## PCPA 2002-Transparency

# Pest Management Advisory Council June 12-13, 2006

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# **Transparency Overview**

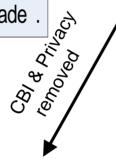
#### Register (S 42):

"Body of information to which the rules of disclosure apply". Section 42 specifies content. Mandatory information placed in the Register as decisions made **REGISTER OF** 

PEST CONTROL RODUCTS

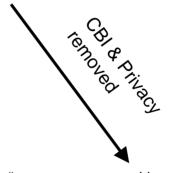
- Mandatory content -

PMRA Access



Upon request to inspect Reading Room





"as soon as reasonably practicable"

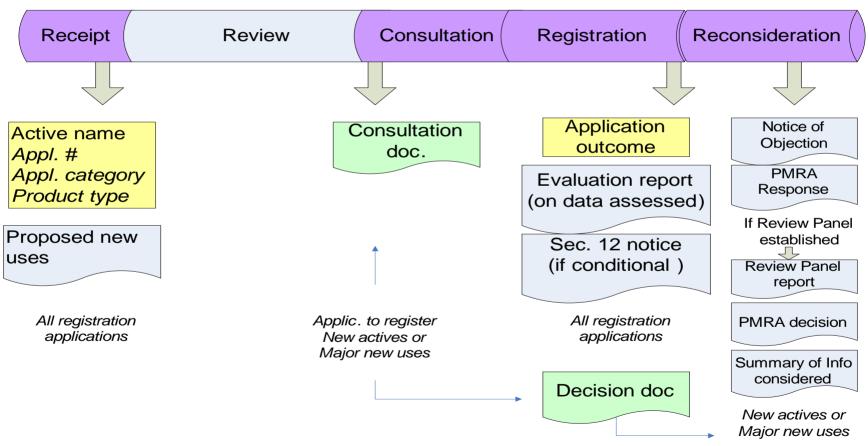
Electronic Public Registry (S 42(7))



Public Access



#### APPLICATIONS TO REGISTER OR AMEND A REGISTRATION





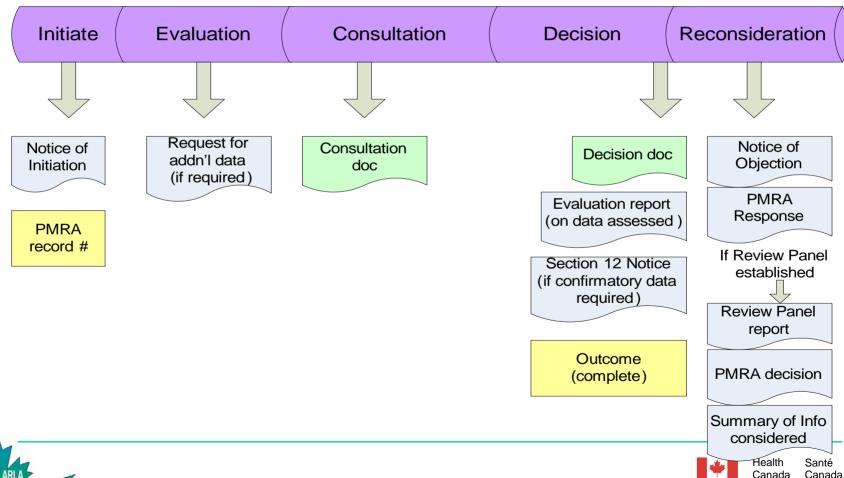


## Exception:

- Where Conditional registration granted :
  - Consultation, access to test data and reconsideration opportunity are delayed until confirmatory data submitted & reviewed, or until registration renewed (whichever comes first) - PCP Regs 14(1)
    - i.e., no consultation or decision documents for conditional registration decisions on new actives or major new uses if a conditional registration
  - But evaluation report will be available



#### Re-evaluation and Special Review



- Pest control products
  - at registration:
    - registration #
    - Validity period
    - Conditions of registration (eg., label)
  - Registration status:
    - Registered, cancelled etc



## **Inspection of Test Data**

#### Data that is relevant to the decision

- Accessible for inspection at time of decision
- CBI, as defined in the Act, must first be removed
- View access via a Reading Room in Ottawa
- ◆ Data continues to be protected by ATI Act, inspection does NOT put the data in the public domain; no copy can be made (\$ 43(8))

### Requires an application with an affidavit

 stating the purpose & that there is no intent to use the data or make it available to others for registering/amending a pesticide anywhere (\$ 43(1))



## **Other Considerations**

- Transitional provisions (S 81); Act applies to:
  - Applications received before "in force" date if decision not yet reached

- Products registered on "in force" date
  - Except that test data supporting decisions made before the "in force" date not accessible until the product is consulted on under the new Act via a major new use application or re-evaluation



## Other considerations

- Required to respect:
  - Official Languages Act
    - Increased translation workload ( PMRA docs)
  - Privacy Act
    - Privacy Impact Assessment done
    - PMRA must remove privacy info from test data, evaluation reports (includes author names for unpublished studies)
  - Copyright Act
    - Where published info used in an evaluation, the publication not put in-registry, only reference to it



# Challenges

## **CBI & Privacy information protection**

- CBI must be designated by registrant, separated from test data & verified by PMRA before Reading Room access (S 43(4),(5),(6),(7)):
  - Publication of guidance to industry
  - Significant new workload for PMRA & industry
  - Need to "catch up" for early decisions
- Privacy information protection
  - Significant new workload
  - Plan to automate as much as possible



# Challenges

#### Efficient electronic delivery has involved:

- Major redesign of e-infrastructure, incl. design/ integration of new tools based on complex business rules
- Conversion of archived test data to electronic (microfilm & paper post1984)
- Ongoing conversion of incoming paper to electronic
- Doc management system/database already contains
   400,000+ docs (up to. 50 million pages) & growing daily
- Re-engineering of processes to accommodate edocument management throughout application lifecycle



# E- Public Registry on Day 1

- What will you see?
  - Single Public registry on PMRA Site with:
    - Listing of "open" registration applications with active etc. but to begin with not new uses
    - Listing of all actives for which re-evaluation started but not yet completed
    - Evaluation reports/other docs added "as soon as reasonably practicable" after decisions made on applications and re-evaluations
    - Listing of all registered products (Labels already viewable via ELSE)



- Not a Google-type search tool
  - But information can be displayed in different ways based on filtering mechanisms via pre-established "buttons"/criteria:
    - E.g., re-evaluations, applications, actives etc.
  - Will consider all feedback





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#### **PMRA Public Registry**



Applications Actives Product Re-evaluation Programs and Special Actions

All New Amendment Renewal Discontinuation

Current Historical All

Applies Numb		Date Received	Category	Purpose	Active Ingredient	Product Type	Outcome	Registration Number	Product Name
2000-0	799	2000-04-10	А	New	PYRACLOSTROBIN	(null)	(null)	(null)	PYRACLOSTROBIN TECHNICAL FUNGICIDE
2000-0	706	2000-03-27	В	New	CARBATHIIN	(null)	(null)	(null)	GAUCHO CS FL (INSECTICIDE/FUNGICIDE SEED TREATMENT)
2000-0	706	2000-03-27	В	New	IMIDACLOPRID	(null)	(null)		GAUCHO CS FL (INSECTICIDE/FUNGICIDE SEED TREATMENT)
2000-0	706	2000-03-27	В	New	THIRAM	(null)	(null)	(null)	GAUCHO CS FL (INSECTICIDE/FUNGICIDE SEED TREATMENT)
2000-0	593	2000-03-10	В	Amendment	CYMOXANIL	(null)	(null)	(null)	CYMOXANIL TECHNICAL FUNGICIDE
2000-0	578	2000-03-08	В	Amendment	DAMINOZIDE	(null)	(null)	(null)	B-NINE WSG PLANT GROWTH REGULATOR
2000-0	495	2000-02-24	А	New	PICOLINAFEN	(null)	(null)	(null)	AC 900001 TECHNICAL HERBICIDE
1999-2	090	1999-11-23	А	New	ACETAMIPRID	(null)	(null)	(null)	ASSAIL BRAND 70 WP INSECTICIDE

Total Row Count in Report- 80 Row(s) 1 - 20







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### **PMRA Public Registry**



Applications

Actives

Product

Re-evaluation

Programs and Special Actions

#### View actives beginning with the letter:

#### ABCDEFGHIJKLMNOPQRSTUVWXYZ 123456789([@

Active Ingredient	<b>Current Applications Registered</b>	Products Current Ro	e-Evaluations
P-CHLOROPHENYL PHENYL SULFONE	0	0	0
P-MENTHANE,3-8-DIOL	0	0	0
P-TERT AMYL PHENOL	0	0	0
PACLOBUTRAZOL PACLOBUTRAZOL	0	0	0
PAECILOMYCES FARINOSUS	0	0	0
PAECILOMYCES FUMOSOROSEUS APOPKA STRAIN 97	0	0	0
PAENIBACILLUS POLYMYXA	0	0	0
PANDORA NEOAPHIDIS MYCELIA	0	0	0
PANTOEA AGGLOMERANS C9-1	0	0	0
PANTOEA AGGLOMERANS STRAIN E325 (NRRL B-21856	) 0	0	0

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### **PMRA Public Registry**



Applications

Product

Re-evaluation

Programs and Special Actions

Registered

Expired

View products beginning with the letter:

#### ABCDEFGHIJKLMNOPQRSTUVWXYZ 1234567890'

Product Name	Active Ingredient	Product Type	Registration Status	Status Expiry Date	Re-Evaluation Status
PERMANONE 10% EC ANIMAL HEALTH	(null)	(null)	Fully Registered	(null)	Not available
POOL LIFE ALGAECIDE 5	(null)	(null)	Fully Registered	(null)	Not available
PRALLE (R) MANUFACTURING USE PRODUCT	(null)	(null)	Fully Registered	(null)	Not available
PUROGUARD ANIMAL REPELLENT	(null)	(null)	Fully Registered	(null)	Not available
P MAX 8 STABILIZED CHLORINATING TABLETS	(null)	(null)	(null)	(null)	Not available
PACIFIC FOR SPAS BROMINE BASE	(null)	(null)	(null)	(null)	Not available
PACIFIC FOR SPAS GENERATOR	(null)	(null)	(null)	(null)	Not available
PACIFIC SYSTEM IONISATION AUTOMATIC	(null)	(null)	(null)	(null)	Not available
PARA SCAB SPRAY	(null)	(null)	(null)	(null)	Not available
PARA VET AEROSOL	(null)	(null)	(null)	(null)	Not available



## **Question to PMAC**

What advice does PMAC have on managing expectations for a more transparent system given the transitional provisions of the Act and the challenges that will be faced in the transition to a new paradigm?

