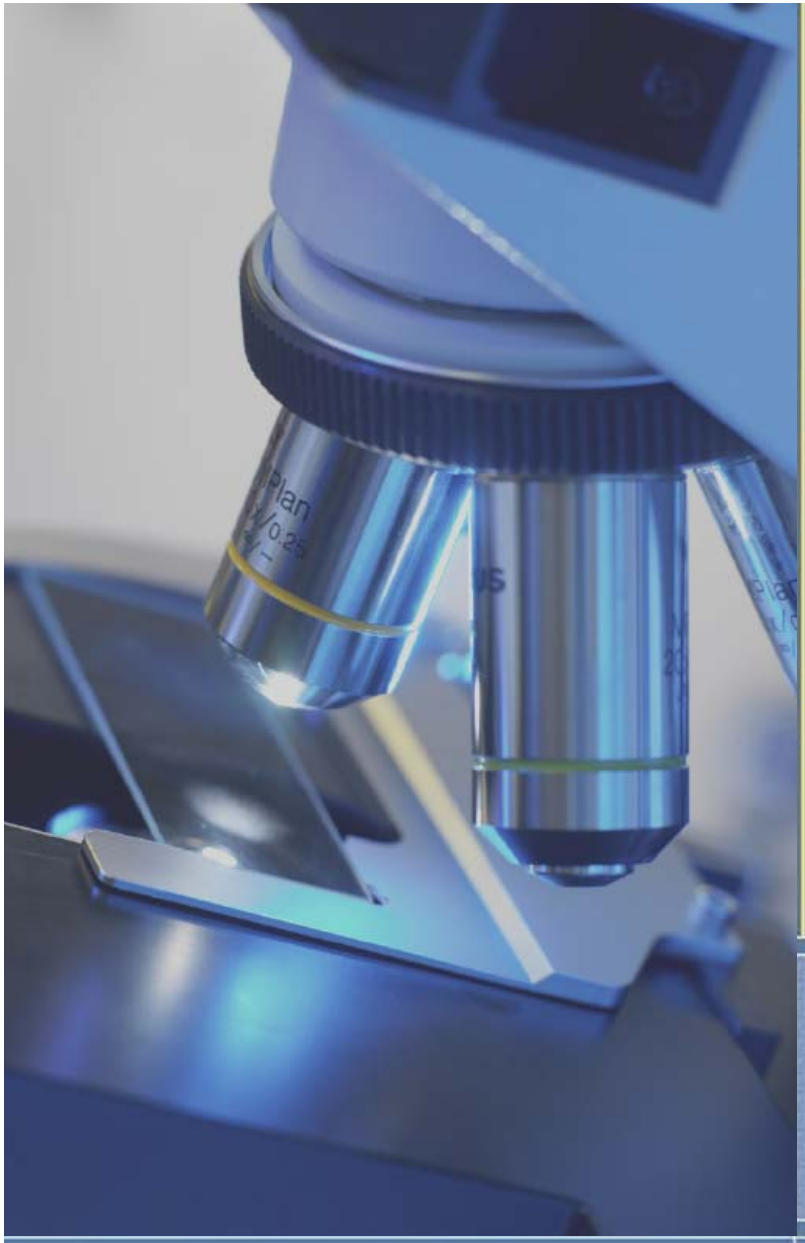


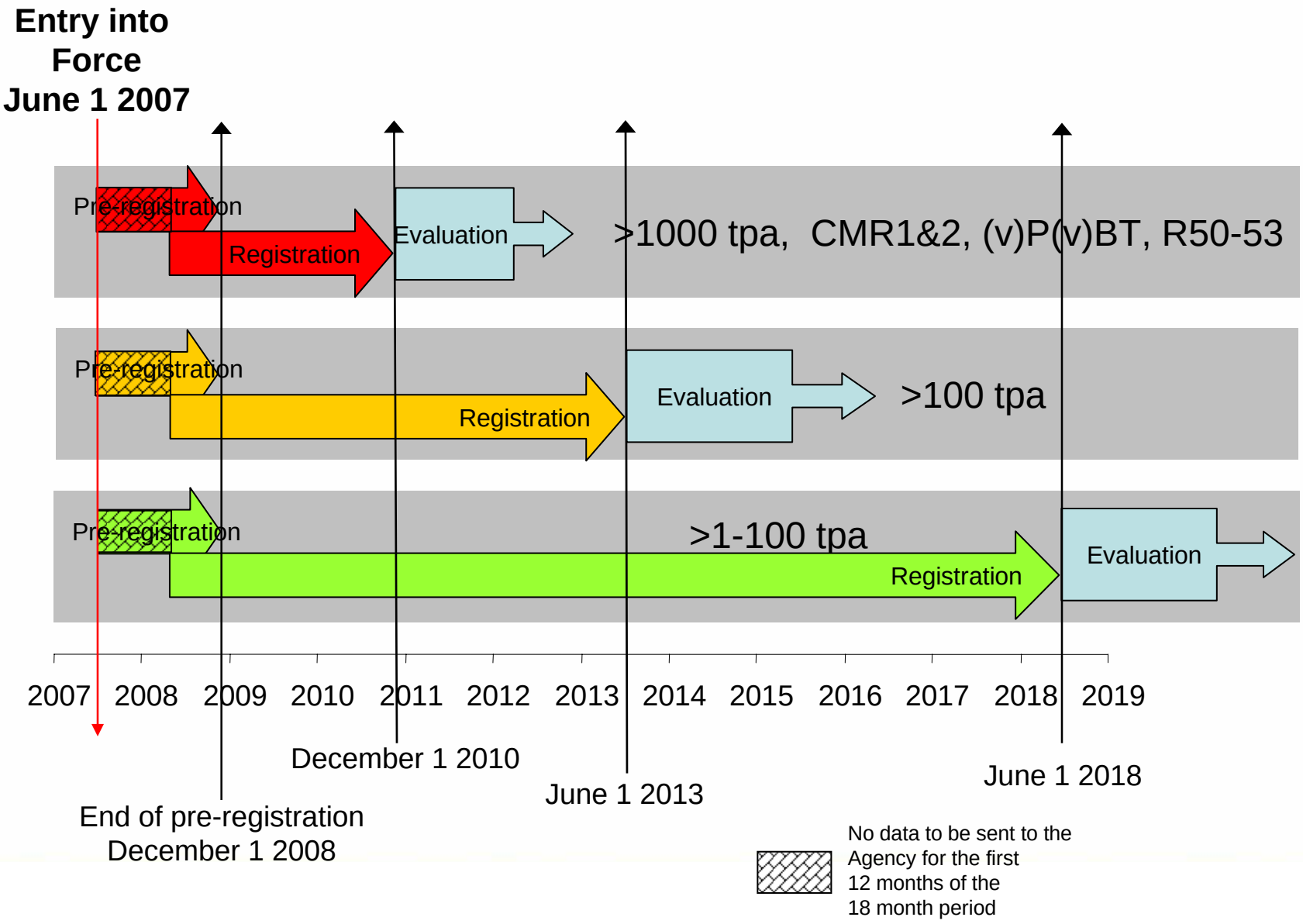
Dossier Development, Registration, and Submission

Carol Mackie

Compliance Services International

"REACH in Practice" Conference
1 June, 2007

Timetable for phase - in substances



REACH registration

- What do I have to register?
  - Substances >1 ton/producer/year
  - Non-registered monomer substances if present at >2% in a polymer
  - Substances in Articles if present> 1 ton and intended for release
  - PPORD exempted from registration for 5 (+ 5) years
  - Polymers — exempted from registration — but EC is committed to consider how polymers can be addressed in the future.
  - Intermediates - reduced requirements

Registration Information Requirements - Technical Dossier

- Common information for all registrations
  - Identity of manufacturer or importer, identity of substance
  - Information about manufacturing process and produced quantity including all identified use(s)
  - Classification and labelling proposal
  - Guidance on safe use (storage, disposal, first aid measures)
  - All relevant and available test data (including a literature search)
  - Indication as to which information has been reviewed by an independent assessor
  - Request for confidentiality
- Information depending on the tonnage
  - Available data
  - Testing proposal

Registration Information Requirements - Technical Dossier

Substances between 1 and 10 t/yr

- Phase-in substances: prioritisation according to Annex IlI
  - If prioritised: Annex VII
  - If not: Only information on phys-chem properties
- Non phase-in substances: Annex VII

Prioritisation criteria according to Annex III

the substance is likely to be CMR category 1 or 2 or PBT or vPvB (according to criteria in Annex XII) on basis of QSAR or other evidence,

or

• the substance has dispersive or diffuse use(s), particularly in consumer preparations or consumer articles

and

• The substance is likely to be hazardous (under Directive 67/548/EEC) on basis of QSAR or other evidence.

Registration Information Requirements - Technical Dossier

Substances >10 t/yr

- 10 - 100 t/yr: Annexes Vll & VIII
- 100 - 1000 t/yr: Annexes VII, VIII and IX + testing proposals for Annex IX
- > 1000 t/yr: Annexes VII, VIII, IX and X + testing proposals for Annexes IX & X
- Adaptations to these testing regimes are described in Annex XI

Registration Information Requirements - Technical Dossier

Technical Annexes

- Annex VII
  - Physicochemical properties
  - Basic human health data
  - Short term aquatic toxicity
- Annex VIII
  - Human health data (including in vivo)
  - Ecotoxicological data
- Annex IX and Annex X
  - Long term, repeat dose, chronic, fate etc
- Annex XI
  - Adaptations of the testing regimes (exposure waiving, read-across, QSARs)

Registration Information Requirements - Chemical Safety Assessment/Report

What is the Chemical Safety Assessment/Report?

- Only obligatory for substances> 10 t/y
- Shall consider all stages of the life-cycle of a substance as defined by the identified uses and will contain the following information:
  - Human health hazard assessment
  - Human health hazard assessment of physico-chemical properties
  - Environmental hazard assessment
  - PBT and vPvB assessment

- if dangerous or a PBT or vPvB
  - Exposure assessment
  - Risk characterisation

Joint submission of data between multiple registrants

SEPARATELY

- Identification of manufacturer or Importer
- Identification of substance
- Information on manufacture and use
- For substances 1 to 10 t, exposure information (section 6 of Anne VI)
- Indications about review by an assessor

CHOICE

- Guidance on safe use
- Chemical Safety Report
- Indications about review by an assessor

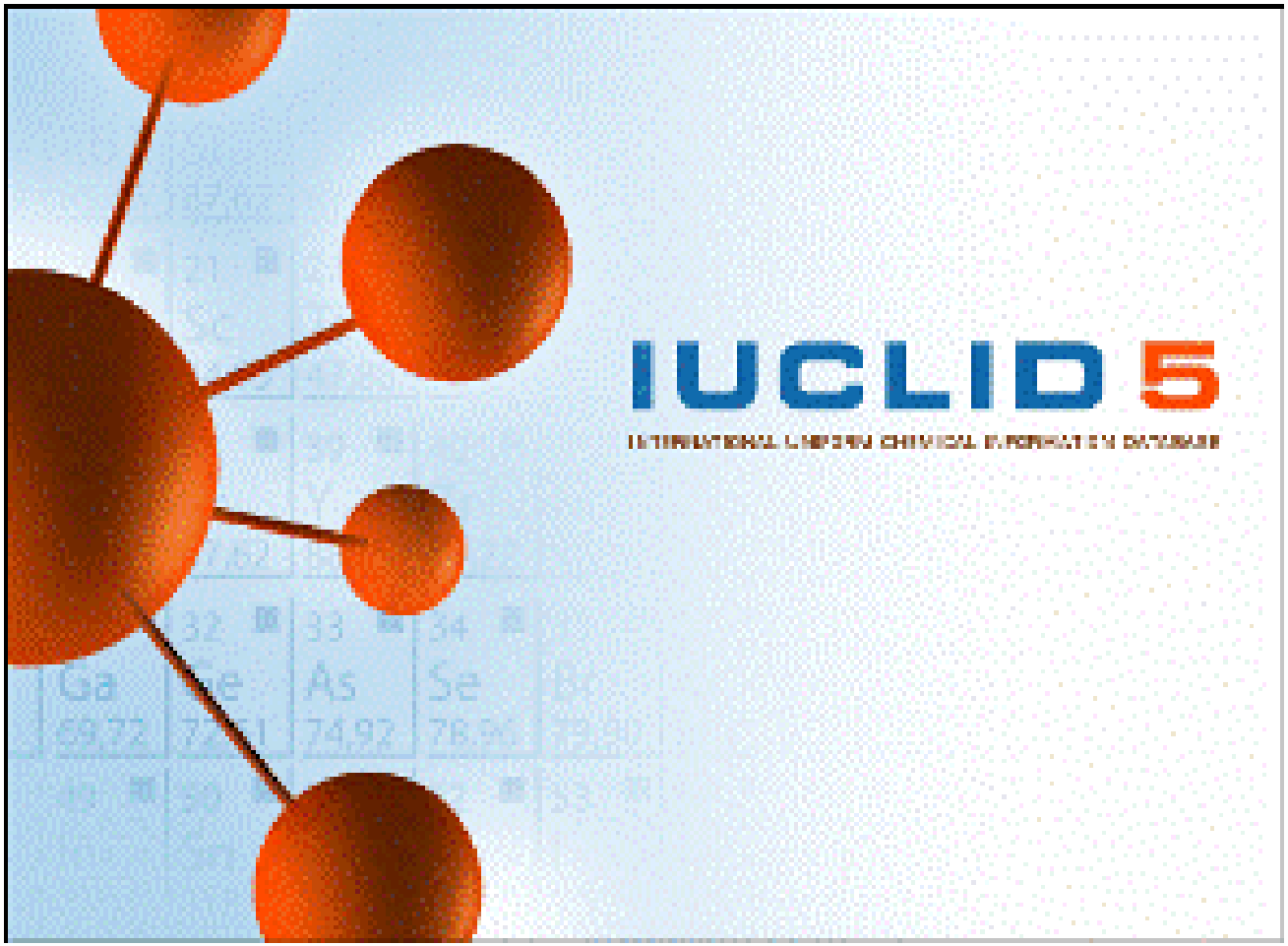
JOINT

- Classification and labelling
- Study summaries and robust study summaries of information derived from application of Annexes VII to XI
- Proposals for testing where listed in Annexes IX and X
- Indications about review by an assessor

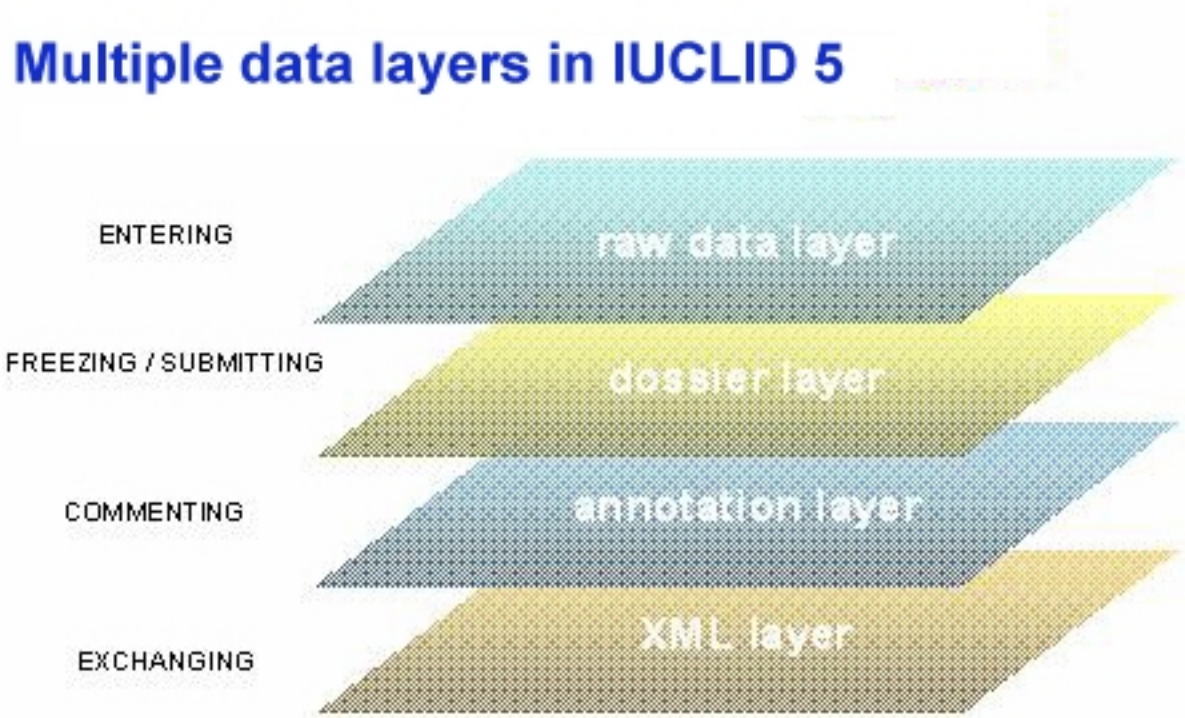
Registration requirements

- Chemical safety report – includes risk assessment, based on TGD, EUSES and R.I.P developments
- Summary of available data in IUCLID 5
- Proposed study plan for vertebrate testing

IUCLID 5



Purpose of IUCLID 5



IUCLID 5

- For the Agency & for Member state competent authorities, IUCLID5 is: - the **central data repository** for all dossiers submitted
  - the basis for evaluating the risks of substances and requiring new information
  - the basis for restricting and authorizing the use of chemicals to manage risks

Dossier submission

- After submission, the registration dossier will be stored in the IUCLID 5 database of the Chemicals Agency
- The dossier will undergo a completeness check and an invoice will be generated
- Once the fee is paid and dossier deemed complete, a registration number will be sent to registrant