

Health Canada's Pesticides Re-evaluation Program

Delly Keen
PEI Potato Day
February 2017





Outline

- PART A: Background
 - Legislative and Policy Frameworks
 - Re-evaluation / Special Review
 - Modernization of the Re-evaluation program
- PART B: Re-Evaluation Process
 1. Pre-Initiation and Initiation
 2. Scoping
 3. Information Gathering
 4. Review
 5. Public Consultation
 6. Final Decision
- PART C: Policy on Cancellation and Amendments

Legislative and Policy Frameworks

- Pesticides in Canada are regulated by the Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* (PCPA), to prevent unacceptable risk to people and the environment.
- Re-evaluations and special reviews are two of the post-registration processes provided under the *Pest Control Products Act* (PCPA) to determine the acceptability or continued acceptability of the health and environmental risks and value of a product registered in Canada.
- These processes differ in both their triggers and review scope
- As a result of the re-evaluation or a special review, PMRA may amend or cancel the registration of a pest control product if it does not consider the risks or value of the product to be acceptable.

Re-evaluation

According to the PCPA:

- A re-evaluation may be initiated if there has been a change in the information required or the procedures used by PMRA to determine that the pesticide meets health, environment and value standards. (ss16(1))
- A re-evaluation is required on a 15-year cycle, based on the most recent major decision affecting the registration, including its initial registration, to determine whether the use of these products continues to be acceptable according to current standards. (ss16(2))
- Considers all currently registered uses of an active ingredient and aspects (value, human health and environment).
- New re-evaluations are initiated every year.

Special Review

- Regulatory Directive: DIR2014-01
- Triggers:
 1. If there are reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.
 2. When an Organisation for Economic Co-operation and Development (OECD) member country prohibits all pesticidal uses of an active ingredient for health or environmental reasons.

Special Review

- Information triggering a special review can come from various sources:
 - Information submitted under the incident reporting program.
 - Information submitted in response to a request under Section 12 of the PCPA.
 - Information from an OECD member country (i.e. prohibition of all pesticidal uses of an active ingredient).
 - Information reported from a federal or provincial government department or agency.
 - Information from scientific literature or other regulatory body (i.e. internationally)
 - Any person may request a special review. The reasons for requesting a special review must be relevant to a registered Canadian use and may include scientific information or other relevant information relating to health or environmental risks or to the value of the product.
- Review scope:

Targeted to address the aspect(s) of concern related to the pest control product that prompted the special review.
- New special reviews can potentially be initiated every year.

Modernization of the Re-evaluation Program

- Recently PMRA has focused on modernising its post-market (re-evaluation) program to provide timely and sound regulatory decisions about registered pesticides by enhancing engagement with a broader range of stakeholders; transparency with the public; and effective collaboration with domestic and international partners.
- Below are three key publications from 2016:
 - In February, PMRA published a 5 year work plan (REV 2016-07) which lists all planned re-evaluations for FY 2015-2020;
 - 105 re-evaluations (40 initiated between April 2014 and December 2015).
 - 28 special reviews.
 - Expected target dates for publication of proposed and final decisions.
 - Updated every year
 - In November, PMRA published the Management of Pesticides Re-evaluation Policy (DIR 2016-04)
 - In December, PMRA published, for consultation, a policy on Cancellations and Amendments Following Re-evaluation and Special Review (PRO 2016-04).

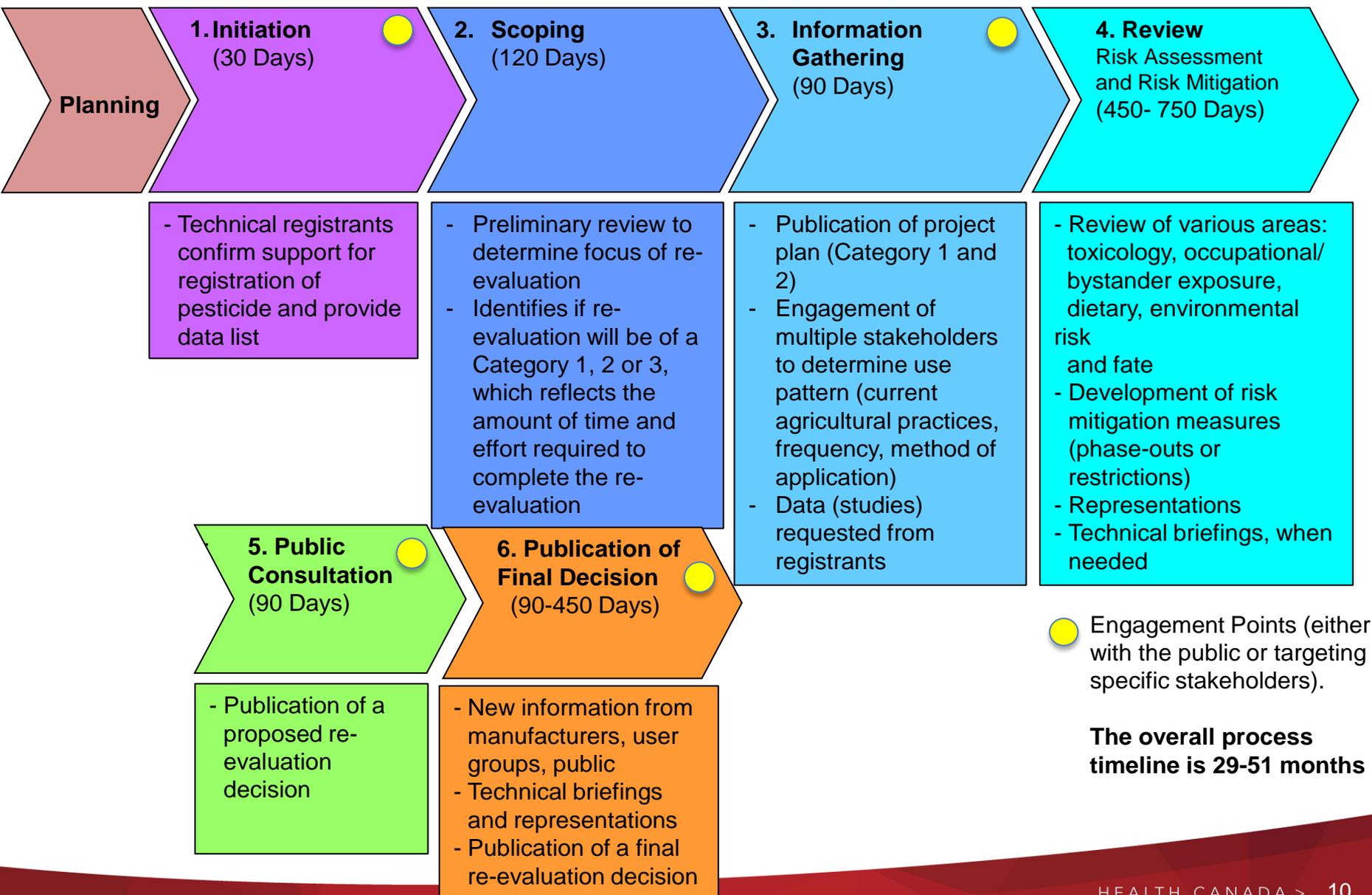
Overview of the re-evaluation policy (Nov 2016)

- The policy (DIR 2016-04) describes in substantial detail the six phases of the re-evaluation process and the timelines that both stakeholders and PMRA are expected to follow in order to arrive at science-based re-evaluation decisions in a timely manner.
- In the policy, PMRA committed to:
 - Update on an annual basis, the multi-year work plan listing scheduled re-evaluations in order to improve transparency for the public and support preparation by regulated parties for re-evaluations.
 - Provide enhanced outreach to user associations to increase awareness of re-evaluations and engage them earlier in the process to provide information.
 - A performance standard to complete 80% of the re-evaluations within the timeframe outlined in the published re-evaluation work plan.
- Increased consultation periods from 60 to 90 days.

PART B

THE RE-EVALUATION POLICY

The Re-evaluation Process – 6 step overview



Part C -Regulatory Proposal PRO2016-04

- Regulatory Proposal PRO2016-04, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* was published December 21st, 2016.
- Open for public consultation until February 19th, 2017
- Purpose:
 - Re-evaluation and special review decisions often result in amendments to product uses (labels amendments), or cancellation of product registrations.
 - PRO2016-04 communicates policy, processes and criteria for establishing implementation timelines for product amendments and cancellations.
- Considerations for determining amendment and cancellation timeframes
 - Level of concern
 - Does the product pose imminent/serious risks, or is it not meeting current standards for protection of health and the environment?
 - Are there suitable alternatives available?
- Next steps – review comments and finalize the policy