Implementation of the New Pest Control Products Act

Richard Aucoin, Ph.D.
A/Chief Registrar
Pest Management Regulatory Agency
Health Canada

PMRA ARLA

Health Canada Santé Canada

Objectives

- What's changing?
- Implementation Challenges
- Status of regulation development
- Communications: Internal/External

Objectives of the New PCPA

- Make the registration system more transparent (e.g. consultations, public access to data and information)
- Enshrine health and environmental protection (e.g. vulnerable groups, all routes of exposure)
- Strengthen post-registration controls (e.g. mandatory reporting of incidents involving pesticides)

What's New?

- Transparency
- Science Assessments
- Registrations and Decision Process
- Maximum Residue Limits

What's New?

- Transparency
  - Public access to what has been submitted for registration and for what purpose
    - what company, what chemical, what crops
  - Detailed evaluation reports
  - Access to test data for all decisions requiring a data assessment
  - Narrower definition of CBI
  - Ability to disclose contaminants and formulants of concern

What's New?

- Mandatory incident (including adverse effects) reporting
- Sales information
- Formal re-consideration of major decisions
- Greater ability to share information and foreign reviews amongst regulators
- Disclosure of terms and conditions of conditional registrations (S.12)

What's New?

- Science Assessments
  - Codifies existing risk assessment practices, particularly with respect to the protection of vulnerable populations (e.g. children); consider both aggregate and cumulative exposure to all sources
  - Requires re-evaluation of older pesticides every 15 years

What's New?

- Science Assessments
  - Explicit description of environmental protection
  - Expedite lower risk pesticides
  - Broader, more explicit definition of value

What's New

- Registrations and Decision Process
  - Consultations:
    - Will continue to consult on new actives, major new uses, re-evaluations, special reviews (S.28)
    - PCPA [28(1)(a) says" …may result in significantly increased health or environmental risks.." – we have interpreted this to mean major new uses/new use sites of existing actives
  - Conditional registrations
    - Previously 'temporary'
    - Stakeholder concern re length, rationale for, risk
    - New PCPA/PCPRs set 'validity periods' and are more prescriptive as to when consultation must take place on conditional registrations

What's New

- Conditional Registrations

  - Frequent now but less so in the future
  - Implications of conditionals : 1) delays formal public consultation on this active/major new use and access to test data by 1-3 years and 2) delays formal reconsideration provisions
  - However does not delay the publishing of detailed evaluation reports

What's New

- Conditionals
  - Transition of temporaries to conditionals [PCPR Subsections 73(3), 73(4)]; establishment of validity periods
  - Technically not required to consult on the conversion of temporaries to full registration but will as a matter of policy
  - Older "temporaries" not subject to reconsideration provisions of the PCPA when consulted on (but mechanisms do exist)

What's New

- Registrations and Decision Process

  - Greater legal authority to amend, cancel, or suspend registrations e.g.
    - make more use of this ability vs. conditional
    - failure to provide requested data/information S.12, 16(3),18(1), 19(1)(a), 20, 25

MRL Setting

- Establishment of maximum residue limits(MRLs) under the PCPA instead of FDA
  - Much needed opportunity to streamline the process
  - Continue to consult
  - Need to time with changes to FDA to avoid confusion

What's New?

- Implementation: Transition Challenges
  - Electronic tools and processes needed for transparency e.g. how to get the data accessible
  - CBI/privacy information segregation
    - In-house data
    - Future submissions
  - Submissions underway/actives currently under re-evaluation

What's New?

- Implementation: Transition Challenges
  - Temporary registration transition to conditional registrations; fixed validity periods
  - New evaluation reports and consultation documents
  - New MRL tracking, setting process
  - Interim procedures (e.g. reconsiderations)

Regulation Development

- Status:
  - Incident reporting: Fall 2006 CG Part II
    - First reports Jan 2007
  - FDA/FDR amendments (for MRLs): Fall 2006 CG Part I
    - New process Fall/Winter 2006
  - Review Panels: Fall 2006 CG Part I

Regulation development

- Status:
  - Sales Information: Fall 2006 CG Part II
    - First reports mid 2008
  - Safety Information: Fall 2007 CG Part II
    - Information 2008
  - AMPs: Winter 2006-2007

Communications

- Proactive approach:
  - communications plan and supporting materials
  - distribution to all stakeholders
- Ongoing support following coming into force
  - new regulations
  - stakeholder training
- PMRA website principal source for all materials

Training on the new PCPA

- PMRA Staff:
  - Management Team
  - All Staff Information Sessions
  - Scientific evaluator training
  - Ongoing as new regulations come into force
- Applicant/Registrant Training
  - Transparency requirements/New procedures
  - Additional sessions as new regulations are finalized

Questions?