Government of Canada | Gouvernement du Canada

Canada's Approach to Prioritizing Chemicals for Assessment

Health Canada and
Environment and Climate Change Canada

November 15, 2018

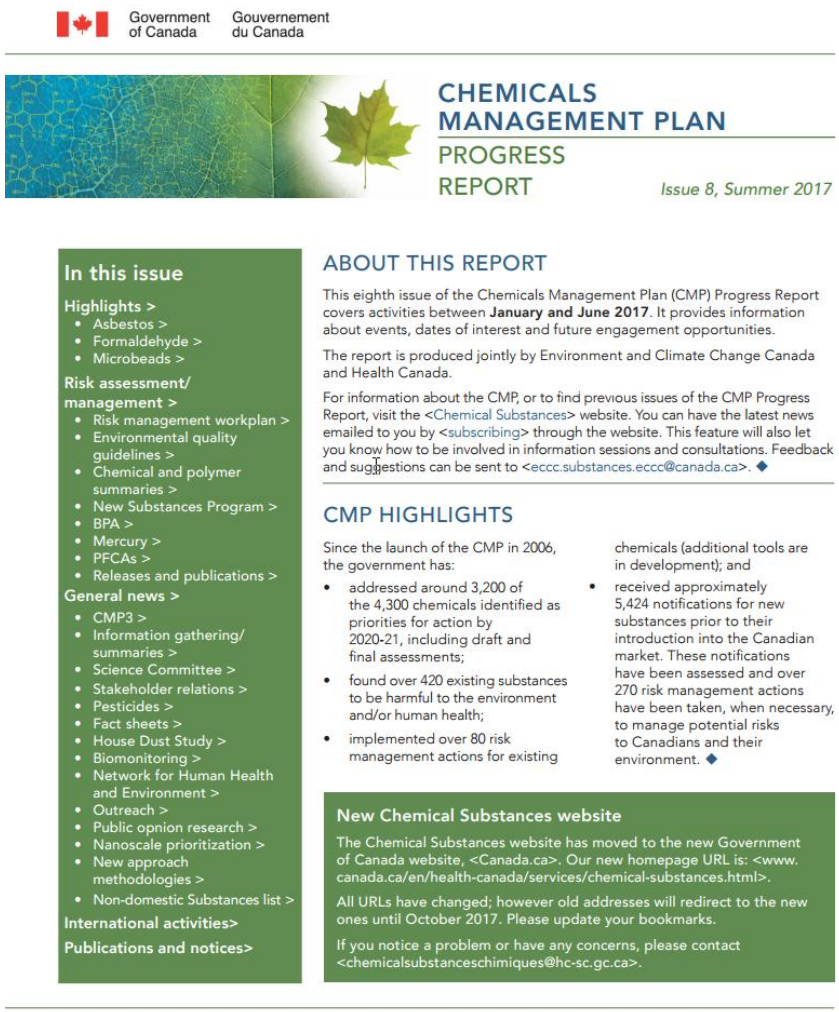
Canada

Canada's Chemicals Management Plan (CMP)

- Protect Canadians and their Environment from the risks of harmful chemicals

- The principle legislation behind the risk assessment and management activities of CMP is CEPA (1999)
  - **CEPA (1999)** covers a range of activities that can affect human health and the environment, and acts to address any pollution issues not covered by other federal laws
  - CMP integrates across Federal Government Programs to ensure appropriate assessment and management of chemicals
  - Comprehensive stakeholder engagement (e.g. NGOs, industry)

- Designed to help Canada meet goals (4,300 priority substances) set by the World Summit on Sustainable Development for the sound management of chemicals by 2020



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CHEMICALS MANAGEMENT PLAN
PROGRESS REPORT
Issue 8, Summer 2017

In this issue

ABOUT THIS REPORT

This eighth issue of the Chemicals Management Plan (CMP) Progress Report covers activities between **January and June 2017**. It provides information about events, dates of interest and future engagement opportunities.

The report is produced jointly by Environment and Climate Change Canada and Health Canada.

For information about the CMP, or to find previous issues of the CMP Progress Report, visit the <Chemical Substances> website. You can have the latest news emailed to you by <subscribing> through the website. This feature will also let you know how to be involved in information sessions and consultations. Feedback and suggestions can be sent to <eccc.substances.eccc@canada.ca>. ◆

CMP HIGHLIGHTS

Since the launch of the CMP in 2006, the government has:

- addressed around 3,200 of the 4,300 chemicals identified as priorities for action by 2020-21, including draft and final assessments;
- found over 420 existing substances to be harmful to the environment and/or human health;
- implemented over 80 risk management actions for existing chemicals (additional tools are in development); and
- received approximately 5,424 notifications for new substances prior to their introduction into the Canadian market. These notifications have been assessed and over 270 risk management actions have been taken, when necessary, to manage potential risks to Canadians and their environment. ◆

New Chemical Substances website

The Chemical Substances website has moved to the new Government of Canada website, <Canada.ca>. Our new homepage URL is: <www.canada.ca/en/health-canada/services/chemical-substances.html>.

All URLs have changed; however old addresses will redirect to the new ones until October 2017. Please update your bookmarks.

If you notice a problem or have any concerns, please contact <chemicalsubstanceschimiques@hc-sc.gc.ca>.

Canada

Chemicals Management in Canada: Evolution

International Goal for the Sound Management of Chemicals

Chemicals Management Plan 3 – 2016

Identification of Risk Assessment Priorities (IRAP)

Chemicals Management Plan 2 - 2011

Chemicals Management Plan 1 - 2006

Post 2020

2020

Management of Chemicals continues beyond 2020

We are here

The Canadian Environmental Protection Act, 1999 (CEPA 1999) - Renewal

Categorization/Prioritization (2000-2006)

New Substances Regulations est. for Organisms - 1997

New Substances Regulations est. for Chemicals & Polymers - 1994

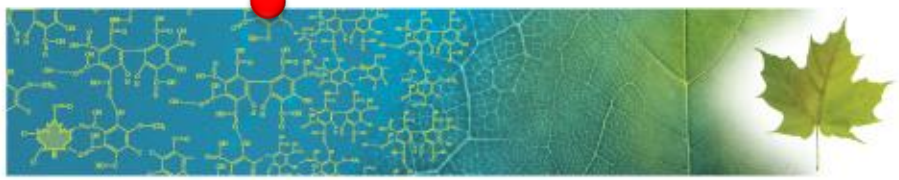
Second Priority Substances List (PSL 2): created 1995

Domestic Substances List (DSL): created 1991

First Priority Substances List (PSL1): created 1989

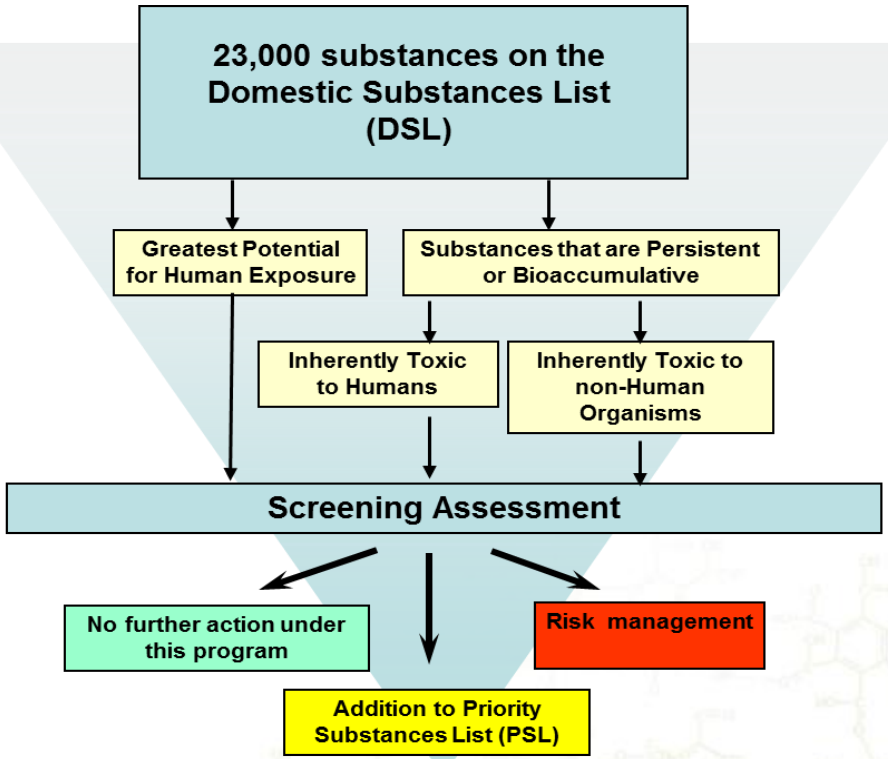
Canadian Environmental Protection Act (CEPA) 1988 Proclaimed

***Environmental Contaminants Act* of 1975**

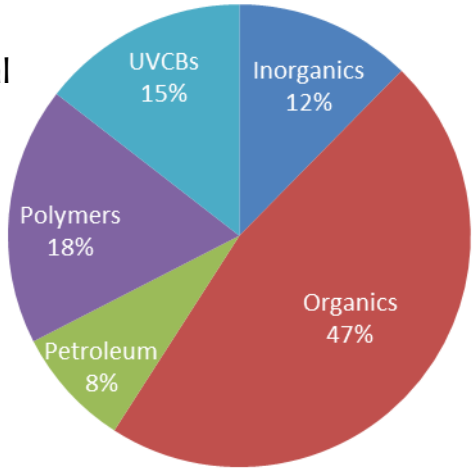


Categorization/Prioritization

- Categorization was a prioritization exercise from 1999-2006 which examined Canada's entire Domestic Substances List (DSL)
  - Used criteria for persistence, bioaccumulation and inherent toxicity to humans and non-human organisms, or greatest potential for human exposure
- Outcome of Categorization was identification of approximately 4300 substances requiring further consideration
  - Led to the creation of the CMP, under which the majority of risk assessment work is focused



Broad Chemical Groupings of the 4300 Categorized Substances



Categorization: Lessons Learned

Technical:

- No precedent, leading development of methodology
- Large number of substances with limited or no empirical data
- Varied types of substances on DSL
- Need to develop protective, transparent, scientifically credible approaches and criteria to identify priorities for environment and/or human health

Non-technical:

- Legislated deadline (7 years)
- Stakeholder engagement (industry concerns, public expectations)
- CEPA 1999 did not address how to further prioritize after categorization

Categorization: Lessons Learned Cont'd

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Evolution of the CMP

- The CMP has been rolled out in 3 phases, with each phase building on lessons learned in the previous phase

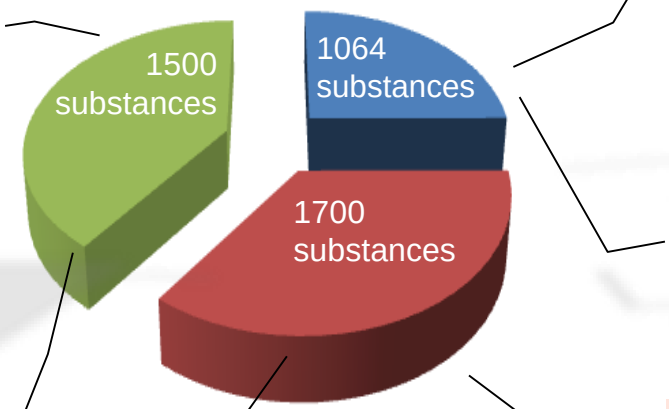
Phase 3: 2016-2020

Remaining Priorities

- Range of data availability (data rich to **data poor**)
- Many with limited data sets
- Opportunity to integrate emerging data (i.e. NAM) & novel approaches

Streamlined Approaches

- ERC, TTC, Rapid Screening IV, Polymer Rapid Screening II, BE/BM approaches, etc.



Phase 1: 2006-2011

Challenge Initiative

- Substance by substance risk assessment
- Used best available traditional toxicity data and QSAR modeling
- Limited use of alternative approaches

Streamlined Approaches

- Rapid Screening: substances of low concern

Phase 2: 2011-2016

Substance Groupings Initiative

- Used best available traditional toxicity data
- Expanded use of alternative approaches
  - *In silico*
  - Read-across
- Aromatic Azo & Benzidine-based substances, Phthalates, moiety based approaches (Selenium) etc.

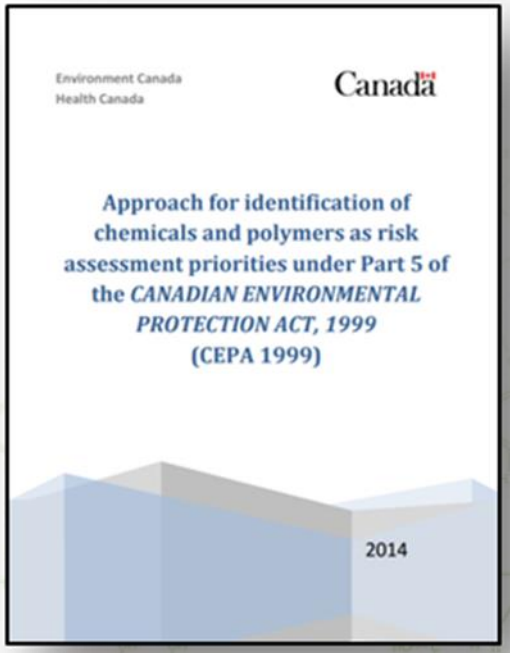
Streamlined Approaches

- Rapid Screening I, II, III and Polymer Rapid Screening I

Identification of Risk Assessment Priorities

- In 2014, the Approach for the Identification of Risk Assessment Priorities (IRAP) was published online, which outlines our approach to compile and evaluate new information on substances to determine if further action may be warranted

- The IRAP involves a review of information and data that occurs on a cyclic basis



Evolution of Priority Setting - Beyond Categorization

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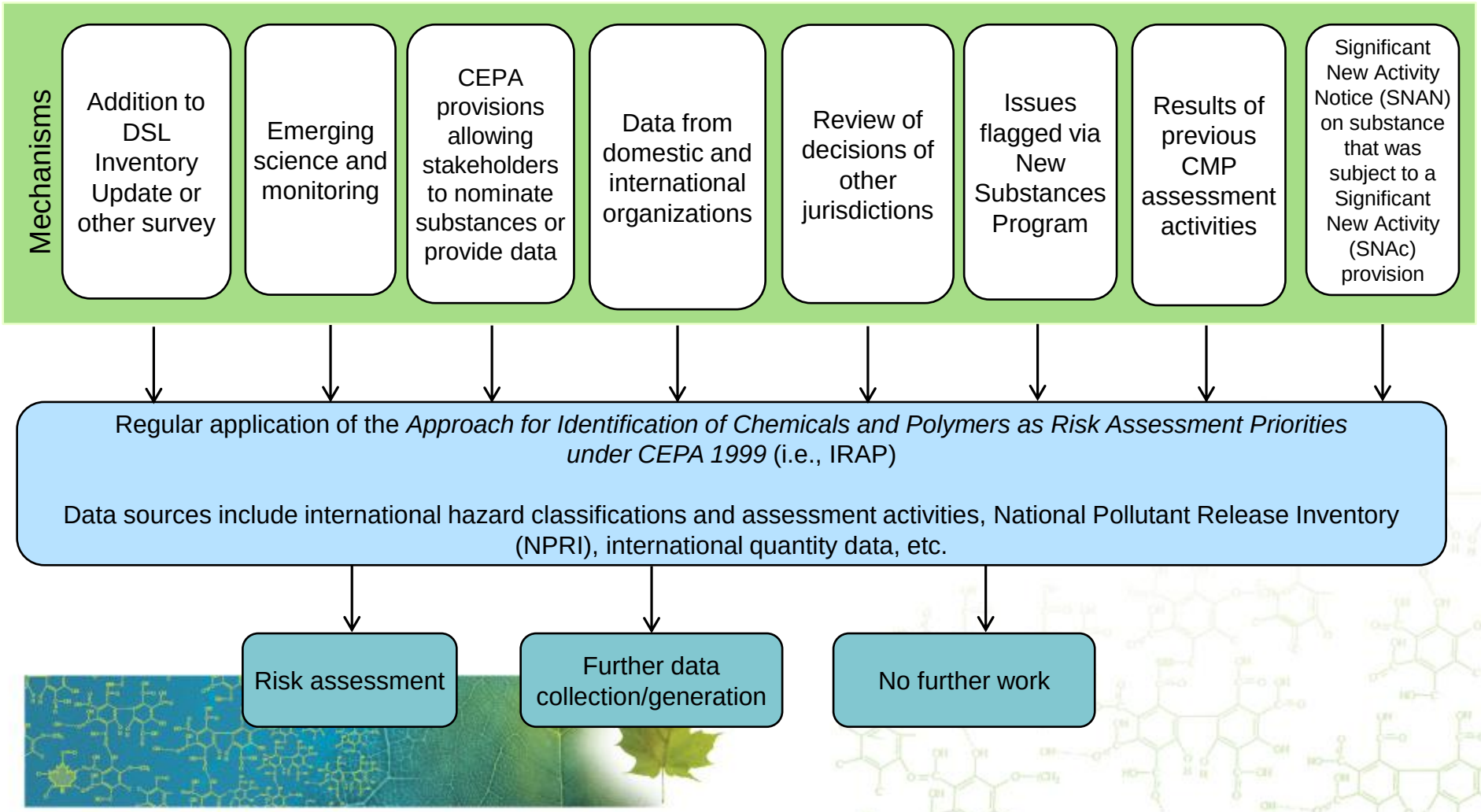
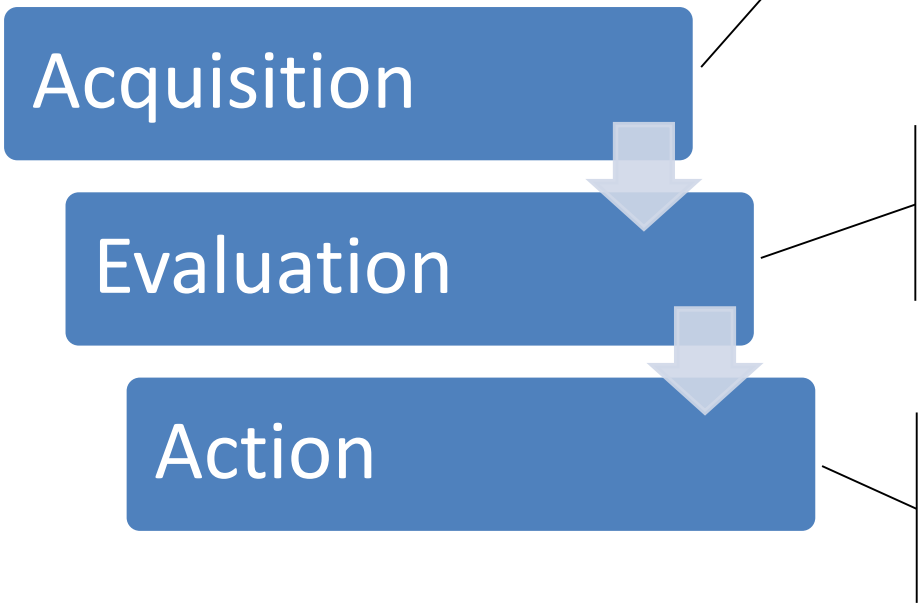


Evolution of Priority Setting (IRAP)

- The IRAP approach outlines 3 general steps:



Active and passive collection of information relevant to the potential health and ecological risks of substances.

Triage of substances for which new information has been received. Requires expert judgement and consideration of the different types of information that may be available for any given substance.

Recommendation of an activity to undertake on a substance identified as a candidate for further work. For example, risk assessment, risk management, data collection, generation of new data, etc.

IRAP Evaluation review process

Ongoing collection of relevant data for IRAP review(s)

Define and propose scope of review

- Considerations include; substance scope limited to DSL, recent/ongoing assessment work outside of scope etc.

Collation of data, identifying potential new sources of hazard/exposure indicators

Send out call for internal nominations to IRAP review cycle

Running queries on internal databases and extraction of data relevant for IRAP review

- identify potential indicators of hazard/exposure flags

Extract results for subset of substances with 1 or more potential flags for evaluation

ECCC conducts evaluation

HC conducts evaluation

Merge results of ecological and human health evaluations

Evaluation decisions binned by outcome (e.g.; risk assessment, require further data gathering). Results brought forward for approval(s)

IRAP: Process for identifying substances

- The goal is to identify substances with both hazard and exposure indicators
- Example data sources considered to date include:

Hazard	Exposure
• Hazard classifications (ECHA Substances of Very High Concern, IARC, EPA, NTP) • Prioritization in EPA & ECHA work plans (e.g., Community Rolling Action Plan-CoRAP) • Conventions (Rotterdam, Stockholm) • S70 substances referred to triggers	• s.71 surveys • EC & HC Monitoring and Surveillance activity • NPRI • Chemical Data Reporting Rule (US TSCA) • Canadian Health Measures Survey (CHMS) Biomonitoring data

Prioritization Considerations

- During the Evaluation stage, the consideration of the new information is used to inform:
  - Whether action needed:
    - Decisions based on relevant, reliable scientific information?
    - Flags from both hazard and exposure indicators are present
    - New data refute key assumptions in past decisions?
  - Timing for action, if needed:
    - New data indicate potential risks are greater than current priorities?
    - Is more information needed? Do we have the right tools for action?
    - Opportunities to collaborate and align with other jurisdictions?
  - Who is best placed to take action, if needed:
    - Better addressed through other Acts or Regulations?

Results of the 2015 and 2016 IRAP Reviews

- Following evaluation, many substances are identified as requiring no further work (i.e., no new data indicating potential risk is identified).
  - These substances will be reconsidered in future rounds of IRAP as new information becomes available.
- The number of substances identified for further action in 2015 and 2016 are identified below:

Recommended Action	Number of Substances
Risk Assessment	38
Data Gathering	377
International Outreach	41

Considerations Moving Forward

- One of the successes of the IRAP process is that the approach is not prescriptive; the process and the data sources can evolve and improve at each iteration

- Challenges identified to date include:
  - Difficulty in capturing hazard and/or exposure data from published literature in a systematic way that is efficient to evaluate for 1000's of substances
  - Lack of readily available Canadian exposure data
  - Difficulty identifying uses of substances in products/manufactured items

- Use of data from New Approach Methodologies (NAMs)
  - Work is being undertaken to advance the application of these data within both IRAP and the program more broadly