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safety... our priority.*

*Votre santé et votre
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The Science of Pesticide Regulation in Canada

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Canada ¹

Purpose

To provide an overview of how pesticides are approved for use in Canada and the science that forms the basis of these decisions.



Presentation Outline

- Federal legislation for pesticide regulation
- Defining risk
- Overview of scientific review process
- Frequently asked questions
- Other initiatives to further reduce risk



What is a pesticide?

- A pesticide directly or indirectly controls, destroys, attracts or repels a pest, or mitigates or prevents an injurious, noxious or troublesome effect.
- Some examples:
 - Herbicides, insecticides, fungicides used in conventional and organic agriculture
 - Swimming pool chemicals
 - Rodenticides
 - Flea and tick products for pets
 - Insect repellents
 - Biopesticides



- **Federal legislation for pesticide regulation**
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Health Canada's Pest Management Regulatory Agency

Health Canada's priority:

- Maintain and improve the health & safety of Canadians
 - Includes: safety of the food supply, as well as non-food exposures
- This same priority is applied when approving all pesticides for use in Canada.



Federal Responsibilities

- Regulate all pest control products imported into, sold or used in Canada under the *Pest Control Products Act*
- Pre-market review (scientific assessment of new products)
- Post-registration oversight
 - Compliance activities
 - Monitoring and surveillance
 - Incident reporting
 - Sales data reporting
- Re-evaluation (scientific re-assessment - 15 year cycle)



Legislative Authority

- *Pest Control Products Act & Regulations (2006)*
- Primary objective under the *Pest Control Products Act* is to “prevent *unacceptable risks* to people and the environment from the use of pest control products”.
- Enable users access to pest management tools:
 - *pest control products*
 - *sustainable pest management strategies*



Pest Control Products Act - 2006

Health Canada's new *PCPA* came into force June 28, 2006

Fundamental changes in *PCPA* 2006:

- Strengthens health and environmental protection
- Existing practices are now set in law (eg., public consultation, take into account sensitive sub-populations, aggregate and cumulative exposures)
- More transparency to the registration system
- Strengthens post-registration controls on pesticides (eg., mandatory incident reporting, re-evaluation, increased fines, etc.)



What is the Distribution of Legislative Responsibilities?

Federal

- New Pesticide Registration & Re-evaluation
- Science-based Health, Value Environment Assessments
- Compliance and Enforcement
- Sustainable Strategies
 - **Agriculture**
 - **Urban**

Provincial

- Transportation, sale, use, storage and disposal
- Training, Certification, Licensing
- Further conditions on use & in accordance with Federal standards

Municipal

- Bylaws for further conditions on use where authority exists & in accordance with Federal standards



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What is Risk and Risk Assessment?

- Exposure to a pesticide does not automatically mean an individual will experience an ill effect
- The possibility of harm increases as the amount of exposure increases (increased exposure increases risk)

Purpose of health risk assessment for pesticides is to minimize the possibility of harm to human health

- One approach is to assure that the level of human exposure is well below the amount that could cause harm



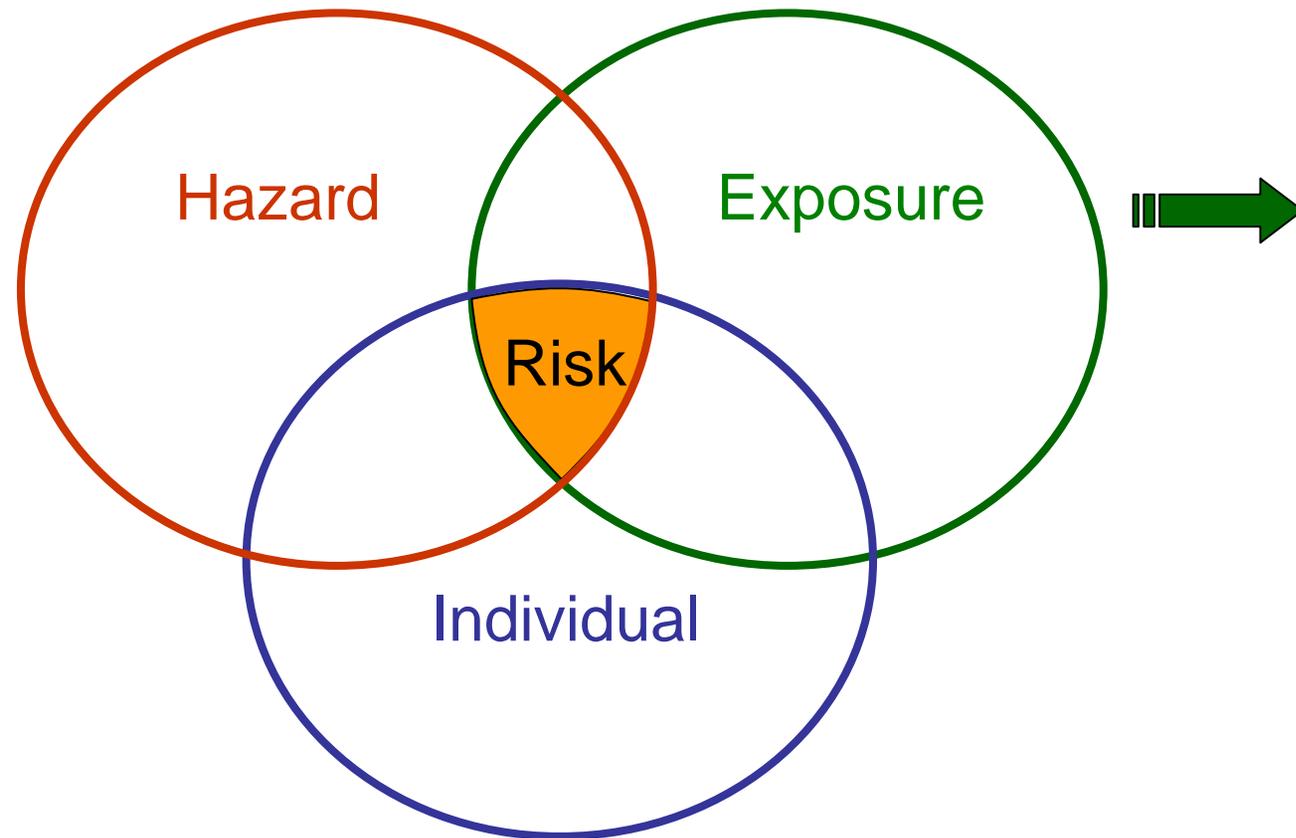
Human Health Risk Assessment

Hazard (toxicity) & exposure must be integrated to understand risk

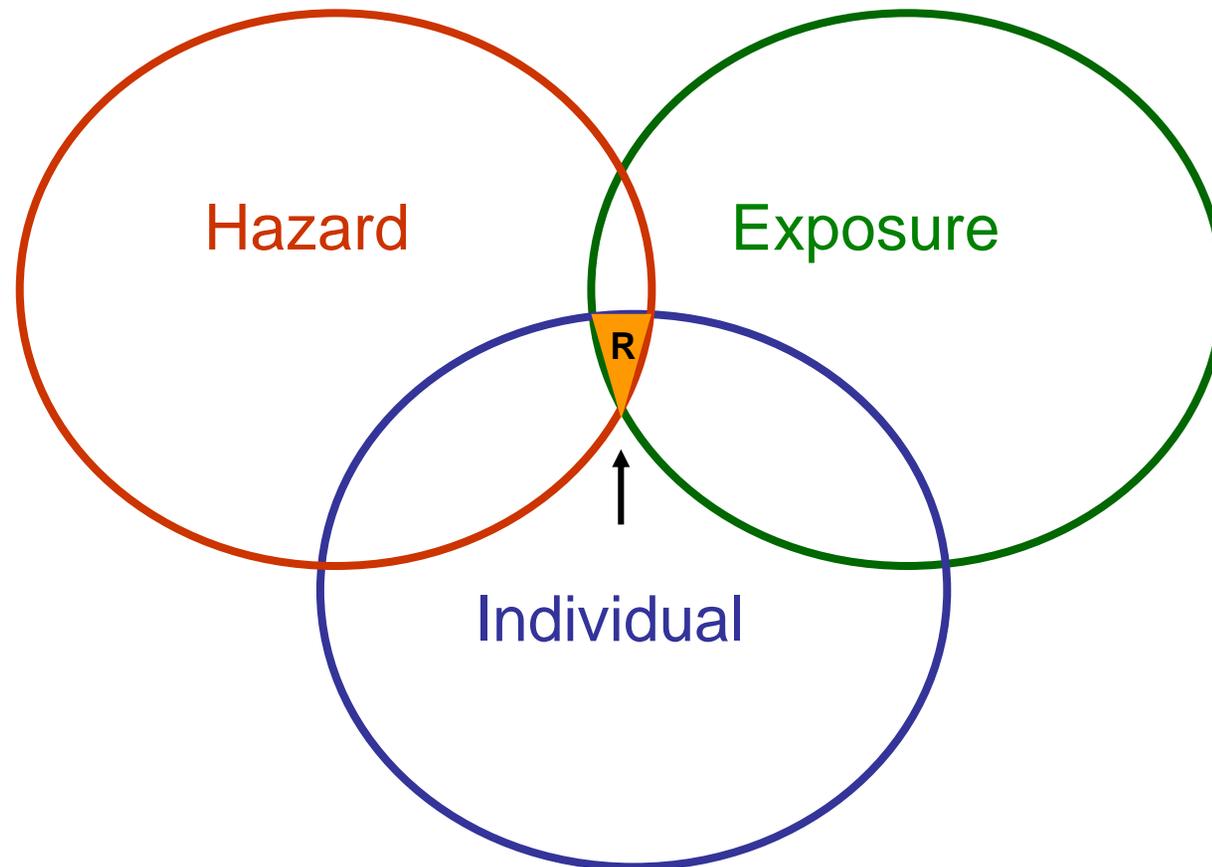
- Most substances have the potential to cause an adverse effect at high enough doses, but there is usually a lower dose where no harmful effect will occur
- Generally, as the amount of exposure increases, so does the risk of a toxic effect
- Health risk assessment puts a strong emphasis on determining both the amount and duration of people's exposures, including sensitive populations



Hazard + Exposure = Risk



Hazard + Exposure = Risk



What is “Acceptable” Risk?

Acceptable risk: Reasonable certainty of no harm

- to health, future generations and environment
- from use or exposure
- when used according to label directions

[As defined in *PCPA* s. 2(2)]



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Scientific Studies

* Require > 200 scientific studies to register a new pesticide

Health Assessment

- Toxicology (Hazard) and epidemiology information
- Occupational & bystander exposure
- Dietary exposure

Environmental Assessment

- Environmental toxicology
- Environmental chemistry and fate

Value Assessment

- Efficacy
- Competitiveness
- Sustainability



Data Submission for a Single Pesticide



Where do Studies Come From?

- Onus is on the applicant to submit all required studies (>200 studies for standard food crop use)
- Individual studies within a submission are often conducted by different independent laboratories
- Studies must follow internationally developed and validated test guidelines for study protocols that adhere to the principles of “Good Laboratory Practice”.
- Extensive data reporting allows Health Canada scientists to conduct independent analyses of the raw data
- Published scientific literature – typically post-registration



Scientific Approach

HAZARD

- What are the hazards and at what doses? (Toxicity profile)
- What is the dose where there are no effects?
- Apply uncertainty factors ($\geq 100x$)
- **Establish acceptable level of human exposure.**

EXPOSURE

- What activities create exposure?
- By what route(s) does exposure occur (diet? skin? inhalation?)
- **How much exposure – quantify the amount.**

What is the risk? (Compare exposure to acceptable level)

Are the risks acceptable?

Approve only those uses that meet HC standards



What types of Hazards do we look for?

- Acute effects – from a single, high dose (oral, dermal, inhalation, eye and skin irritation and allergic reactions)
- Short-term exposures (2 weeks - 3 months)
- Reproductive effects over 2 generations
- Birth defects
- Neurotoxicity
- Long-term (lifetime) exposure
- Cancer potential over lifetime, including genotoxic potential

Examine available epidemiology information in conjunction with toxicity findings



Why Animal Toxicity Studies?

- A range of doses are tested to cause toxic effects in order to understand what levels are non-toxic
- Allows us to compare effects across different mammalian species for consistency and to identify which species are most sensitive
- Non-toxic level in the most sensitive species is the basis of setting acceptable level for human exposure
- The acceptable level of exposure is at least 100X lower than the non-toxic dose



How do we Assess Cancer Potential?

- Cancer studies – 2 mammalian species: Daily exposure over a lifetime
- Cancer studies examine all organ systems, clinical chemistry - blood and urinary testing, tissue pathology, clinical symptoms
- Series of *in vivo* & *in vitro* mutagenic tests – examine for DNA effects
- Check for pre-cancerous lesions in other animal studies
- Examine available metabolic and mechanistic studies to better understand how a chemical behaves in the body and causes its effect
- Check for similarities with other known chemicals
- Epidemiology studies



How do we Measure Exposure?

Dietary Exposure:

- Specific studies show how much pesticide residue may be present:
 - Treated crops
 - Drinking water
 - Transferred to meat, milk, eggs

Non-Dietary Exposure:

- Specific studies measure how much pesticide residue can be transferred to people, including children, when they do certain activities
 - Farmers in their fields
 - Homeowners using a product
 - Children playing on treated grass



Exposure Levels and Risk

- Health Canada determines the amount Canadians may be exposed to through diet and other activities
- These potential exposure levels are determined for various sensitive populations and age groups, including infants, toddlers, children, adolescents and adults
- Potential exposure is overestimated for protection
- Health Canada registers only those uses where human exposures are well below a level that is non-toxic - at least 100X lower



How do we Determine Cancer Risk?

Threshold or Non-threshold?

- Threshold assumes cancer occurs only above a certain dose
 - Non-genotoxic
 - Threshold applies a NOAEL / safety factor approach – (the no-effect level is divided by safety factors to set acceptable level)
 - Requires well defined mode of action – i.e., understanding the way the substance causes cancer
- **Examples:**
- Tumours resulting from irritation, enzyme induction
- Accepted modes of action:
- Certain thyroid tumours (rat)
 - Certain liver tumours (male mice)



How do we Determine Cancer Risk?

Non-Threshold

- Threshold cannot be identified
- Pertains to genotoxic substances, or non-genotoxic substances if the mode of action is not well defined
- Assumes linear dose-response relationship at lower end of the dose-response curve
- Non-threshold involves statistical modelling of animal toxicity data to predict likelihood of developing cancer over a lifetime (“linear low dose extrapolation”)
- Essentially negligible risk – 1 in 100,000 to 1 in a million

Health Canada applies highly stringent approach when assessing cancer risk

- Approach is consistent with, or surpasses that applied by international regulatory authorities (WHO, US EPA)



Summary of Scientific Approach

- Large number of in-house qualified scientists with a wide range of expertise (~ 350 scientists)
- Strong reliance on a comprehensive body of scientific evidence and scientific methods that examine both hazard and exposure
- Consistent with approach of international regulatory bodies
- Science is the basis of all HC regulatory decisions for pesticides
- Approach is precautionary



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What is a Maximum Residue Limit (MRL)?

- The maximum amount of pesticide residue legally permitted to remain on food sold in Canada
- MRLs serve as an enforcement tool for compliance with the Canadian registered pesticide label
- Used to monitor imported food commodities for compliance with acceptable residue levels
- MRLs are important to ensure that pesticides are being used properly so Canadians have access to a safe food supply that includes a large variety of fresh fruits and vegetables.



How are Maximum Residue Limits Enforced?

- MRLs are enforced by the Canadian Food Inspection Agency (CFIA)
- >99% of Canadian fruits and vegetables and 99% of imports tested well below Canada's MRLs, indicating a very high rate of compliance
- No residues detected in 90% of Canadian fruits and vegetables & in 89% of imports, at CFIA's analytical limit



What About Older Products on the Market?

Pesticide Re-evaluation Program:

- In 2000, HC committed to review 401 pesticide active ingredients registered prior to 1995
- 75% have been addressed (September, 2008)
- Target date for completion is end of 2009
- Re-evaluation follows a 15 year cycle from when a given pesticide is first registered (as per *PCPA*)



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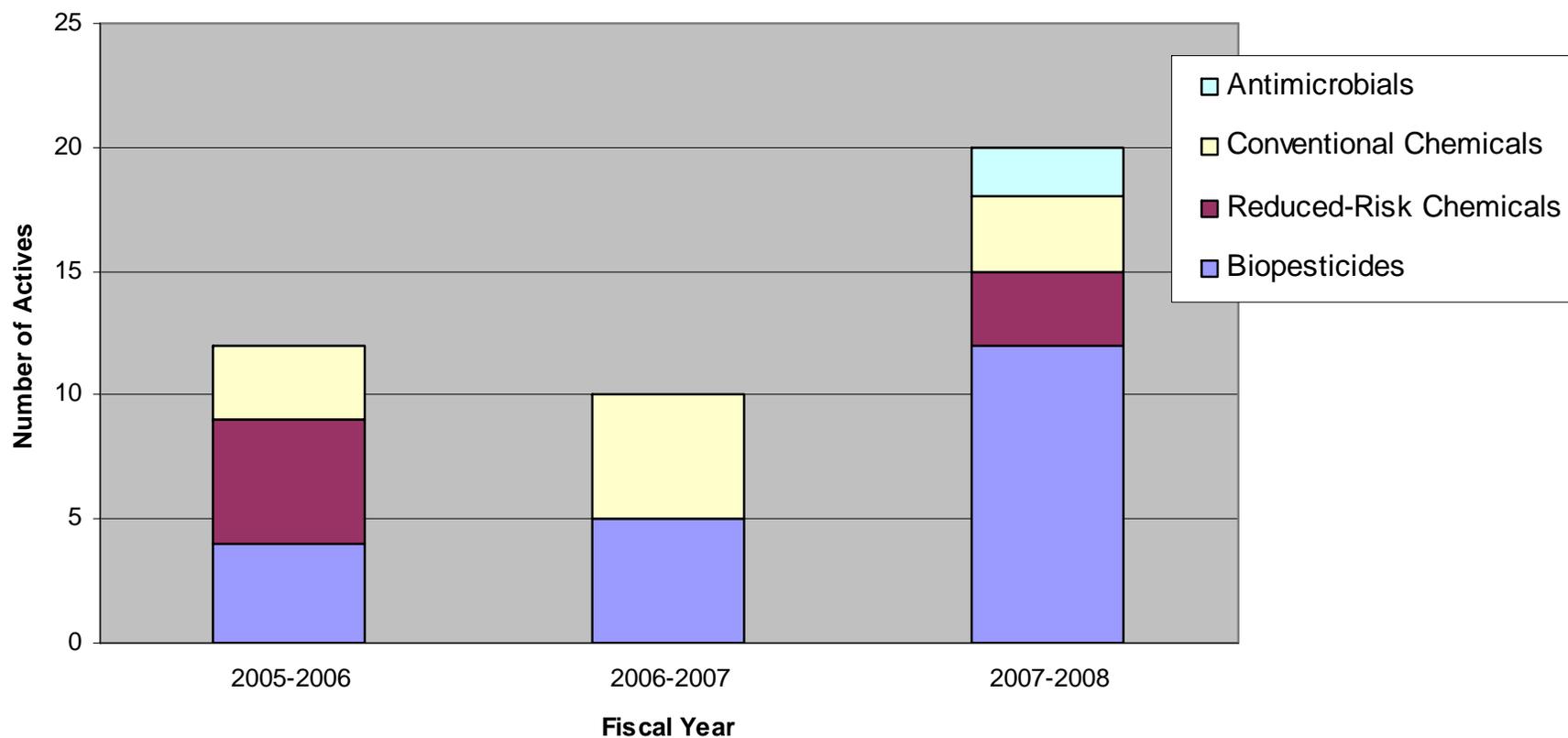
Other Programs / Approaches

- Registration programs for:
 - Reduced risk products
 - Biopesticides and other alternative products
 - Many programs involve international collaboration & sharing of scientific expertise
- Establish lowest effective rate to keep usage to the minimum amount necessary
- Label improvement programs to update mitigation measures
- Compliance activities promote best practices
- Mandatory incident reporting program will help identify areas that require follow-up



New Pesticide Registrations

Number of Actives Registered by Type
New Actives First Appearing in Registered Products



Summary

- Pesticides are among the most rigorously tested substances in the world. Health Canada's scientific review process ensures that pesticides approved for use in Canada can be used safely when label directions are followed.
- Health Canada is actively involved in various initiatives to provide Canadians with access to newer and lower risk pesticides.
- All pesticides registered in Canada for agricultural, forestry, structural and lawn and garden uses must all meet the same stringent health and safety standards.
- Health Canada approves only those pesticides that show no increase to health risk, including cancer.



Reminders

- Use pesticides judiciously and only for their intended use.
- Carefully follow label directions, and take measures to become better informed about their safe and effective use.
- To prevent accidents, always store pesticides safely in original clearly marked containers and out of the reach of children.
- If you have a pest problem, please take measures to become better informed about various control options, including pest prevention.





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