

US EPA ARCHIVE DOCUMENT



NAFTA Technical Working Group on Pesticides  
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas  
Le groupe de travail technique de l'ALENA sur les pesticides

# Biopesticide Registration Improvement Course

## **PMRA Risk Assessment and Decision-Making Process for Non-Conventional Pest Control Products**

**Brian Belliveau, Ph.D.**

**Head, Microbial & Biochemical Evaluation Section,  
Health Effects Division I, Health Evaluation  
Directorate,**



Health  
Canada

Santé  
Canada

**PMRA, Health Canada**



BRIC – CCRB – CAAB

## On-line Resources

- A Primer on Scientific Risk Assessment at Health Canada
  - <http://www.hc-sc.gc.ca/sr-sr/pubs/about-apropos/2010-scientif-ris/index-eng.php>
- Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks
  - [http://www.hc-sc.gc.ca/ahc-asc/alt\\_formats/hpfb-dgpsa/pdf/pubs/risk-risques-eng.pdf](http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/pubs/risk-risques-eng.pdf)
- Science Policy Notice SPN2000-01: *Technical Paper* - A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency
  - [http://www.hc-sc.gc.ca/cps-spc/pubs/pest/\\_pol-guide/spn2000-01/index-eng.php](http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2000-01/index-eng.php)
- Pest Control Products Act
  - <http://laws.justice.gc.ca/en/P-9.01/>
- PCPA List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern
  - <http://gazette.gc.ca/rp-pr/p2/2008/2008-06-25/html/si-tr67-eng.html>
- Regulatory Directive DIR2006-02, Formulants Policy and Implementation Guidance Document
  - [http://www.hc-sc.gc.ca/cps-spc/pubs/pest/\\_pol-guide/dir2006-02/index-eng.php](http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2006-02/index-eng.php)
- Health Canada, Health Products and Food Branch, Food Allergies – Information for Consumers
  - <http://www.hc-sc.gc.ca/fn-an/securit/allerg/fa-aa/index-eng.php>
- Federal Toxic Substances Management Policy (TSMP)
  - <http://www.ec.gc.ca/toxiques-toxics/default.asp?lang=En&n=2A55771E-1>



## List of Abbreviations

CEPA	<i>Canadian Environmental Protection Act</i>
EP	end-use product
HPFB	Health Products and Food Branch (Health Canada)
PCPA	<i>Pest Control Products Act</i>
SMC	science management committee
SOC	science operations committee



*BRIC – CCRB – CAAB*

## Risk Characteristics

- Characteristics of products eligible for review under Regulatory Proposal PRO2010-06 are flexible
  - Active ingredients must have some (not all) of the following characteristics:
    - Low inherent toxicity to humans and other non-target organisms; metabolites must also be of low toxicity
    - Low potential for use to result in significant human or environmental exposure
    - Not persistent in the environment
    - Already widely available to the public for other uses with a long history of safe use at equivalent exposure levels
    - Pesticidal action is not the result of toxicity to the target organism
    - Unlikely to select for pest resistance



## **Risk Characteristics**

- Pheromones and other semiochemicals are a subset of non-conventionals, but are covered under a separate streamlined registration guideline (Regulatory Proposal PRO2002-02)
  - Straight-Chain Lepidopteran Pheromones are widely recognized for being of low toxicity to humans and other non-target organisms (many health and environmental toxicology data requirements waived); also consider natural background levels to assess risks
  - Non-SCLP pheromones and other semiochemicals also generally recognized as being of low inherent toxicity to humans and other non-targets; data requirements tiered and customized during presubmission consultation process



## Guidelines

- Strong focus on product registration
  - Regulatory Proposal PRO2010-06 is a registration guideline and does not address scheduling or exemption as regulatory options
    - No PMRA equivalent to U.S. EPA's list of active ingredients exempted from registration under Section 25(b) of *Federal Insecticide, Fungicide and Rodenticide Act*
  - Regulatory Proposal PRO2002-02
    - Registration is required except if pheromone/semiochemical is a lure used in a trap for pest population monitoring purposes



*BRIC – CCRB – CAAB*

## **Non-Conventionals: How is the Process Working?**

- We are learning through experience:
  - “Case-by-case” approach has been adopted and is working well
  - Totality of evidence is considered
    - Flexible, weight-of-evidence approaches to health, environment and value assessments
    - Information requirements and assessment efforts are commensurate with expected level of risk
  - Data requirements for Domestic (home and garden) and Commercial/Restricted (agriculture, forestry) class products may differ; the process for domestic uses will usually be simpler



BRIC – CCRB – CAAB

## ***Pest Control Products Act (PCPA)***

- PMRA's mandate is to administer the *PCPA* which regulates products that are manufactured, or used as a means for directly or indirectly controlling, destroying, attracting/repelling a pest for mitigating or preventing its injurious, noxious or troublesome effects [s. 2(1)]
- Prevent unacceptable risks to people and the environment from the use of pest control products [s. 4(1)]
  - “acceptable”: reasonable certainty that no harm to human health, future generations, or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration
- Only pest control products that are determined to be of acceptable value are approved for use in Canada [s. 4(2)(d)]
  - Value is further defined as including efficacy; effect on host organisms (e.g., crop tolerance); and health, safety and environmental benefits and social and economic impact [s. 2(1)]



*BRIC - CCRB - CAHB*

## How Does Health Canada Deal with Risk?

### *The Process Perspective*

At a high level, the logic underlying a risk assessment is identical for all contexts, including health and environmental risks. It can be expressed in the following formula:

$$\text{Risk} = \text{Probability of Event} \times \text{Seriousness of Consequences}$$

Or more simply a function of inherent toxicological hazard and exposure:

$$\text{Risk} = \text{Hazard} \times \text{Exposure}$$



## How Does Health Canada Deal with Risks?

This risk formula can also be shown in a graphical way as shown below. This matrix can be used to carry out a rudimentary risk assessment (the darker the background of the cells, the higher the concern; replacing “seriousness of consequences” with “yield from the consequences” would result in a tool for benefit assessment):

		<i>Seriousness of Consequences</i>		
		Low	Medium	High
<i>Probability of Event</i>	High			<b>Top Concern</b>
	Medium			
	Low	Little Concern		

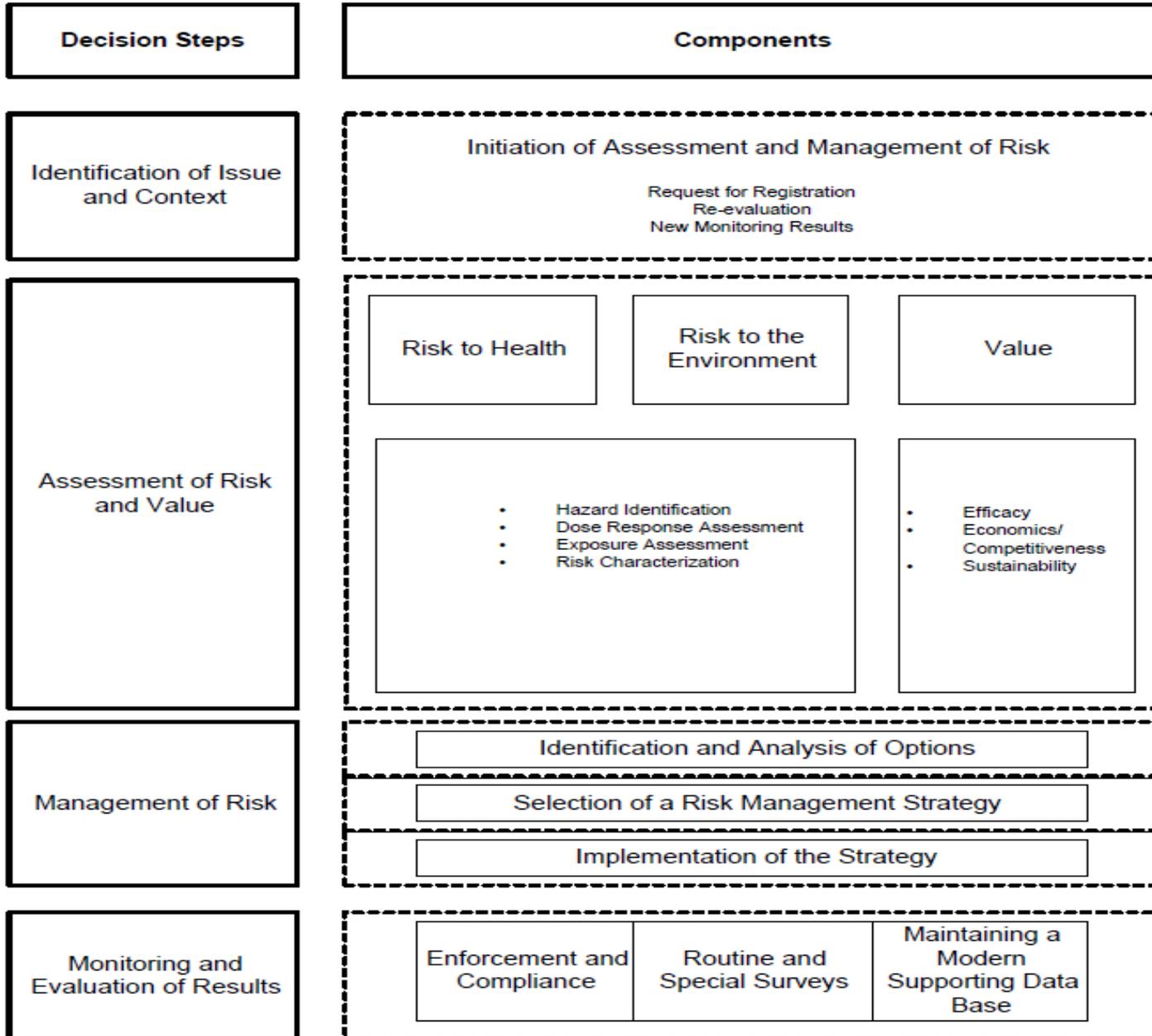


## PMRA Approach

- PMRA formalized a decision-making framework based on assessment and management of risk for all pesticide products (SPN2000-01, *Technical Paper: A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*)
  - Applied to all pesticide classes, including non-conventionals and pheromones and other semiochemicals



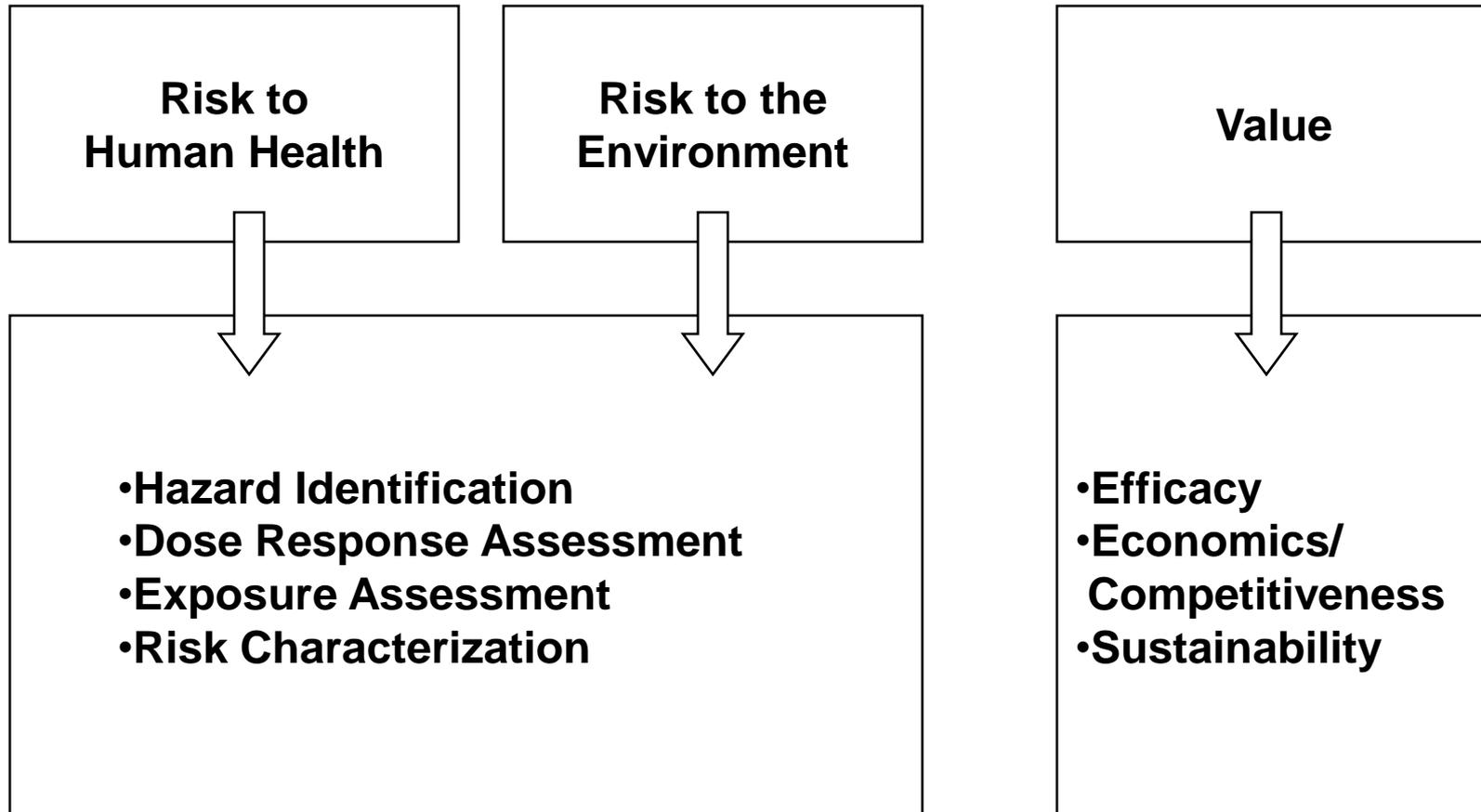
# BRIC - CCRB - CAAB





*BRIC - CCRB - CAAB*

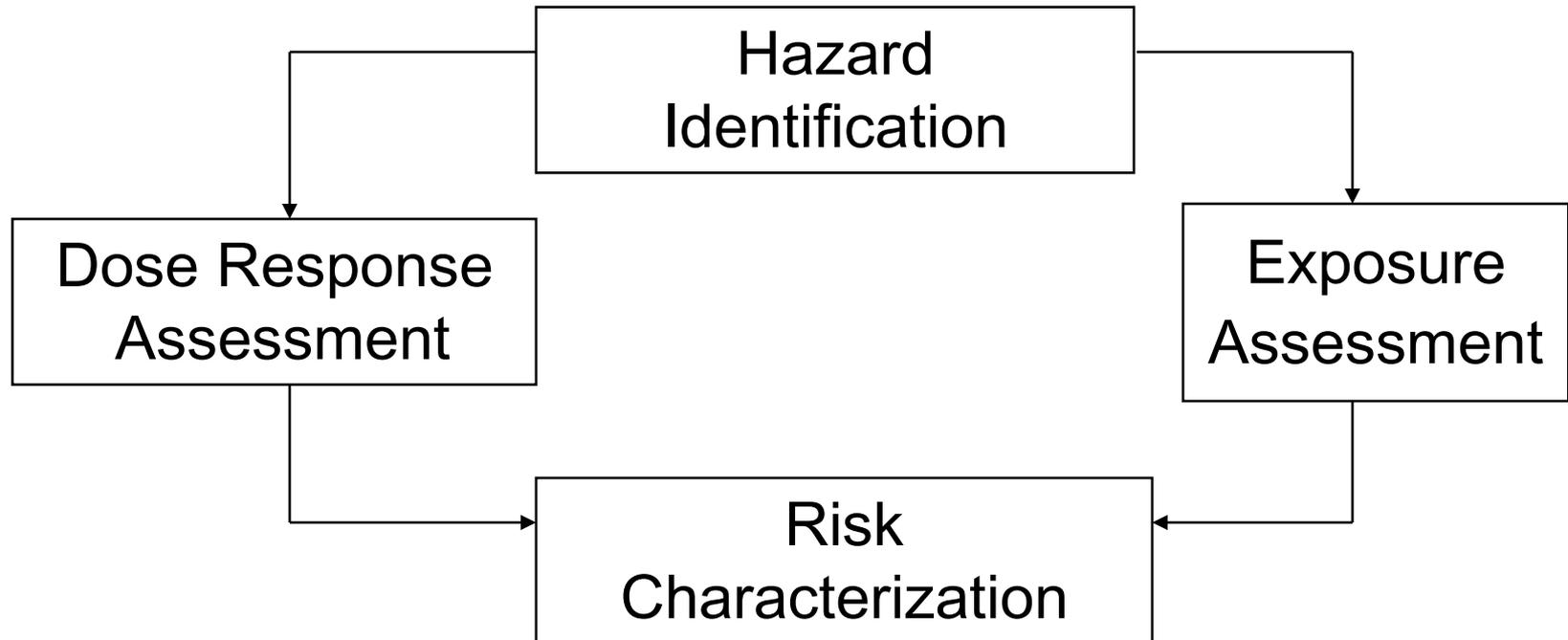
## Assessment of Risk and Value





*BRIC - CCRB - CAAB*

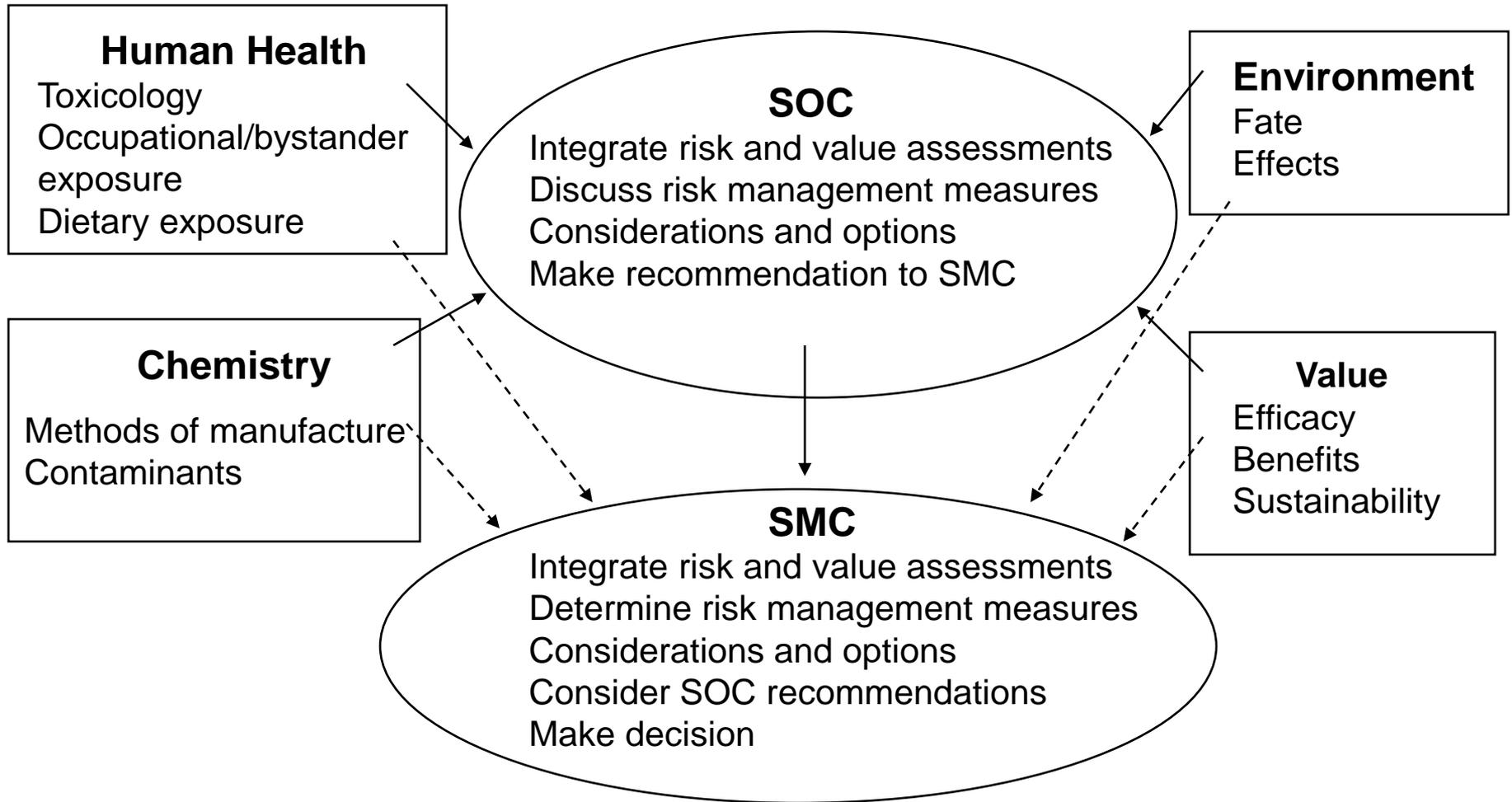
## Risk Assessment Paradigm





*BRIC - CCRB - CAAB*

# PMRA Decision-Making Process





*BRIC – CCRB – CAAB*

## Other Considerations May Impact Decisions

- Formulants
  - Make an effort to formulate products with List 4A or 4B formulants (inerts)
  - Avoid Toxic Substances Management Policy Track 1 substances (those that are “CEPA-toxic” or equivalent, predominantly anthropogenic, persistent and bio-accumulative)
  - Avoid priority allergens as formulants
- If active ingredient is a priority allergen (or EP contains a priority allergen), direct use of product on food crops may not be supportable
  - Health Canada/HPFB: peanuts, eggs, milk, tree nuts, wheat, soy, sesame seeds, seafood (fish, crustaceans, shellfish), sulphites, mustard
  - PMRA: crustaceans, fish, milk, peanuts or their shells, sesame seeds, soy, sulfites, tree nuts, wheat



*BRIC – CCRB – CAAB*

## Registration

- Decision making:
  - No: Health or environmental risks or value unacceptable
  - No: Insufficient information
- Decision making
  - Yes: risks and value acceptable
  - Yes: with conditions (e.g. confirmatory chemistry data; long-term monitoring)
  - Yes: consultation



## Transparency Documents

- After a decision to register a pesticide or after re-evaluation, the public is encouraged to review the published evaluation report and decision documents, which explain the risk and value assessments supporting a registration decision and include a summary of the information considered
- 3 types of documents are required by *PCPA*:
  - Consultation Document (full registration)
  - Decision Document (full registration)
  - Evaluation Report (conditional registration)



*BRIC - CCRB - CAAB*

**THANK YOU!**

