Best Practices for Classifying Chemicals of Concern

August 22, 2019

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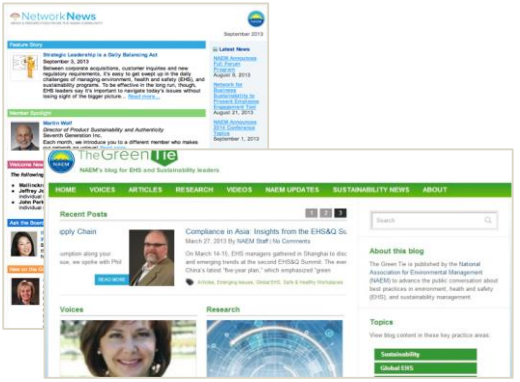

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Today's Presenters

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Sr. Regulatory Analyst

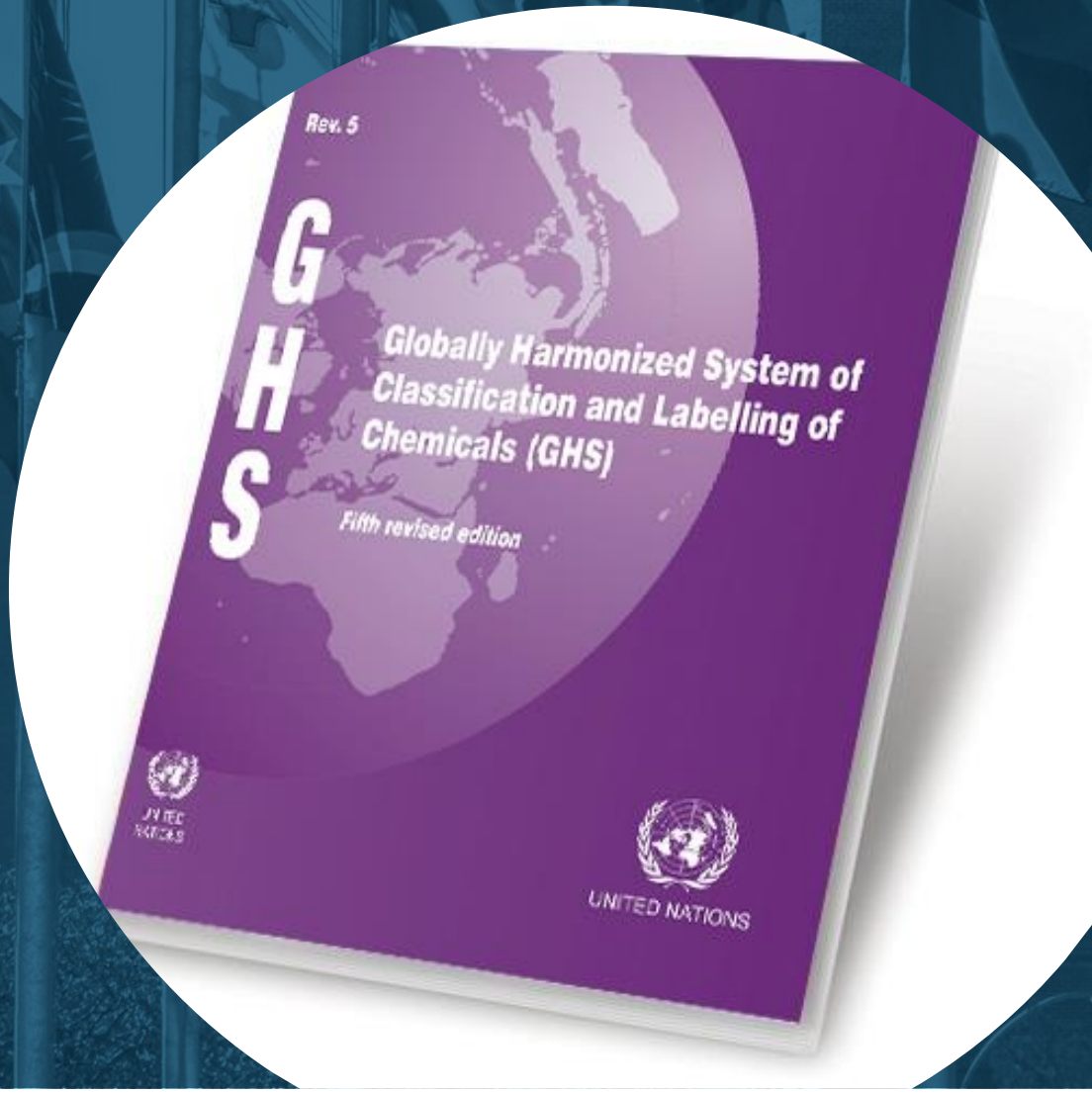
Katie McGee

Sr. Regulatory Data Analyst

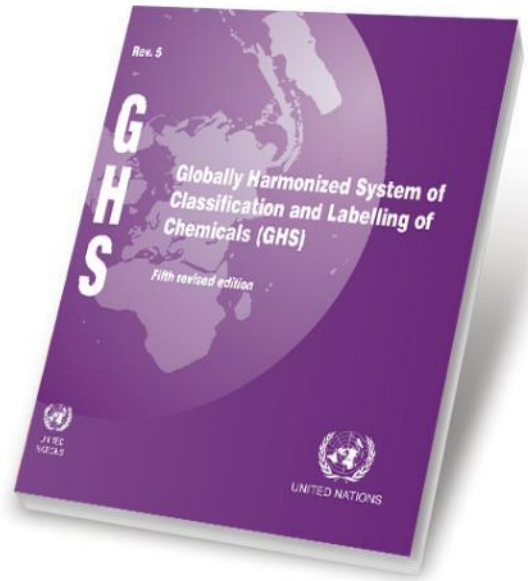
What are we talking about?

Classification Framework

Means of classification



Harmonization



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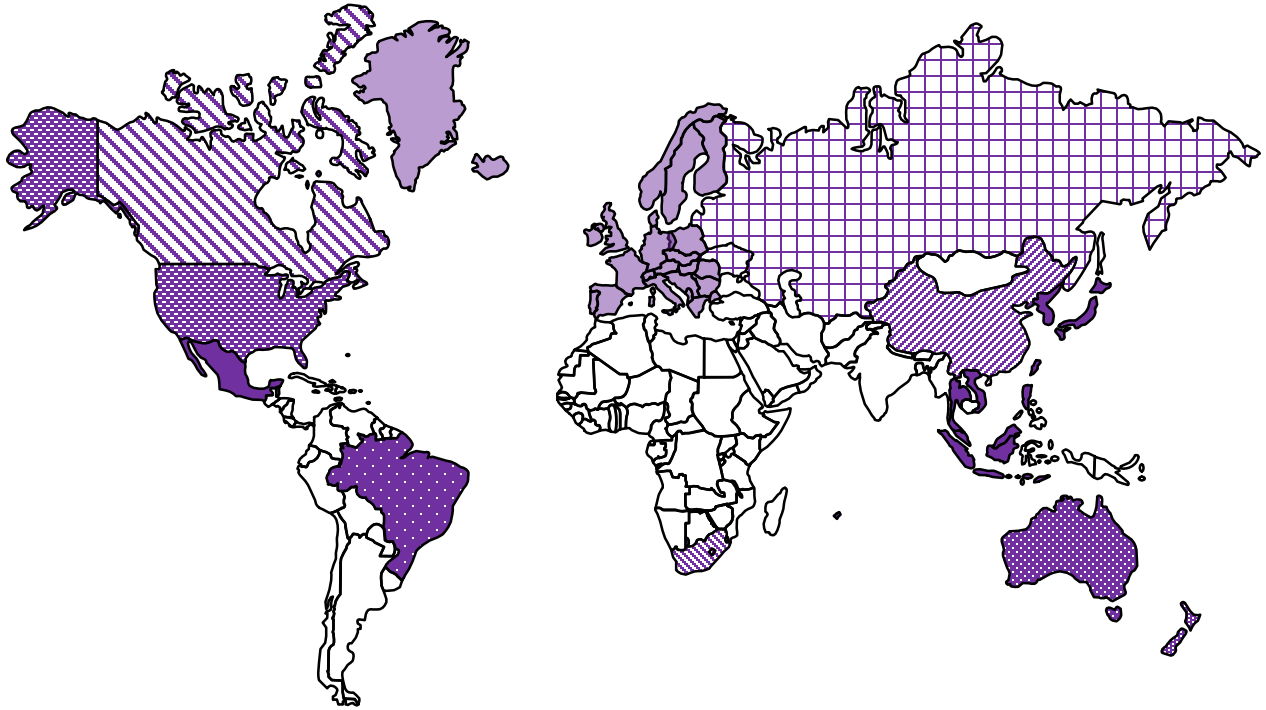
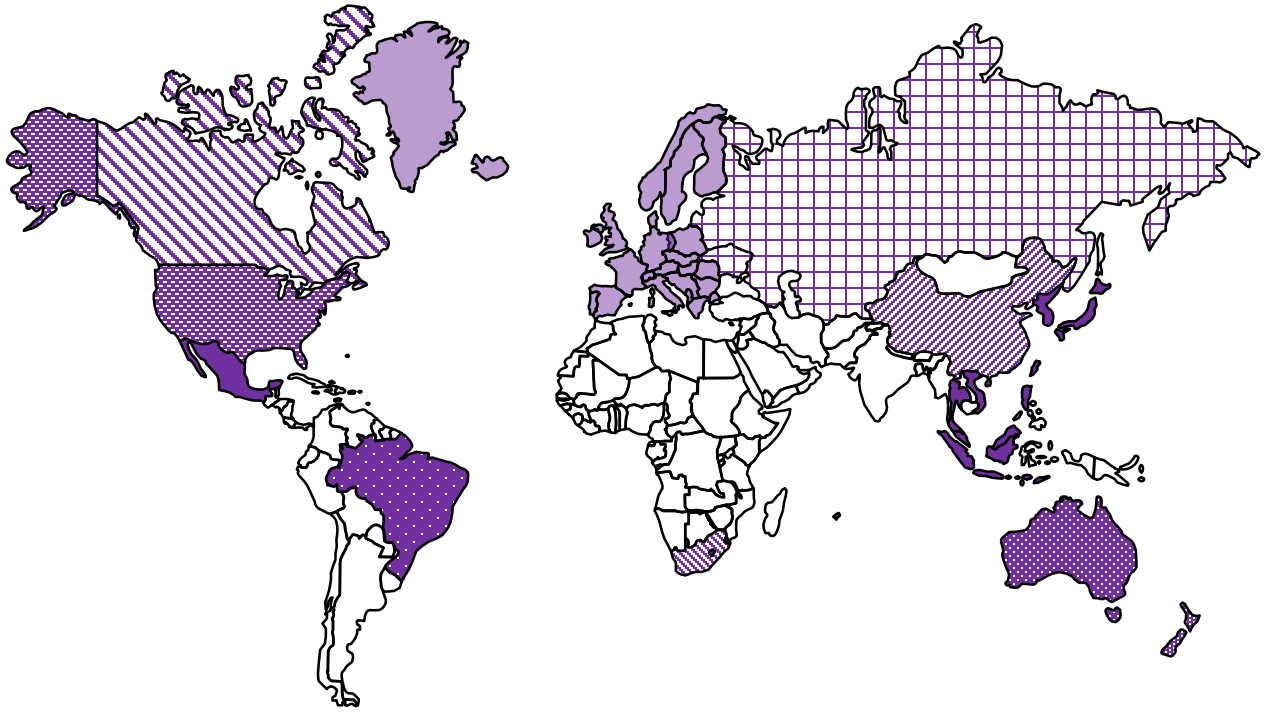
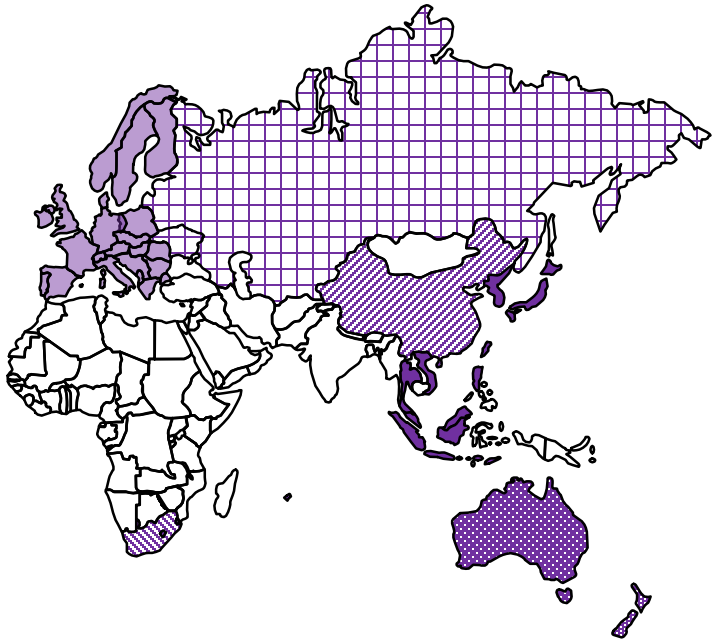


Substance classification



Using Substances for Mixture Classification



Poll Question

How are you determining classifications for chemicals of concern (authoring SDSs)?

For Example: Commercial Software, Home-grown system, Microsoft Office (Word, Excel, etc), Other

Types of Data

Types of Data

SUBSTANCE TEST DATA

MANDATORY CLASSIFICATION LIST DATA

ADVISORY AGENCY CLASSIFICATIONS, DATA & ASSESSMENTS

RAW MATERIAL DATA

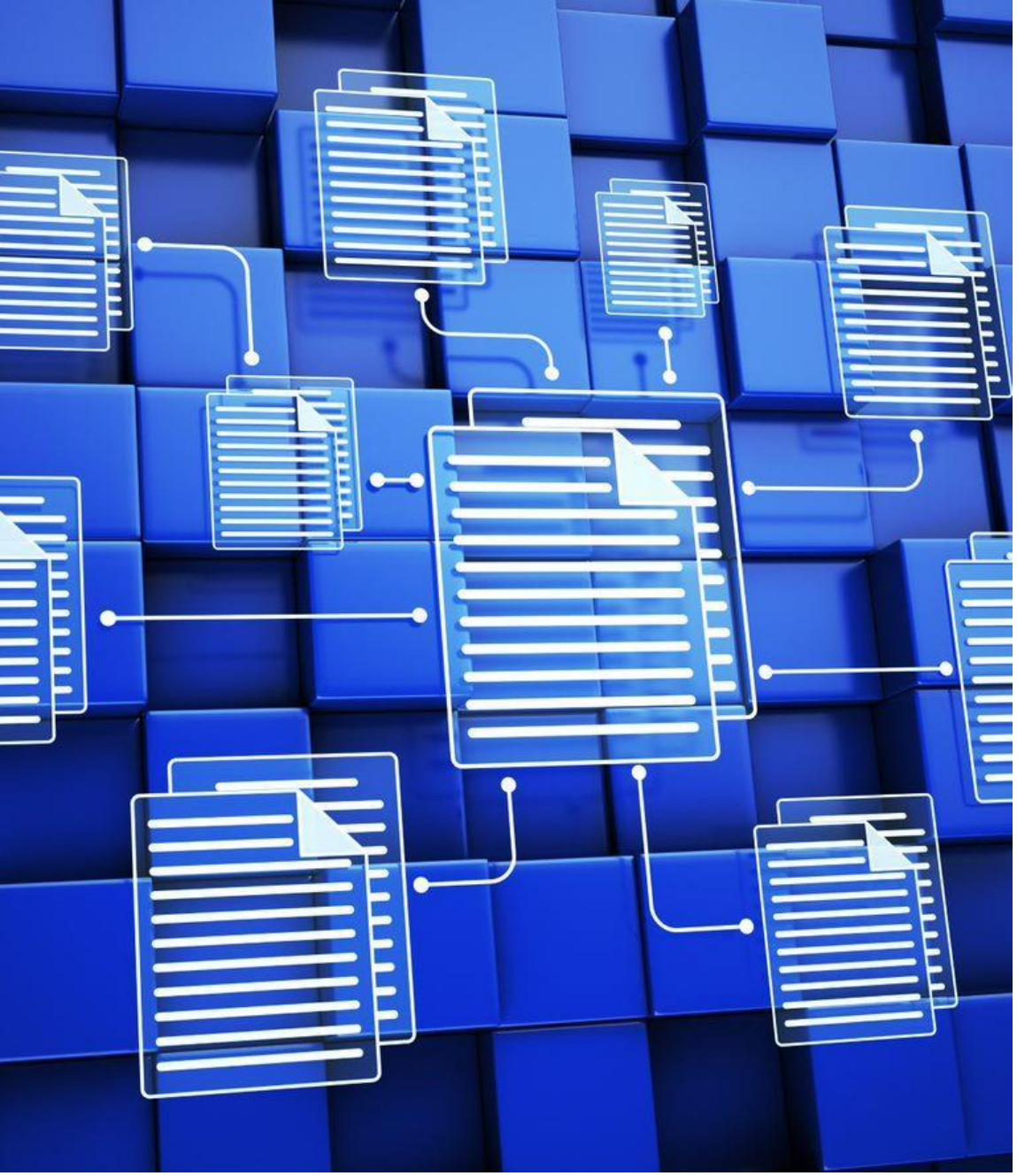
PRODUCT DATA

Substance Test Data

- Vast amounts of data
  - Published studies – health effects, physical properties, ecotoxicity, others
  - Alternative test methods
  - Predicted or modelling data
  - Epidemiological data
- Foundational

Overall Value : High

Sources	RTECS, ECHA Registration Dossiers, Scientific literature, eCHEM Portal, *and many, many others*

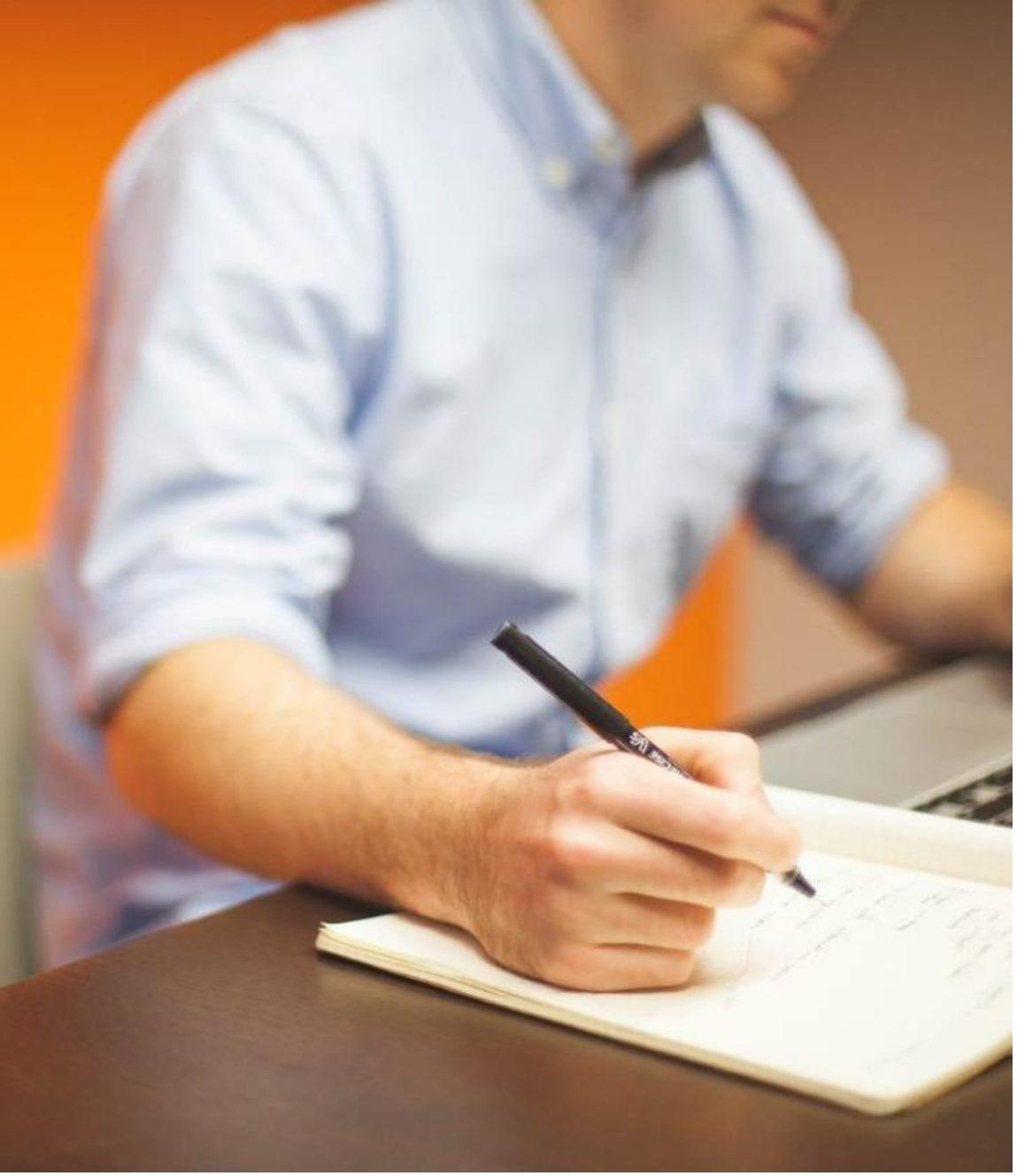


Mandatory Classification List Data

- ***Multiple*** lists to manage & understand
- Each country maintains their own list
- Lists can have rules around how to use them

Overall Value : High

Sources	EU CLP Annex VI, S. Korea GHS Classifications for Toxic Chemicals (NIER), China List of Hazardous chemicals, etc.



Advisory Agency Classifications, Data & Assessments

- Lists are compiled in different ways, affecting ***accuracy*** of the classification
- Includes lists issued by a country
- Includes lists issued by trade organizations or other industry groups

Overall Value: Medium

(Dependent on the Source)

Sources	ACGIH, IARC, Australia GHS Hazardous Chemical Information List, CSSNET, etc.

Raw Material

- Documents
  - Supplier SDSs
  - Tech Sheets
- Data
  - Ingredients – identity & concentration
  - Material Classifications
  - Ingredient Classifications
  - Test data (raw material)
  - Test data (ingredients)

Overall Value : ???

Sources	Manufacturers, Distributors, Suppliers, etc.

Product Data

- Test studies
  - $$$$$$?
  - Rare
  - But sometimes might make sense
- Knowledge of product in use
  - Adverse effect reports
  - Effects that don't apply

Overall Value : High *(if available)*

Sources	Company sponsored testing, Industry groups, Customers

Poll Question

What data type do you use the most in completing a classification?

A. Substance Data and/or List Classifications

B. Raw Material Data

C. Product Data

D. Combination of the above

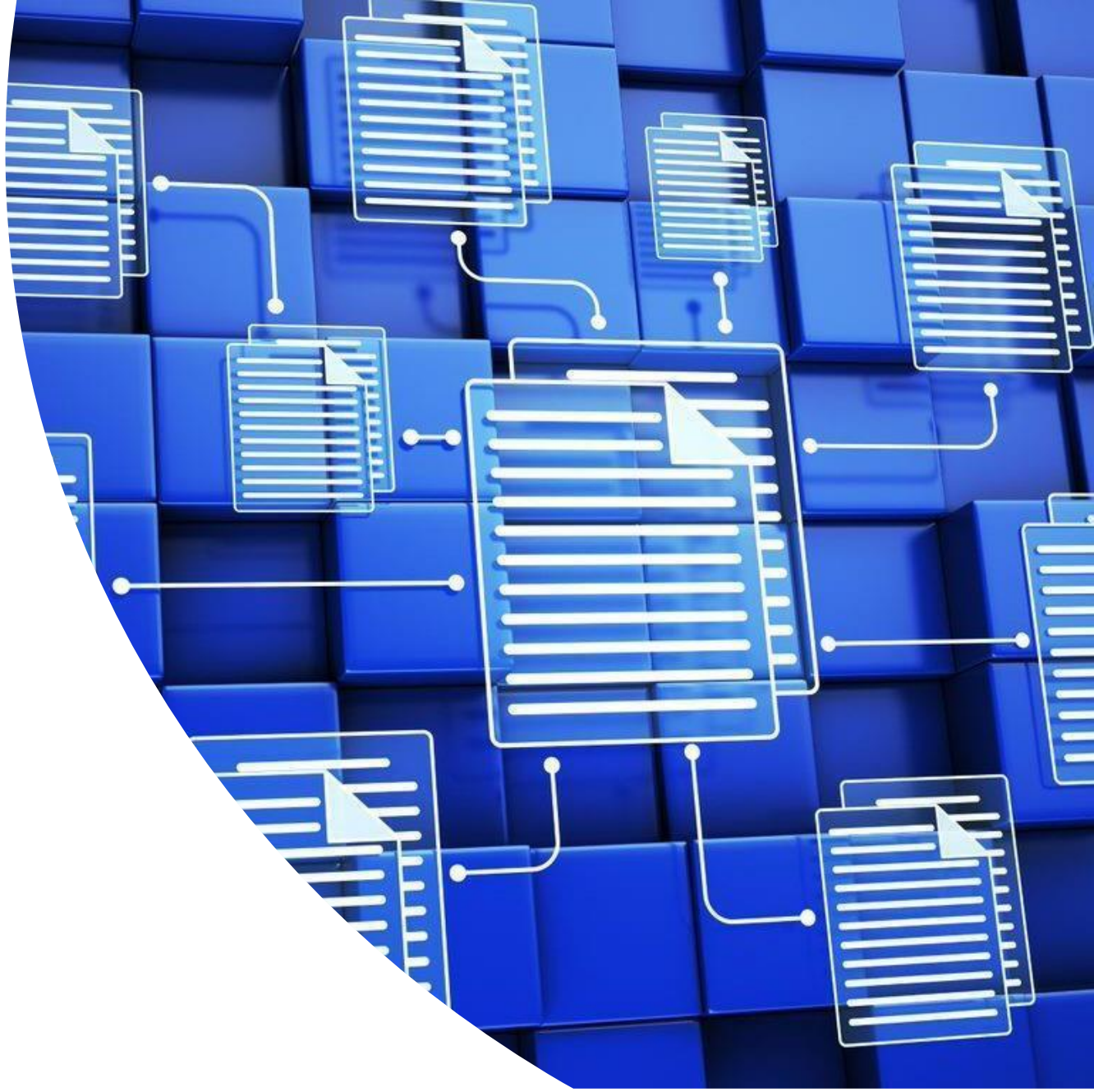
E. Not quite sure

Best Practices for Data Sources

Best Practices
Substance Test Data

- Quality and Reliability
  - Scientifically sound
  - Klimisch score
  - Test Method/protocol
  - Part of weight of evidence
- Is the test data unique?
- Applicability of the test result
  - Site of action
  - Route of exposure
  - Mechanism or mode of action

Best Practices
Mandatory Classification List Data

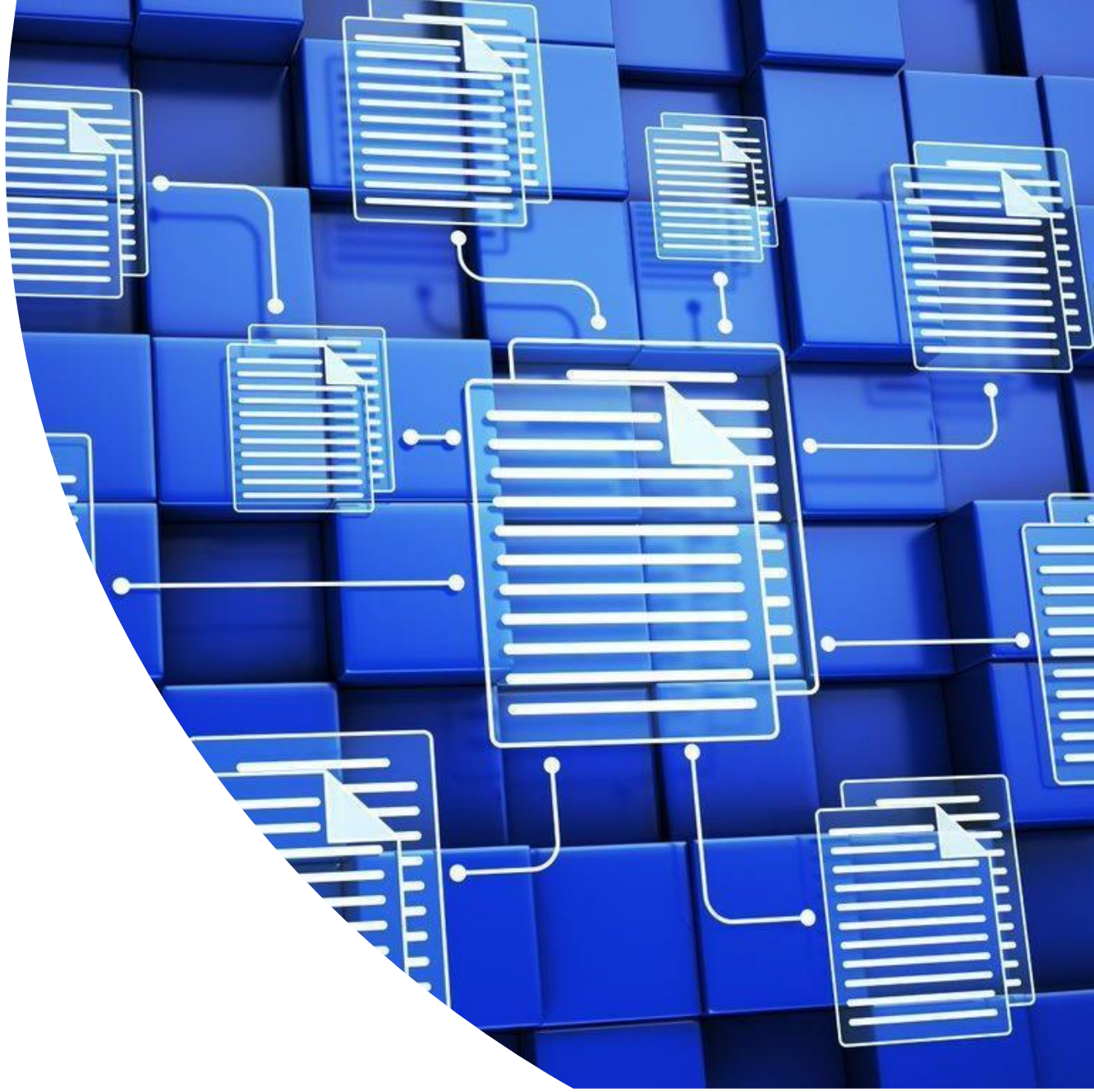


- Read the regulation in order to understand how the list should be used
- Is the list considered to be complete, or is it a starting point?
- Know which countries have mandatory lists

Best Practices
Mandatory Classification List Data

082-001-00-6	lead compounds with the exception of those specified elsewhere in this Annex	—	—	Repr. 1A Acute Tox. 4 * Acute Tox. 4 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H360Df H332 H302 H373 ** H400 H410	GHS08 GHS07 GHS09 Dgr	H360Df H332 H302 H373 ** H410		Repr. 2; H361f: C ≥ 2,5 % * STOT RE 2; H373: C ≥ 0,5 %	A1

Best Practices
Mandatory Classification List Data



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Best Practices
Advisory Agency Classifications, Data & Assessments

- For classification data, understand how the list was compiled
- Other lists may not give a direct classification, determine how you will use that data and what that data represents
- Determine your confidence level in the data

Best Practices

Advisory Agency Classifications, Data & Assessments

Approximate Equivalences Among Carcinogen Classification Schemes		
IARC	**GHS**	**NTP RoC**
Group 1	Category 1A	Known
Group 2A	Category 1B	Reasonably Anticipated (See Note 1)
Group 2B	Category 2	

Best Practices

Advisory Agency Classifications, Data & Assessments

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Best Practices
Raw Material Data

- Ingredient limitations
- SDS Quality (reverse engineer)
  - Section 2 & Sections 3, 9, 11, 12 & 14
  - Section 3 & Sections 11 & 12
  - And potentially other information
- Check SDS data against substance research & List classification data
- Relationships with suppliers

Best Practices
Product Data

- Potentially consider testing in some scenarios
  - *Ex: Physical Properties (flashpoint), irritation/corrosion*
- Other Product Data uses - "Bridging Principles"
- Make sure any Industry data is applicable

Best Practices for Evaluation Processes

Best Practices
Evaluation Processes

- ☑ Understand your Software
- ☑ Have a defined process
- ☑ Who classifies substances?
- ☑ Document, document, document!

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