Electronic Public Registry

Presentation to PMAC

May 17, 2004

Valerie Robertson

Overview

- New transparency requirements
- Definitions
- Register of pest control products
- Electronic registry
- Summary of Register/E-registry content
- Transitional provisions
- How will it happen?

Transparency Requirements

- PMRA must establish:
  - Register of pest control products
  - Electronic public registry
    - "…..*as soon as reasonably practicable*"
  - Mechanism for inspection of confidential test data
    - controlled access
    - no copy may be obtained

Definitions

Confidential Test Data

Test data to which access may be refused under ATI Act

Confidential Business Information

- *Manufacturing and quality control processes*
- *Methods for determining composition*
- *Name and concentration of formulants and contaminants that are NOT of health and environmental concern*
- *Financial information incl. monetary value of sales data*

Register of pest control products

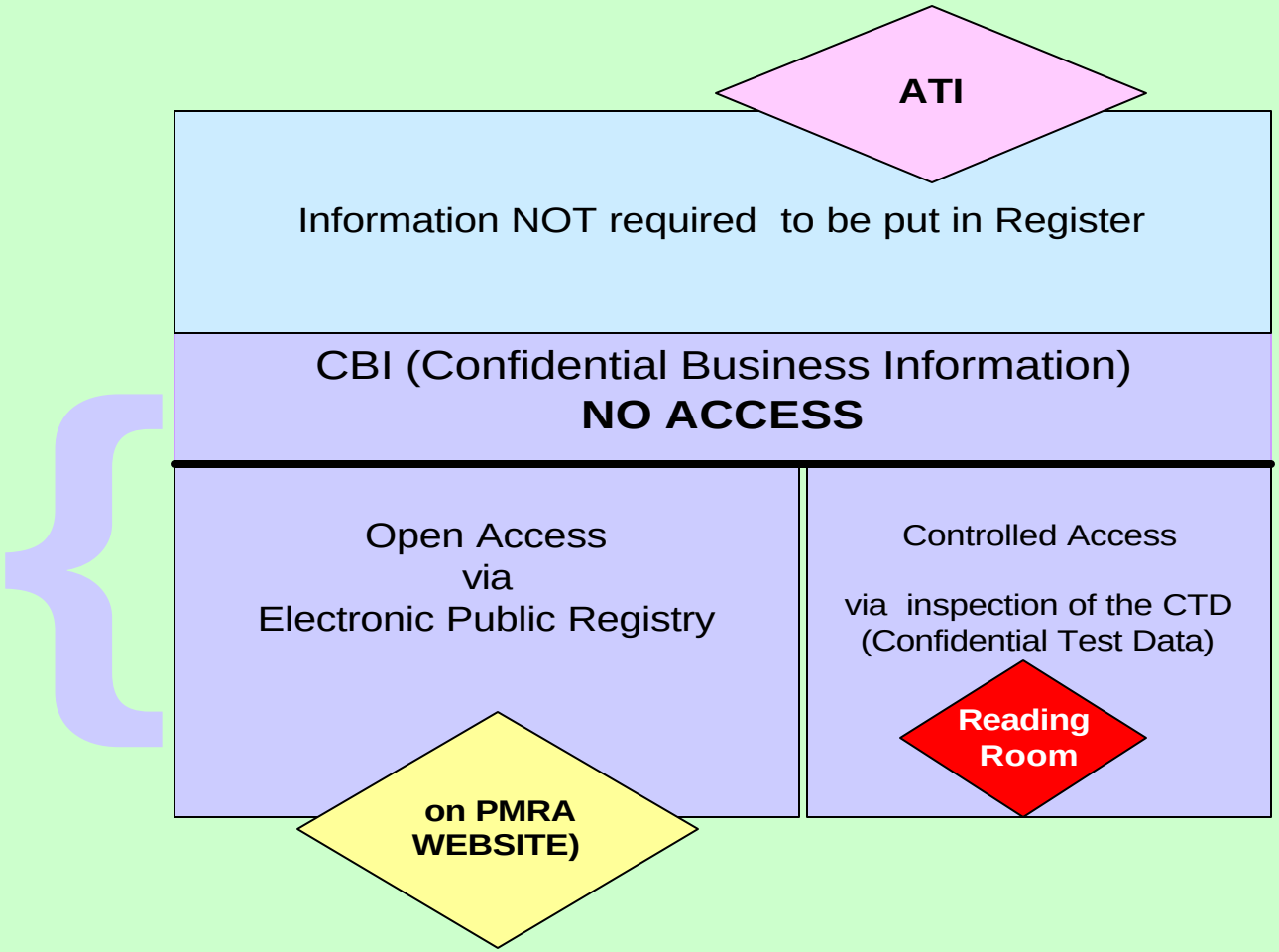
- A concept, NOT a physical location
- " a *body of information* re. applications & registered products to which rules of access under new PCPA must be applied"
- new Act specifies the content (mandatory)

Electronic public registry

- New PCPA specifies content:
  - MOU with other Federal Depts.
  - International harmonisation activity reports
  - Regulations/proposed regulations
  - Policies, guidelines, codes of practice
    - at public consultation & finalization
  - Info. required to be in **Register of pest control products** (except CBI & CTD)
- Delivery via PMRA Website

Access to information re applications/registered products

****Register of pest control products**



***** Register : body of information to which the rules of disclosure, under the PCPA, apply***
The PCPA defines the mandatory info that must be put into the Register

What information?

ATI

Access subject to ATI

Correspondence
- internal memos, meeting minutes,- deficiency letters, clarifaxes etc

No Access to CBI

Formulants (not of health or environmental cnoncern); Manufacturing Process, etc

Open Access (not incl CTD/CBI))

Application:
- active ingredient name
- proposed new uses/uses to be withdrawn
- Consultation & desicion stmts (PRDD, RDD)
-- Application outcome (registered, withdrawn, rejected)

- If Application outcome is positive (registered)
  - advice requested from 3rd party
  - other information considered
  - evaluation reports (mongraphs)
  - notices requiring more data/monitoring as condition of reg'n

- Registered product:
  - Registration number & validity period
  - Conditions of registration
    - product label & specifications
    - conditions specified in notice

Reconsideration information:
- notices of objection, decision to hold a review panel or not
- info submitted to review panel
- rev panel recommend'n
- final decision

PMRA WEBSITE

Controlled Access

(not incl CBI)

Application:
- Confidential Test Data (CTD)

- provided by applicant: index, CDS, study reports, waivers, etc

- data provided by third party (not in public domain)

Reading Room

What information?- cont:

ATI

Access subject to ATI

Correspondence
- internal memos, meeting minutes, clarifaxes etc

No Access to CBI

Formulants (not of health or environmental cnoncern); Manufacturing Process, $$ Sales info, etc

Open Access (not incl CTD/CBI))

Re-evaluation/Special review:
- announcement initiating re-eval/special review

- consultation and decision statements
- notices requiring more data/monitoring as condition of reg'n
- other info considered (non-registrant)
- formal advice sought from 3rd party
- PMRA evaluation reports
- conditions of rcontinuing registration

Reconsideration information (re. re-eval .special review decision)
- notices of objection, decision to hold a review panel or not
- rev panel recommend'n
- final decision

Adverse effect conclusions
- REgulations to address AER reports

Sales information by volume

PMRA WEBSITE

Controlled Access

(not incl CBI)

Re-evaluation/Special review:
- Confidential Test Data (CTD)
(provided by registrant
- index, study reports,waivers etc)

- data provided by third party
(not in public domain)

Reading Room

Transitional provisions

- RE: registrations & applications existing when new Act proclaimed:
  - CTD & evaluation reports not placed in Register until the active has been subject to consultation under new PCPA

How will this happen?

- Electronic delivery leveraging Oracle database/PRS
- PMRA business rules, processes & tools being realigned
- Applicant must designate CBI; PMRA will confirm
- PMRA must identify/separate CBI in evaluation reports etc.
- Piloting Monograph assembly
- Quality assurance
- Language of Monograph
- Web presentation/ user interface

Key success factors

- Effective electronic information & document management
- Awareness of CBI requirements (Industry & PMRA)
- Documentation & communication of the rules/processes
- Sound QA measures
- Roles defined

Enabling Electronic Business

Presentation to PMAC

May 17, 2004

PMRA ARLA

Why go electronic?

- PMRA – responsible for the regulation of pesticides in Canada
- 3000 submissions/3000 decisions annually
- Re-evaluation of existing products; 401 active ingredients and their end use products
- Compliance
- Limited resources
- Cost recovery and performance standards
- Large volume of information, scientific data and documents received in paper format

Needs

- Program needs
  - Data submission, Evaluation
  - Tracking
  - Reporting, Archiving
  - Document Management
  - International Worksharing
  - Efficiencies for government, for industry
  - Transparency
  - Consistency

In the beginning (…….1995)

- Data produced at bench by industry; handled, rewritten and revised may times prior to being put into a paper submission ($ 40, 000.00 just to put the paper together)
- Delivered by truck; 6 + copies
- Received, handled, reviewed as paper
- Archiving by hand; paper shredded
- Few public documents produced

1995-2003

- Submission screening, preliminary review, timelines, cost recovery all put rigour into the system
- Electronic submission tracking system put in place
- Scanned in label collection on web
- Work book developed…document management tool for all evaluation documents, by submission

1995-2003

- Common formats for submissions
- Common formats for reviews
- Data requirements, formats and forms on web site
- Requirements for submission of electronic labels
- Training for industry , staff

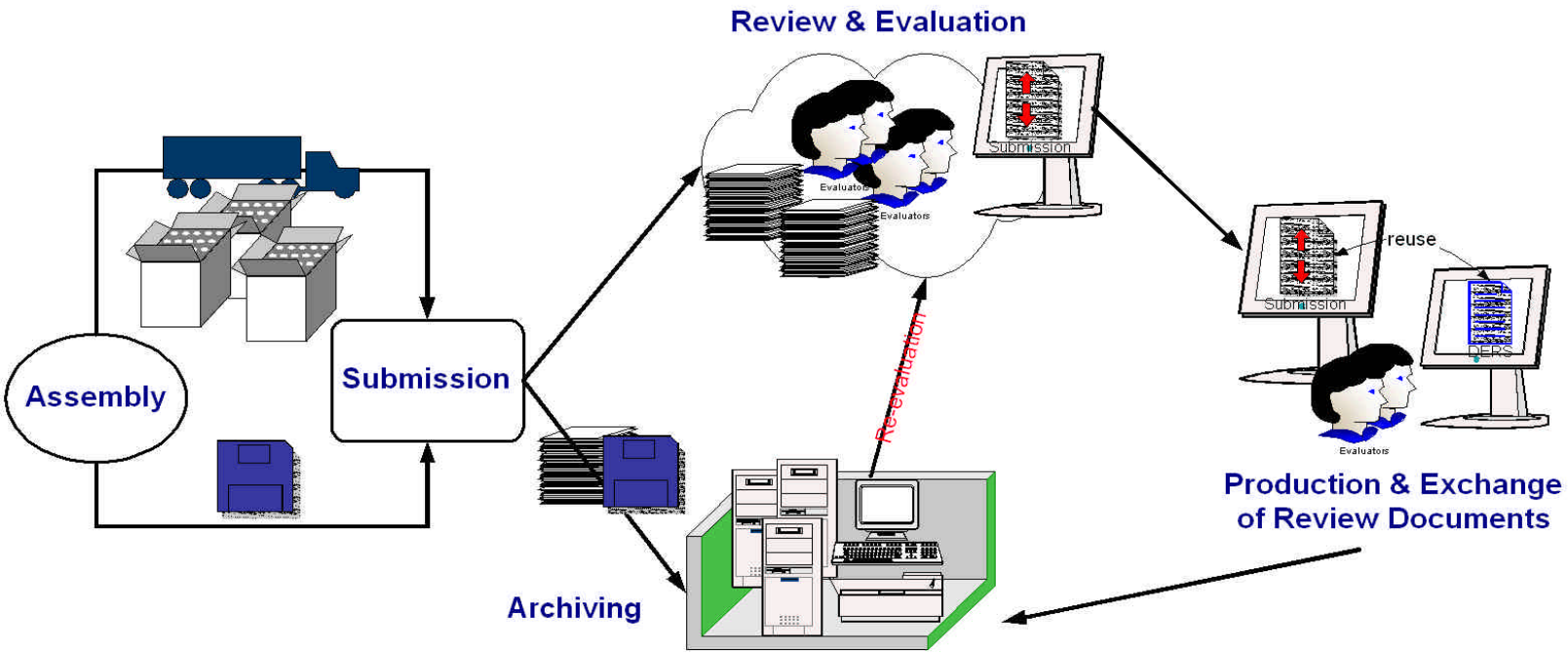
1995-2003

- OECD workshop hosted by PMRA on electronic tools
- Joint work with US EPA on electronic tools under NAFTA

Results

- PMRA ability to track, review and document results electronically
- Large number of public risk assessment decision documents
- Industry ability to develop electronic submissions
- Increased efficiencies
- But……. Delivery mechanism still paper or disc; etc.
- But……..New Pest Control Products Act needs

Where we are today
Electronic Regulatory Framework
Fall 2003



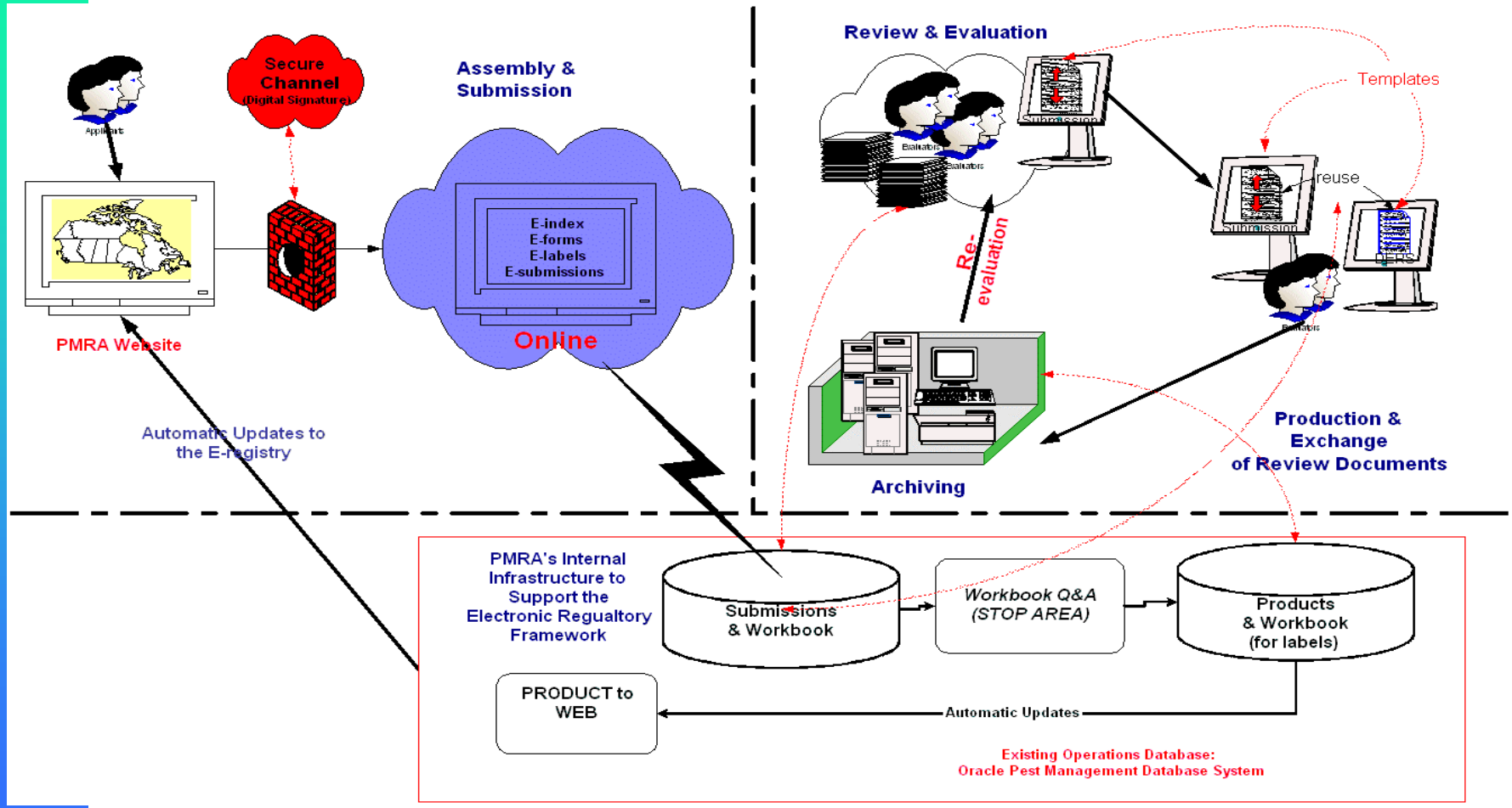
2003 Evolution to .....

- Seamless electronic approach– E-Regulatory Project
- Internal process alignment activities
  - Augment Electronic framework
  - Automate data capture
    - Consolidation of forms
    - Convergence of paper & electronic processes
- NAFTA support for PMRA's approach for electronic submission assembly

Incorporating Assembly and Submission

- Automate data capture
  - *Reduce Processing Times*
- Incorporate validation prior to submission
  - Increase *Quality*
- Support one format, electronic
  - *Efficient use of Resources*
- Automate transparency reporting – public registry, consultation documents
  - *Processing Times, Quality and Resources*

Where we will be
Electronic Regulatory Framework
Summer 2004



What does this mean?

- Registrants – submit their applications, forms, other transactions via the web
- Submission receipt and archiving at PMRA will be automated as will the placement of documents on the register and public registry
- 1st country in the world to go online for pesticide applications
- Increased efficiencies for government, for industry
- Increased transparency for public

Question

- What advice does the Council have concerning the implementation of the electronic registry?