The New
Pest Control Products Act

Pest Management Advisory Council, June 3, 2003

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PMRA ARLA

New *Pest Control Products Act* (PCPA)

- Strengthens health and environmental protection
- Makes the registration system more transparent
- Strengthens post-registration controls on pesticides

What is not changing

- Pesticides must be registered
- Registered pesticides must be used according to label directions
- Health and environmental risks, and value, must be acceptable

Strengthen health and environmental protection

- Definitions
  - health risk
  - environmental risk
  - value
- Acceptable risk
  - reasonable certainty that no harm to human health, future generations or the environment will result from exposure to, or use of, the product when used as directed

Strengthen health and environmental protection

- Current practices enshrined in law
  - different sensitivities of subgroups
  - additional safety factor to protect children
  - aggregate exposure from food, water, use in homes and schools
  - cumulative effects of pesticides that act in the same way
  - Toxic Substances Management Policy

Make the registration system more transparent

- Categories of information
  - confidential test data
  - confidential business information (CBI)
  - all other information available through public registry
    - status of registered pesticides
    - applications
    - re-evaluations and special reviews
    - detailed evaluations of risks and value

Make the registration system more transparent

- Confidential test data
  - public may inspect confidential test data supporting registered pesticides in a reading room
  - not available in hard copy or electronically

Make the registration system more transparent

- Definition of CBI
  - financial information
  - manufacturing processes
  - methods for determining a product's composition
  - formulants *not* of health or environmental concern
- Identity and concentration of formulants that *are* of concern not included in definition of CBI

Make the registration system more transparent

- CBI and confidential test data can be shared under certain circumstances, *in confidence*, with:
  - federal and provincial/territorial regulators
  - regulators in other countries
  - medical professionals

Make the registration system more transparent

- Consultation on major registration decisions
  - new active ingredients
  - major new uses
  - re-evaluations and special reviews
- Consultation document
  - summaries of risk and value assessments
  - proposed decision and rationale

Make the registration system more transparent

- Reconsideration of decisions
  - anyone may file a notice of objection
  - review panel may be established
    - if not, written reasons provided
  - open process
  - recommendations considered in deciding to confirm, reverse or vary original decision
  - new regulations required

Strengthen post-registration controls

- New conditions of registration
  - safety information must be provided to workplace
  - sales data must be provided to the Minister
- New regulations required

Strengthen post-registration controls

- Re-evaluations and special reviews
  - re-evaluation after 15 years
  - may take action if registrant does not respond to a data call-in
  - must apply the precautionary principle in determining appropriate actions during the review

Strengthen post-registration controls

- Mandatory reporting of adverse effects
  - new information indicating that risks or value may not be acceptable
  - new regulations and guidelines required
  - could trigger a special review
- Other triggers for special review
  - information from other departments
  - ban in OECD country
  - request from public

Strengthen post-registration controls

- Strengthened enforcement
  - clearly defined offences
  - increased powers of inspectors
  - higher maximum penalties

Data protection

- Industry working group to recommend revised policy
- New regulations to be developed
- Need for broad consultation

Sustainable pest management and risk reduction

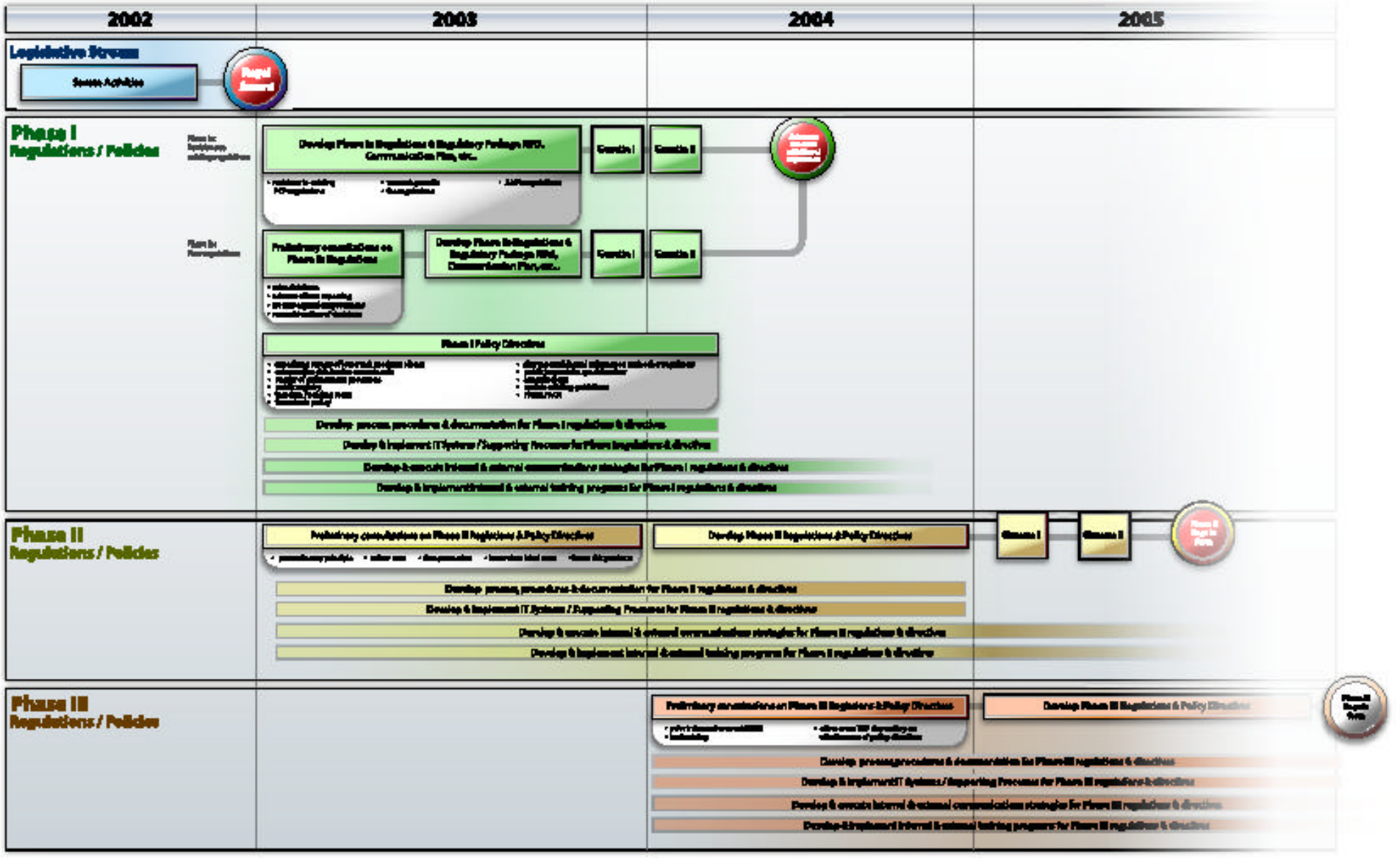
- Mandate includes
  - minimize health and environmental risks
  - encourage sustainable pest management and reduced risk pesticides
- Expedite the review of reduced risk pesticides
- Authority to conduct comparative risk and value assessments

Sustainable pest management and risk reduction

- Additional resources for Health Canada and Agriculture and Agri-Food Canada
  - better access to minor use and reduced risk pesticides
- Authority to make regulations respecting minor uses of pesticides

Pest Control Products Act – "A Phased Approach to Implementation"

April 2003



Implementation Plans

- New Act brought into force by Order of Governor in Council
  - aiming for spring 2004
- Phased approach to implementation
  - regulations
  - policies
  - IT systems / supporting processes
  - communications / training

Phase I (2003-2004)

- Revise existing regulations
  - PCP regulations
  - research permits
  - consequential amendments
    - fee regulations
    - AMPs regulations
- Make key new regulations
  - sales data reporting
  - WHMIS-equivalent provisions
  - adverse effects reporting
  - reconsideration of decisions

Phase I (2003-2004)

- Regulatory Process
  - preliminary consultation on proposed content of new regulations with F/P/T, PMAC, EMAC, OGD (spring 2003) and general public via website
  - Canada Gazette Part I (fall 2003)
  - Canada Gazette Part II (spring 2004)

Phase I (2003-2004)

- Develop policies
  - public registry / reading room
  - sharing confidential information with other regulators
  - public request for special review
  - consultation document templates (PRDD, PACR)
  - formulants policy
  - comparative risk and value assessments
  - new enforcement provisions
  - annual report
  - update existing guidelines

Phase I (2003-2004)

- Supporting elements
  - processes, procedures & documentation
  - IT systems
  - internal / external communications
  - internal / external training
- Make Order to bring Act into force
  - some provisions not in force, if necessary

Phase II (2003-2005)

- Make new regulations
  - data protection
  - lower than label rates
  - lower risk products
  - minor uses
- Develop policies
  - precautionary principle
- Supporting elements

Phase III (2004 and on)

- Amend / make new regulations
  - tank mixing
  - prior informed consent (TBD)
  - amend / make other regulations as necessary
- Evaluate / revise policies
- Supporting elements, as necessary