

**RISK ASSESSMENT AND RISK MANAGEMENT IN
THE PMRA**

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HEALTH CANADA
DECISION MAKING

HEALTH PROTECTION BRANCH APPROACH TO
RISK ASSESSMENT - RISK MANAGEMENT
DECISION MAKING

HIGH LEVEL

DEFINED STEPS AND STRUCTURE TO DECISION
MAKING

VARIOUS COMPONENTS

INTERRELATIONSHIP AMONG COMPONENTS

BASIC STEPS AND PRINCIPLES APPLY TO RISK
ASSESSMENT - RISK MANAGEMENT FOR MANY
SITUATIONS INCLUDING CHEMICALS

RISK ASSESSMENT AND RISK MANAGEMENT IN THE PMRA

DOCUMENT - DESCRIBES RISK ASSESSMENT AND
RISK MANAGEMENT STEPS/COMPONENTS FOR
PESTICIDES

BY NECESSITY - PROGRAM SPECIFIC
REGULATORY ASPECTS OF PCP ACT AND
FDA SETS THE PARAMETERS FOR WHAT IS
DONE

ACTS SET FLEXIBILITY WE HAVE -
CONSULTATION

RISK ASSESSMENT AND RISK MANAGEMENT IN THE PMRA

DESCRIBES OUR FRAMEWORK BASED ON EXAMPLE
OF A TYPICAL NEW CHEMICAL ACTIVE
INGREDIENT

RECOGNIZE

NOT A SOP WITH DETAILED PROCESS
DESCRIPTIONS FOR EVERYTHING

MANY DECISIONS NOT AS COMPLEX AS FOR
NEW ACTIVE

- Formulation amendments
- Modification of existing
registrations; another pest or crop

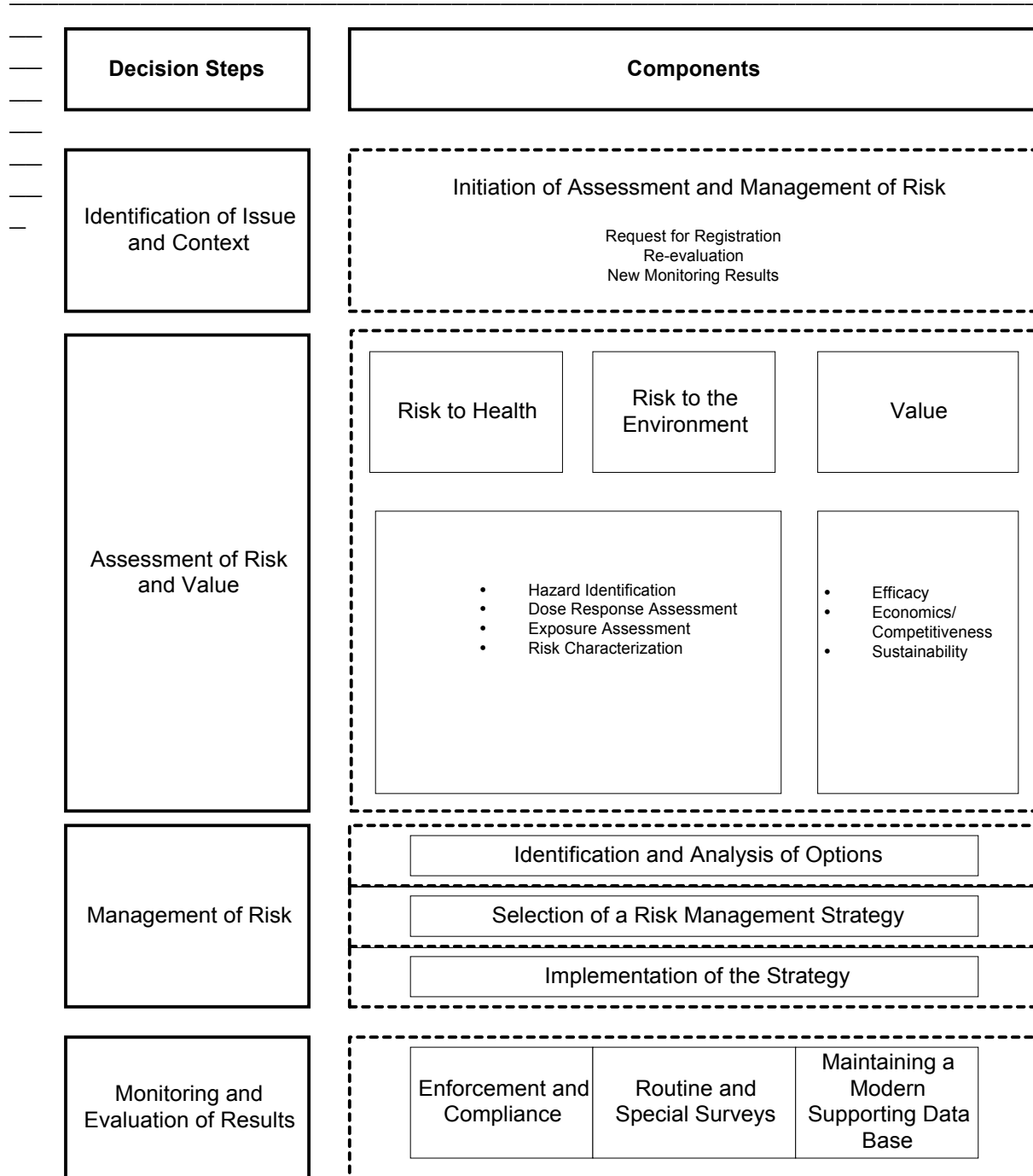
REFERENCES - TO OTHER DOCUMENT;
TSMP POLICY, DATA REQUIREMENTS

APPLIES TO ALL CHEMICAL PRODUCTS UNDER
RE-EVALUATION

WITH MODIFICATION - SPECIFIC SITUATIONS

- MICROBIAL PESTICIDES
- PHEROMONES

DECISION FRAMEWORK OF PMRA



DECISION STEP 1:

IDENTIFICATION OF ISSUE AND CONTEXT

**COMPONENT: INITIATION OF ASSESSMENT
 AND MANAGEMENT OF RISK**

REQUEST FROM REGISTRANT

RE-EVALUATION

NEW MONITORING

DECISION STEP 2.

ASSESSMENT OF RISK AND VALUE

COMPONENTS:

HEALTH RISK	ENVIRONMENTAL RISK	VALUE
	Hazard identification	Effi cacy
	Dose response assessment	Economic s/ Comp etit iven ess
	Exposure assessment	
	Sustainability Risk characterization	

DECISION STEP 3.

MANAGEMENT OF RISK

COMPONENTS:

IDENTIFICATION, ANALYSIS OF OPTIONS

SELECTION OF RISK MANAGEMENT STRATEGY

IMPLEMENTATION OF STRATEGY

DECISION STEP 3.

MANAGEMENT OF RISK

POINT OF CONVERGENCE OF ALL
ACTIVITIES

COLLECTIVE DETERMINATION OF
ACCEPTABILITY

Chemistry - contaminants,
quality,

analytical
methodologies

Health risks

Environmental risks

Efficacy and value

Consistency - other Federal
policies/Acts

-
international
agreements

Decision Step 4.

MONITORING AND EVALUATION OF RESULTS

COMPONENTS:

ENFORCEMENT AND COMPLIANCE

ROUTINE AND SPECIAL SURVEYS

MAINTAINING A MODERN AND SUPPORTING
DATA BASE

CONSULTATION

EVOLVED FROM NO PUBLIC PARTICIPATION

PUBLIC INPUT NOW MORE REGULAR
PRDDs, Regulatory Notes, Committees -
EMAC, PMAC and FPT

CURRENT PCPA POSES A CHALLENGE -

Submission information is confidential

Require Registrant permission for
disclosure

- other agencies, negative
decisions, public

DOCUMENT DESCRIBES EXISTING
CONSULTATION PROCESS - expect this to
change in near future

AMENDMENT TO LEGISLATION - will expand
ability to consult

RISK ASSESSMENT AND RISK MANAGEMENT AT PMRA

PROCESS STEPS DESCRIBED SEQUENTIALLY

ACTUALLY - HIGHLY ITERATIVE

- MANY TASKS CONDUCTED IN
PARALLEL

- MANY FEED BACK LOOPS

USUALLY - RISK MANAGEMENT OPTIONS PROMPT
RE-CALCULATION OF RISKS UNDER NEW
MITIGATION CONDITIONS

INTERNATIONAL CONTEXT

APPROACH TO RISK ASSESSMENT AND RISK MANAGEMENT

LONG HISTORY - REGULATORY AGENCIES
MUST MAKE WITH PRE-MARKET DECISIONS

APPROACH EVOLVED INTERNATIONALLY IN
CONSISTENT MANNER FOR VARIOUS
REGULATED SITUATIONS

Food additives

Pharmaceuticals

BASIC SCIENTIFIC PRINCIPLES AND
PRACTICES FOR PESTICIDES ARE SIMILAR

INTERNATIONAL PROCEDURES FOR RISK
ASSESSMENT AND RISK MANAGEMENT ALSO
HARMONIZED

PMRA APPROACH FOR PESTICIDES -
CONSISTENT WITH THAT OF OTHER MAJOR
REGULATORY AGENCIES IN WORLD

CONCLUSION

SCIENTIFIC APPROACHES WILL CONTINUE TO EVOLVE

- cumulative risk
- aggregation of exposure
- better methods to detect endocrine disruption

APPROACH TO RISK ASSESSMENT AND RISK MANAGEMENT WILL ALSO EVOLVE

PMRA APPROACH TO RISK ASSESSMENT AND RISK MANAGEMENT OF PESTICIDES WILL KEEP PACE WITH SCIENTIFIC ADVANCEMENT
