PCPA 2002-Transparency

Registrant Training
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Transparency Overview

REGISTER OF

PEST CONTROL RODUCTS

- Mandatory content -

PMRA Access

CBI & Privacy removed

CBI & Privacy removed

Reading Room

Public Access

Register (S 42):

Body of information to which

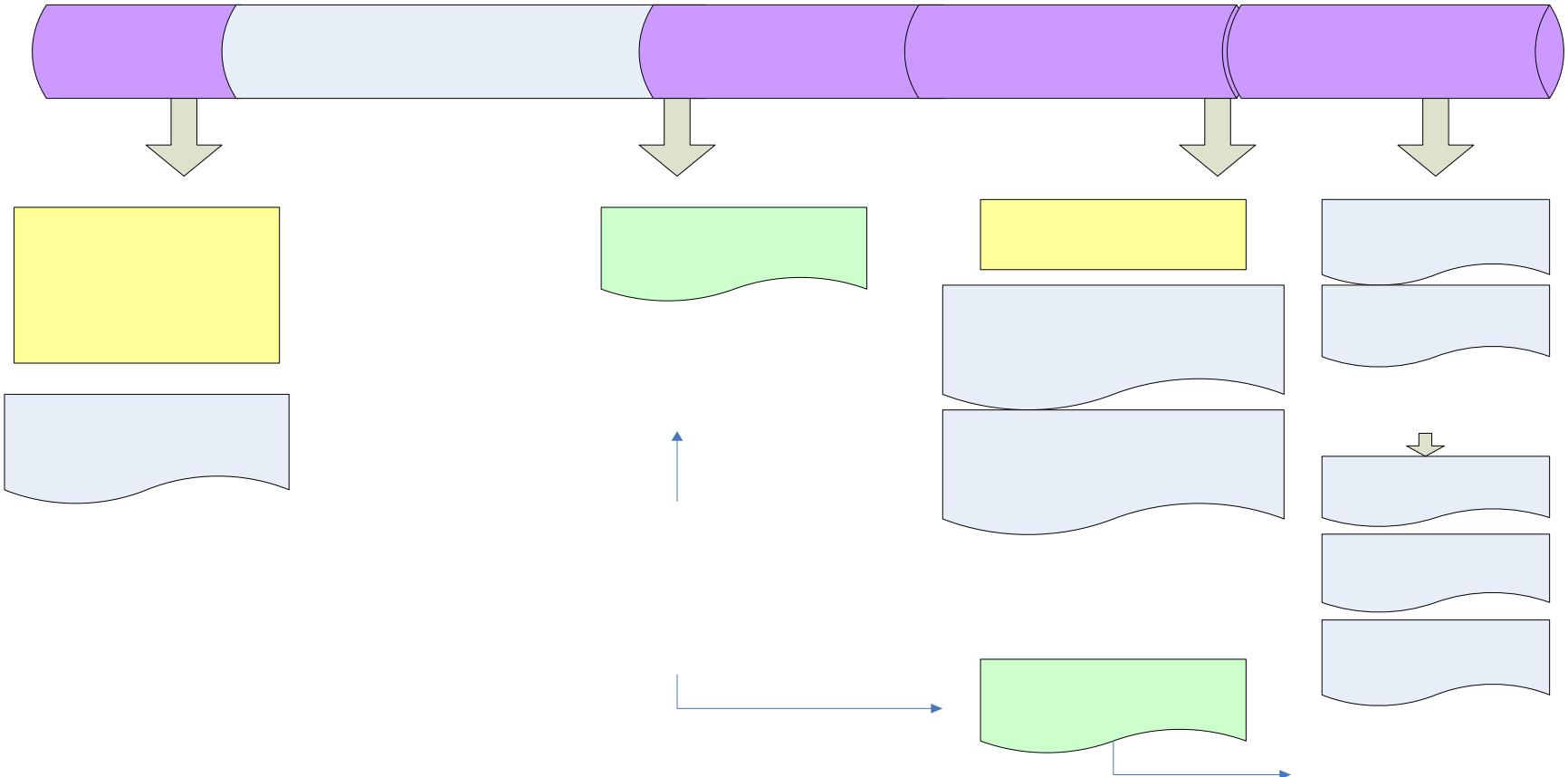
PMRA ARLA

Health Canada Santé Canada

Confidential Business Information

- Defined in PCPA {S 43(4) &(5)} as information designated by the provider and that concerns:
  - *Manufacturing & quality control processes*
  - *Methods for determining composition of the product*
  - *Value of sales, other financial /commercial info.*
  - *Identity & concentration of formulants & contaminants EXCEPT those on List of Formulants & Contaminants of Concern (Canada Gazette II, December 2005)*
- PMRA must verify the CBI designations & notify the applicant/registrant if it does not meet the definition {S 43(6)&(7)}

E-Public Registry
What information & When?



APPLICA

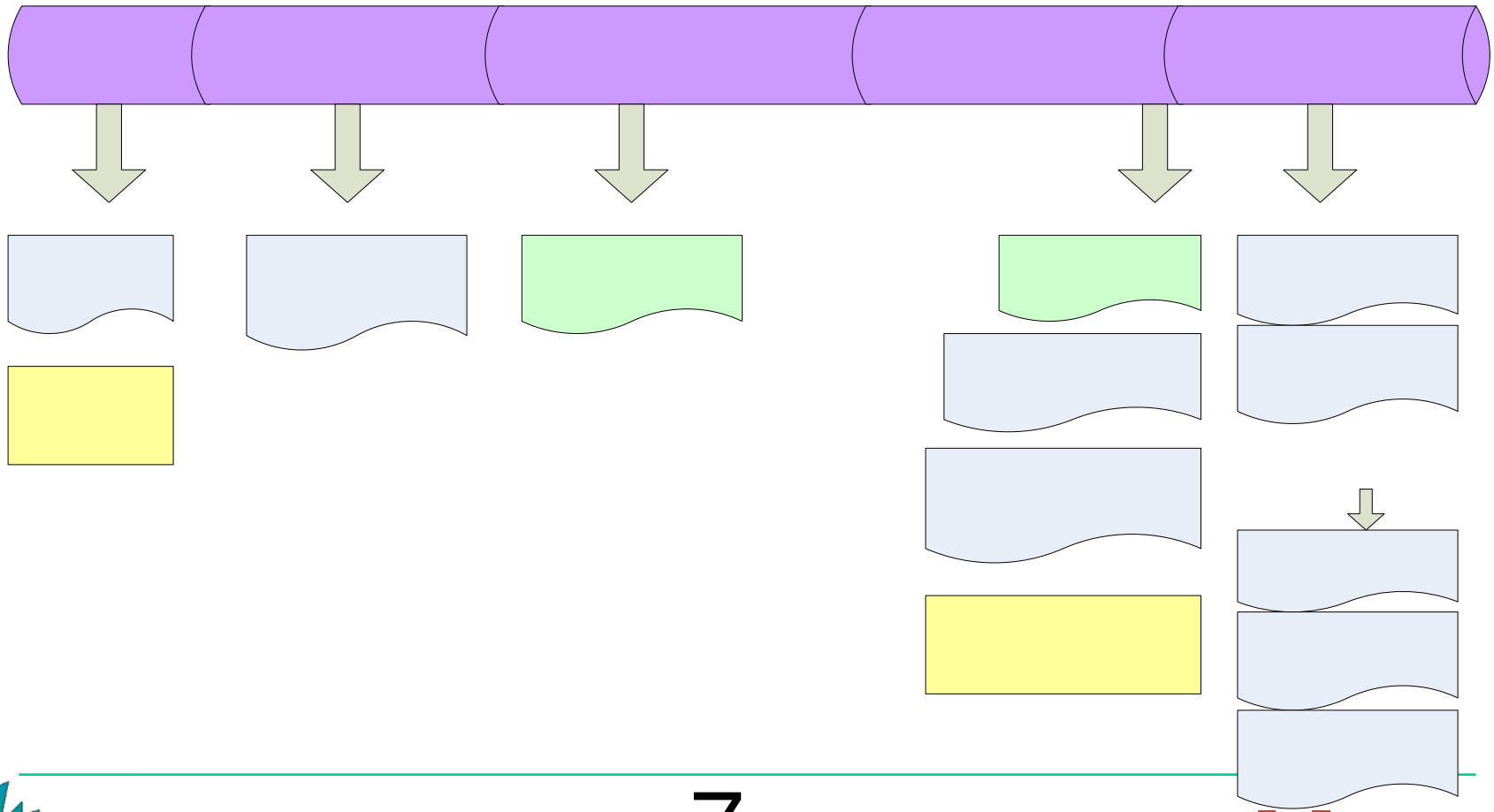
E-Public Registry
What information & When?

- Modifying provisions { PCP Regs 14(1)}:
  - When a conditional registration granted :
    - *Consultation, access to test data and reconsideration opportunity are delayed until confirmatory data submitted & evaluated, or until registration renewed (whichever comes first) i.e., no consultation or decision documents for conditional registration decisions on new actives or major new uses when a conditional registration*
    - *However, evaluation report will be available*

E-Public Registry
What information & When?

- If the registration application is withdrawn before registration, or registration is denied
  - *Evaluation report, test data etc will not be put in the Register, the e-public registry or the Reading Room*

E-Public Registry
What information & When?



Additional Information Considered

- Act provides authority to consider additional information in an evaluation {S 7(5),19(1)},
  - *ie., not supplied by applicant/registrant;*
- Reference in evaluation report satisfies the requirement to place in the Register {PCPRegs S.10}
- Must allow applicant/registrant an opportunity to "make representations" on it before evaluation complete {7(5),19(1)}
  - *If info. confidential to the provider, registrant must submit an affidavit agreeing to return it & not copy, share or use it for any other purpose*

Inspection of Test Data

- Data that is relevant to the decision
  - *Accessible for inspection at time of decision*
  - *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 (S 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 (S 43(1))*
- PMRA must notify registrant of inspection

Inspection of Test Data

- Reading Room security:
  - *Test data viewable electronically on computer with no external connections*
  - *Copying, taking pictures etc will not be allowed*
  - *Obtaining copies not allowed (by Act)*
  - *Supervision by a PMRA employee*
- Note taking will be allowed for purpose of working up an argument to support an objection to a decision

Transitional Provisions

- **Section 81 states that the Act applies to**:
  - Applications received before “in force” date if decision not yet reached
    - *i.e., applies to submissions in progress*
  - 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, or when studies are cross-referenced in a new application*
      - *and then only the data relevant to the new decision will be put in the Register & be made accessible*

What Does Not Change

- For new actives, major new uses, re-evaluations (PRDD/PACR):
  - *Consultation document (now publish the PRDD/PACR)*
  - *Decision document (now publish the RDD/RRD)*

What is New

- **Application receipt & outcome made public**
  - *New form for reporting proposed new uses*
- **Permission to publish consultation doc. not required**
  - *But, error correction step will be incorporated*
- **Evaluation report made public**
  - *For new actives, major new uses, re-evaluation will be similar to the consultation document /Reg Note*
  - *For other submissions with data it will be a short integrated summary of the evaluation (a few pages).*
  - *Will not include CBI or personal information (Privacy Act)*
  - *Will include a reference list of test data & additional information considered*

What is New

- Confidential test data available for inspection
  - *CBI must be designated by applicant/registrant & verified by PMRA* {S 43(4),(5),(6),(7)}:
  - *For new test data, CBI must also be segregated*
  - *Directives re. designation/segregation methodologies/processes published*
    - DIR 2006-03 & DIR 2006-04
    - E-Index Builder Tool for submitting index & e-docs
- Opportunity for public to request reconsideration of major decisions

Transition Challenges

- Transparency is:
  - *New for Industry, the PMRA and the public*
  - *Involves increased workload for industry & the PMRA*
  - *Involves new processes & new electronic tools*
- CBI protection
  - *Applicant/registrant designation & segregation in test data submitted under the new Act*
  - *Applicant designation required for previously submitted data; PMRA will segregate*
  - *PMRA can only protect CBI if designated & verified*
    - Need to work together to accomplish this – PMRA help available
    - Time constraints

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.*
    - *Listing of all actives for which re-evaluation started but not yet completed*
    - *Listing of all registered products (Labels already viewable via ELSE)*
  - Evaluation reports/other docs added "*as soon as reasonably practicable*" after decisions made on applications and re-evaluations

Transparency

QUESTIONS?