A crosswalk of the exposure science requirements of REACH, TSCA, CEPA, and Biocides Legislation

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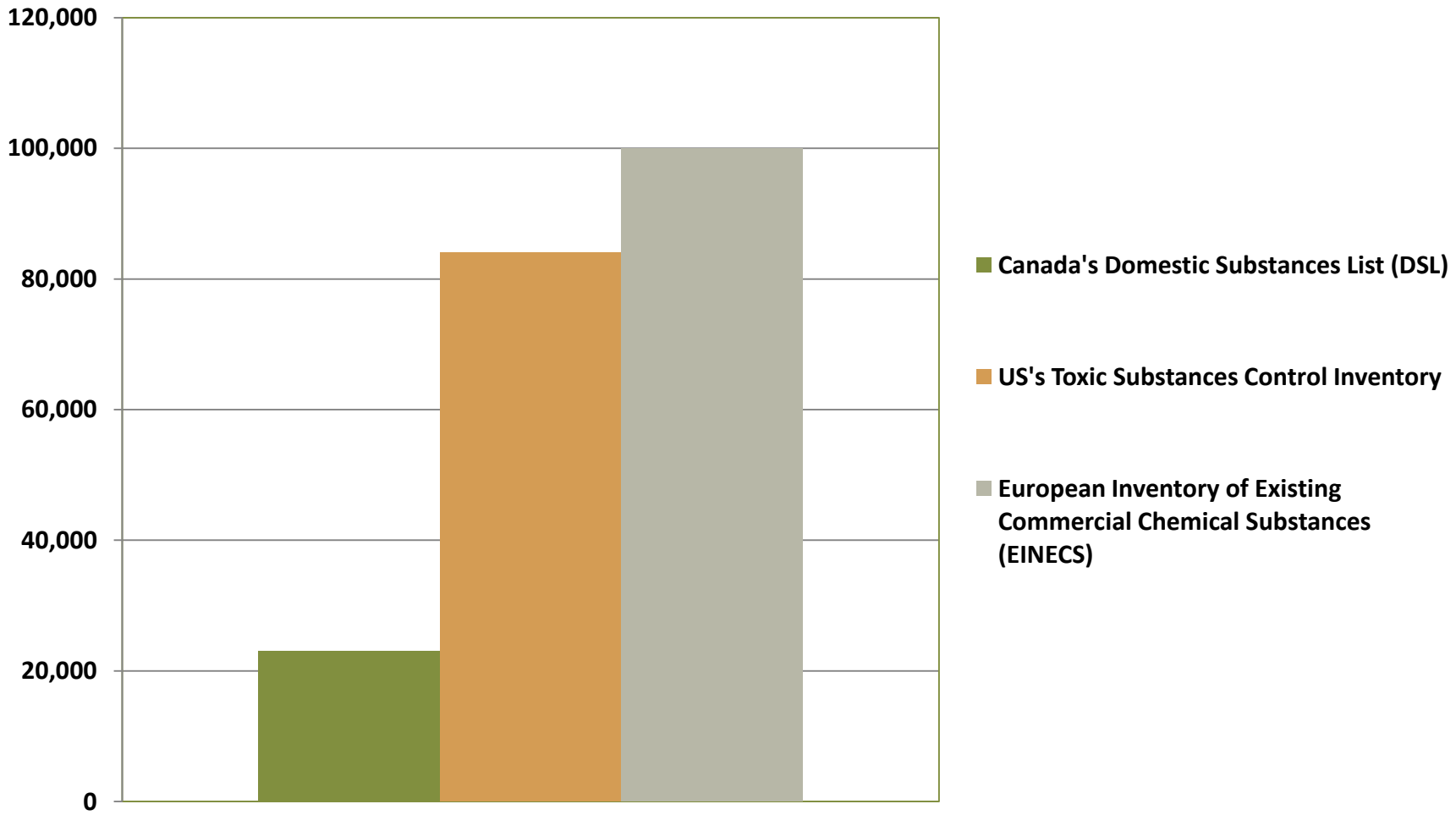
Why are we here today?

- Unprecedented growth in exposure science
- Opportunity to work together
- Compare REACH, BPD, TSCA, and CEPA 1999
- Existing chemicals
- Science focus

Outline

- Background on legacy chemicals
- Regulatory context
- Compare and contrast underlying scientific issues
- Remaining challenges

International chemical inventories



Underlying scientific issues

1. Exposure-based triggers
2. Predictive models
3. Availability of guidance
4. Subpopulations
5. Precaution and uncertainty
6. Data sharing

Regulatory context

- Who is the responsible party?
- What are science challenges that arise under each legislation?

REACH 2006

- Industry-led science
- Science challenges:
  - Requirements driven by tonnage
  - Exposure-based waivers
  - Lifecycle approach
  - Standardized data format
  - Risk-based priority setting

BPD 1998

- Industry- and government-led science
- Science challenges:
  - Tools for nano and UVCBs
  - Approaches for aggregate, cumulative, and mixtures assessments
  - Scenarios and evaluation

TSCA 1976

- Government-led science
- Science challenges:
  - Data access and confidentiality
  - Susceptible subpopulations
  - Include humans and environment
  - Risk-based prioritization and screening
  - Higher-tier analyses

CEPA 1999

- Government-led science
- Science challenges:
  - Data access and confidentiality
  - Practical implementation of precautionary principle
  - Substance grouping
  - Cumulative risk
  - Identifying safer substitutes

Biocides in Canada and US

- Pest Control Products Act in Canada
- Federal Insecticide, Fungicide, and Rodenticide Act and Federal Food, Drug, and Cosmetic Act, and Food Quality Protection Act in US

Exposure-based triggers for ecological and human health

- Thresholds: 1 TPA for REACH; 100 kg in 1986 for CEPA
  - Threshold of toxicological concern
  - Rapid screening tools
- Hazard- and exposure-based findings for TSCA
- No real “trigger” for BPD

Predictive models

	Priority Setting	Human Health	Ecological	Single Source or Sum of Single Source	True Aggregate (for consumers)	Cumulative	Susceptible Subpopulations
REACH		**ECETOC TRA** EUSES ConsExpo Stoffenmanager	ECETOC TRA ESDs SpERCs EUSES SimpleTreat	**ECETOC TRA** ESDs EUSES			
TSCA		ChemSTEER EPI Suite E-FAST PIRAT ReachScan	**ECOSAR**	ChemSTEER E-FAST PIRAT			ChemSTEER E-FAST PIRAT ReacjScam
CEPA	**SimET**	**ConsExpo** **ChemCAN**	ESDs ASTreat SimpleTreat	**ConsExpo** **ChemCAN**			
BPD		EUSES ConsExpo ESDs BEAT	**EUSES**	EUSES ConsExpo ESDs			

Human health subpopulations

				
REACH	✓	✓	✓	✦
BPD	✓	✓	✓	✦
TSCA	✓	✓	✓	✦
CEPA	✗	✓	✓	✦

Availability of supporting guidance and/or SOPs

- Is guidance available for type of assessment required?
  - Yes with exceptions (e.g., cumulative, mixtures)
- Is guidance prescriptive or is expert judgment acceptable?
  - REACH and BPD prescriptive
  - TSCA and CEPA judgment expected

Application of precaution and approaches to uncertainty

- Tiered analysis
- “Reasonable worst case”, “high end”, “upper bound”
- Role of assumptions

Data sharing

1. What data can be shared?
2. How can we share data?
   - MOUs
   - Work sharing
     - Creosote, pentachlorophenol, chromated copper arsenate
   - Public forums and databases
     - Communication and Information Resource Center Administration
     - European chemical Substances Information System
     - ECHA Info on Registered Substances
     - EPA Inventory Update Rule
     - Toxics Release Inventory and National Pollutant Release Inventory

Remaining scientific challenges

- Harmonization of terminology: substance, cumulative, aggregate
- Susceptible subpopulations
- Model/approach development and evaluation
- Data access
- Consistency of methodologies

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Thank you!

- Questions?