (DEGME)
		Updated Disinfectant Drugs Guidance Document (Methyloxirane)

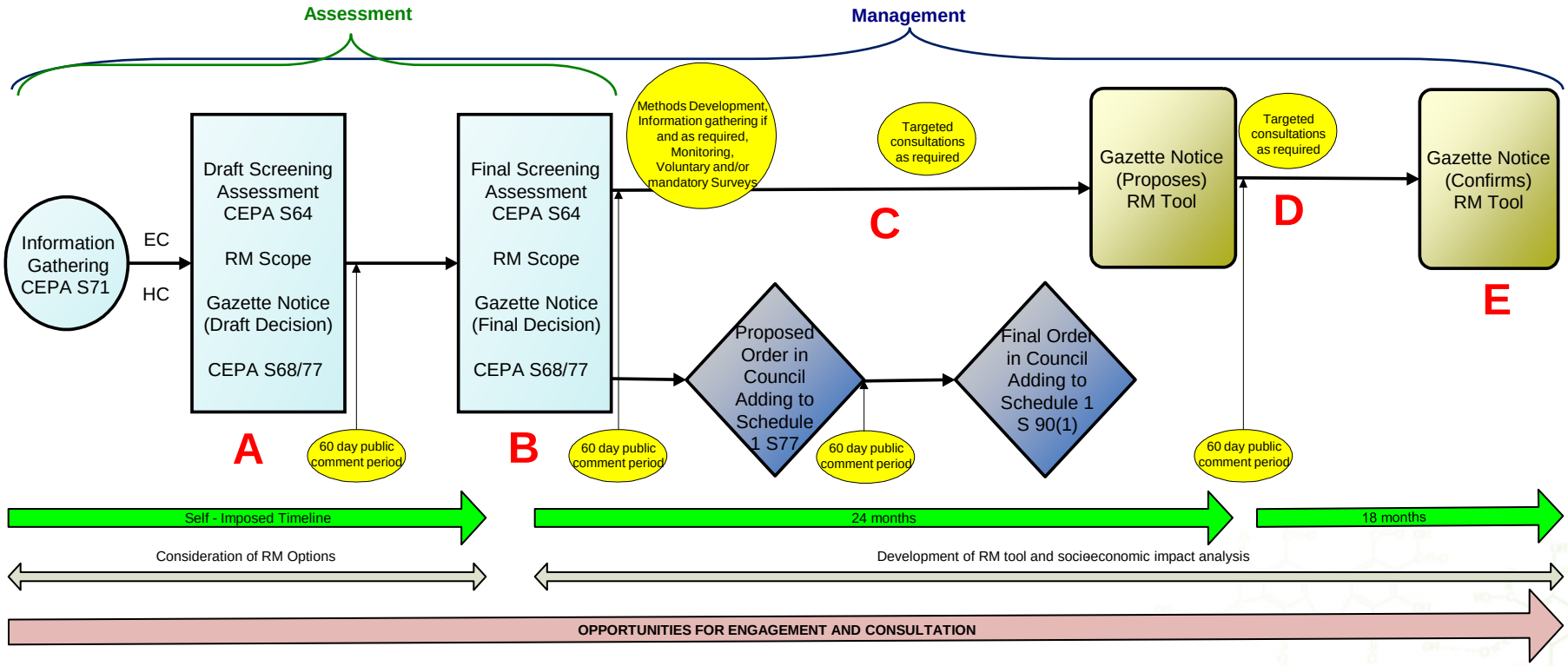
Enforcement and Compliance

- Compliance and enforcement taken into consideration as part of the instrument design
- Compliance is secured through two types of activity: promotion and enforcement
- Promoting compliance contributes to the awareness and understanding of regulated communities of their obligations

Performance Measurement (PM) of RM Instruments

- Planning for PM is initiated during the design phase of the instrument – logic model and indicators developed
- During and after the implementation of an instrument, PM assesses:
  - success and effectiveness of the instrument in meeting the objectives and determine if additional actions are required, such as:
    - additional compliance promotion
    - amending the instrument
    - use of a different instrument
  - ongoing relevance of the instrument
- Broader, substance-based performance measurement may be undertaken

Stakeholder Engagement Opportunities



Canada's Risk Assessment and Management of Existing Substances

Opportunities for Engagement in RM

A. Risk Management Scope

- RM Scope: Intent is to engage stakeholders as early as possible on potential options for risk management, and obtain feedback to inform the RM Approach

B. RM Approach

- RM Approach: Intent is to engage stakeholders with more details on proposed risk management and obtain feedback to inform the development of instruments

C. Post RM Approach

- Post RM Approach Work: Intent is to design “best” instrument to meet Risk Management Objective, (i.e.: preventative, elimination, reduction, controls, monitoring/measuring, etc.)
  - Further consultations with Stakeholders and Industry

D. Post - Proposed RM Instrument

- Post –Proposed RM Instrument Work: Intent is to review, refine and finalize the proposed RM Instrument to best suit the risk; input from the public consultation process is reviewed and considered.
  - Final consultations with Stakeholders/ Industry:

E. Risk Management Effectiveness

- RM Effectiveness: Intent is to measure progress, monitor compliance

TDIs Case Study

Risk Management of TDIs*

A case study demonstrating the importance of stakeholder engagement in determining the most appropriate instrument

* CAS RN 26471-62-5; 2,4-diisocyanato-1-methyl-benzene (2,4-toluene diisocyanate = 2,4-TDI), CAS RN 584-84-9; and 2,6-diisocyanato-1-methyl-benzene (2,6 toluene diisocyanate = 2,6-TDI) CAS RN 91-08-7]

Context

Risk Assessment Conclusion

- Toluene Diisocyanates (TDIs) were found to be toxic to human health under CEPA; but not to the environment
- Added to Schedule 1 of CEPA 1999 on May 12, 2010

Uses

- Not manufactured in Canada; Quantity imported in 2006: 24,000 tonnes
- Primarily used to produce flexible and rigid polyurethane foam (97%)
- Other uses (3%): Coating, adhesives, sealants and elastomers

Releases and Exposure in Canada

- Main releases are to air
  - NPRI reported a release to air in 2006 of 2,000 kg, with 70% from one PU-foam manufacturing facility in Quebec, approximately 20% from Ontario and 10% from Alberta
  - No known natural releases
- Human exposure potentially higher near facilities that manufacture polyurethane foam

TDIs -- Human Health Objective/RM Objective

- Human Health Objective for TDI: To minimize human exposure to the greatest extent practicable

- Risk Management Objective for TDIs: To achieve the lowest level of release to the environment that is technically and economically feasible

- Consultation on the proposed risk management via the Risk Management Scope and Approach documents as well as during the development of the risk management instruments

Considerations for Instrument Selection

- Key existing RM
  - Air quality criteria for TDIs in ambient air set in Ontario
- Availability of substitutes
- Alternative technologies and/or technique
- Children's exposure

TDIs -- Risk Management Instruments

- Initial RM Approach for TDI proposed:
  - Instrument that prescribes maximum TDI concentration at air stack exhaust to control and reduce TDI releases to the environment from the foam industry
  - Investigation of the management of non-foam consumer products
  - Addition of TDI to the Cosmetics Ingredient Hotlist

- Upon further consultations with industry stakeholders and a study group
  - the complexity of addressing releases of TDI through an air stack exhaust limit became evident
  - Sector based Pollution Prevention (P2) Planning Notice was then considered to be the most appropriate risk management instrument

TDIs -- Pollution Prevention (P2) Plans

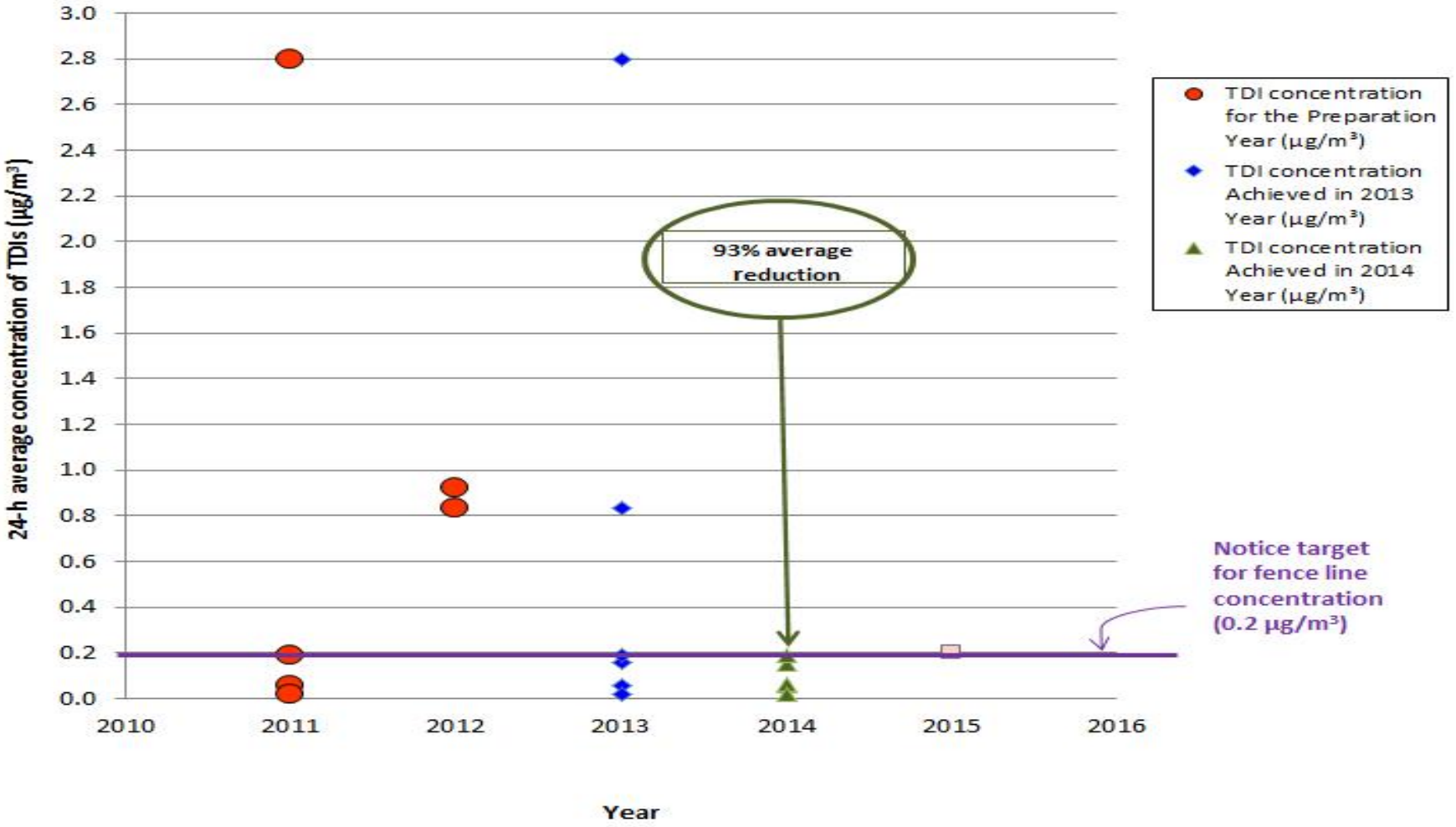
- P2 Plan Notice published on November 26, 2011
  - Objective: to reduce potential human exposure in the vicinity of facilities releasing TDIs to air.
  - Applies to owners or operators of facilities within the polyurethane and other foam sector (except polystyrene) which, at any time, purchases, imports or uses greater than 100 kg/year of toluene diisocyanates (TDIs) and is involved in the activities specified in the Notice.
  - Facilities required to reduce their emission of TDIs to air, to the greatest extent practicable, through the application of best available techniques economically achievable, to the following limits:
    - less than 100 kilograms per year (kg/yr); or
    - a fence line concentration at or below 0.2 micrograms per cubic metre ($\mu g/m^3$).

Performance Results (Oct. 2015) for TDIs P2 Plan

- 100% of the reporting facilities have a P2 plan in place and anticipate meeting the risk management objective of this Notice.
- 85% of facilities have implemented their P2 Plan actions.
- The remaining facilities have committed to implementing their P2 plan by the end of the reporting period (i.e., November 2015).

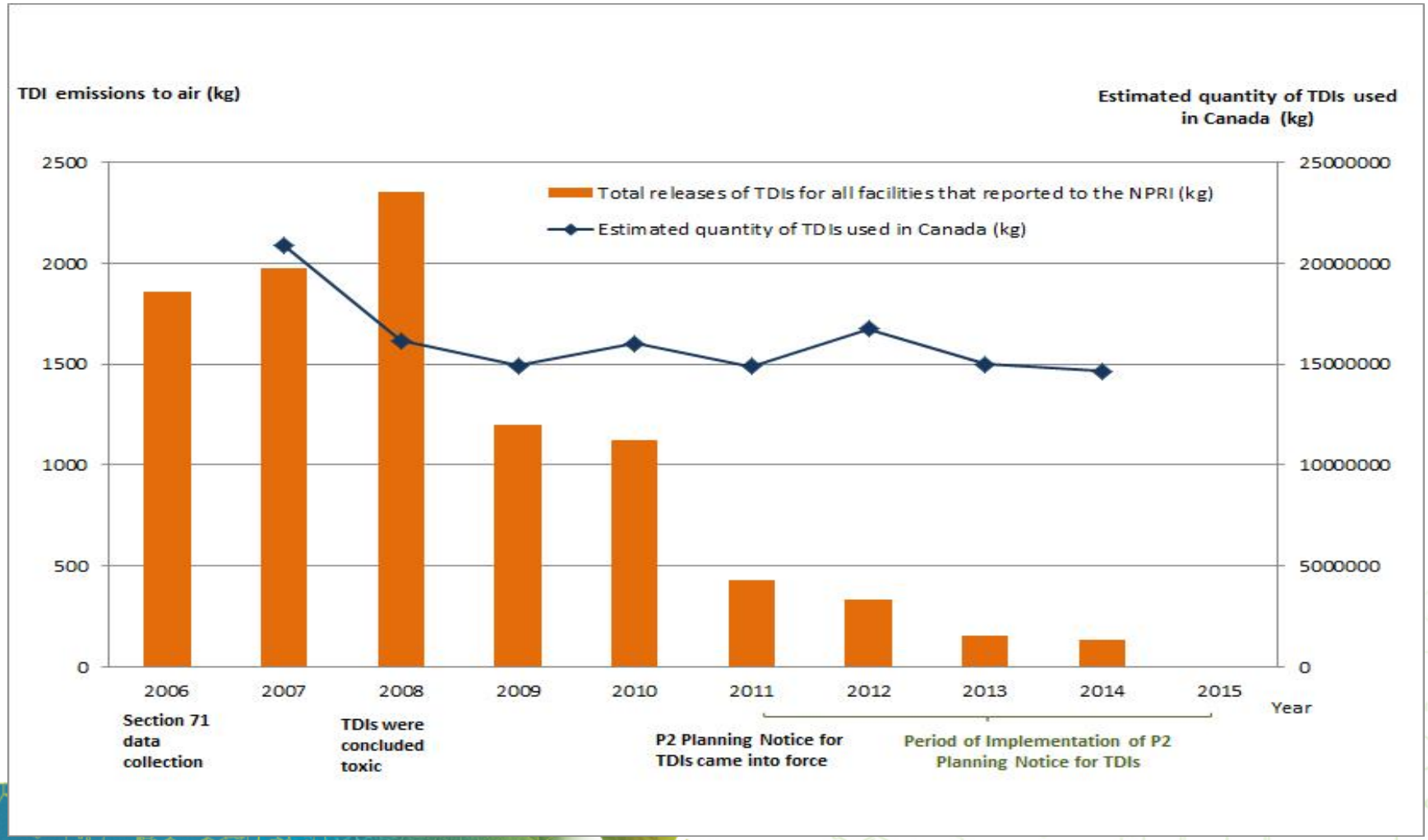
P2 Plan - Performance Results for TDIs – (contd.)

TDI concentration at the fence line



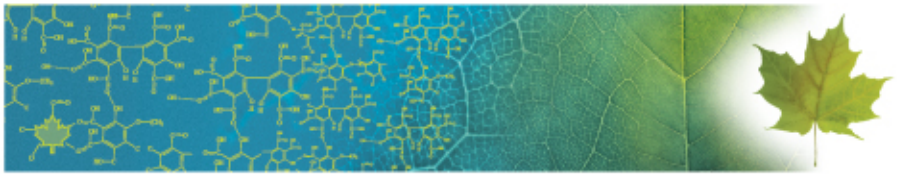
P2 Plan - Performance Results for TDIs – (contd.)

Releases of TDIs reported to the NPRI and estimated quantity of TDIs used in Canada (dual scale)



Lessons Learned

- RM is an ongoing process and does not end when an RM instrument is implemented
- Evaluation of our progress towards achieving our objectives (performance measurement) is an important part of the RM process
- Importance of periodic data collection (i.e. via mandatory surveys, voluntary surveys, monitoring & surveillance) to evaluate our progress and determine whether further RM actions are needed
- RM decision-making is flexible and is adjusted based on evidence
- Consultation with stakeholders is an important element in our RM decision-making and is done throughout the process
- Evidence provided by stakeholders is critical and supports sound RM decision-making
- Working with industry to encourage voluntary actions can achieve the RM objectives and may provide other benefits such as efficiencies and flexibilities



ANNEX 1

Examples of Risk Management Instruments

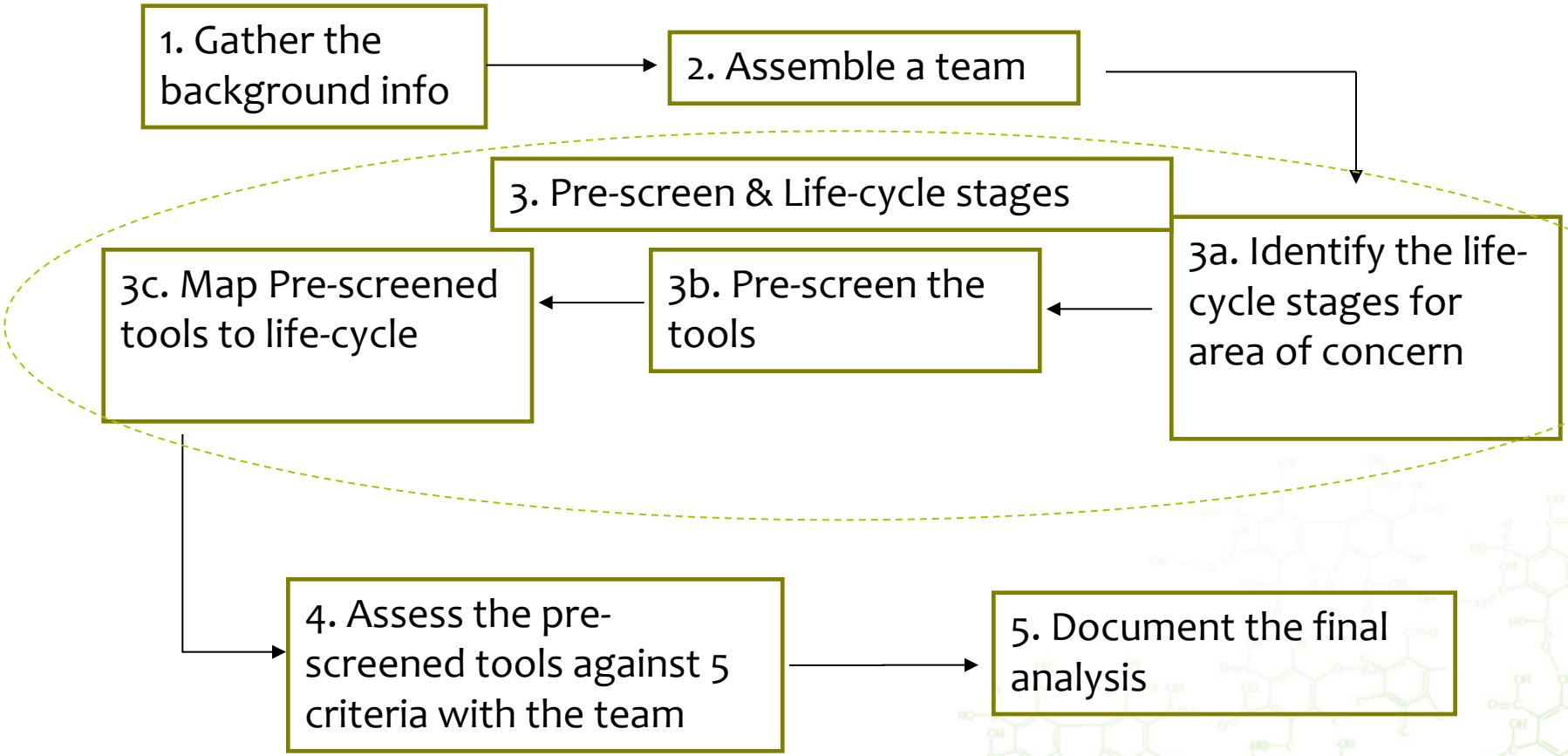
Voluntary Approaches	Joint Federal/Provincial/Territorial Approaches	Market-Based Instruments (regulatory and non-regulatory)	Regulatory Measures
Performance Agreements	Canada Wide Standards	Financial Incentives and Subsidies	Pollution Prevention Planning Notice
Environmental Labelling	Codes of Practice	Environmental Taxes and Charges	Environmental Emergency Regulations
Standards, Certification and Auditing	Guidelines	Feebates	Significant New Activity Notice
Codes of Practice		Tradable Units Systems	Regulations under CEPA 1999
Release Guidelines		Deposit-Refund Systems	Regulations under another federal Act (e.g. *Fisheries Act, Consumer Products Safety Act, Food and Drugs Act)*
Environmental Quality Objectives and Guidelines			Equivalency Agreements (with Provincial, Territorial, or Aboriginal governments

Increasing certainty; burden of proof required for instrument development; increasingly stringent instrument requirements

ANNEX 2

The Instrument Choice Framework

What the process looks like



Gracias!