


**Looking Over the
Horizon to 2012 and
Beyond – Data
Management**

Topic for Discussion

- Framing the Data Management Issue
 - Data Sources
 - Options Used to Manage Data
 - Issues for Consideration
 - The Future
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Our Known To Do List

- REACH Registration (3, 6, and 11-yr phase-in);
- ChAMP (2012 commitments under SPP);
- TSCA IUR Reporting Cycles
- Canadian Chemicals Management Plan;
- GHS (international deadlines/OSHA pending);
- SAICM (ICCM in 2009, 2012, 2015 and 2020);
- UNEP Commission on Sustainable Development (CSD) 2010-2011 Cycle on Chemicals
- New Consumer Product Safety Improvement Act (CPSIA) deadlines for phthalates and lead;
- Endocrine screening requirements;
- Global Products Strategy (GPS) requirements

Framing the Data Management Issue

- Scope of data needs and its management is **Global**
 - Domestic
 - Federal
 - State (e.g. CA Green Chemistry)
 - Municipal ?
 - Non-domestic (e.g. REACH)
 - Non-governmental
 - Retailers
- Data requirements may be different based on regulation but...
 - Basic principle is to
 “develop it once and use it many times”
 - First and foremost requirement you need to know
 “what is the chemical really”

Data Sources

- Company developed records
 - Product composition
 - Knowledge of process
 - Analysis
 - Laboratory results (e.g. phy-chem, toxicology data)
 - Cost basis for possible reimbursement situations
 - Production records
 - Sales history
- Supplier provided information
 - Composition of raw materials
 - Certification of compliance

Examples of Data Management and Use

- Company A
 - 2006 IUR HSE groups collected required information and maintained it in a Microsoft Access database

- Company B (decentralized operations; high degree of autonomy among Business Units)
 - Employed relatively simple databases such as Lotus Notes to collect and store data for IUR and other reporting requirements
 - Separately using IUCLID5 for synergy with REACH-IT
 - SAP for some EHS data and MSDS management

Examples of Data Management and Use (cont.)

- Company C (centralized systems and Product Safety group)
 - Developed an in-house SAP add-on to maintain “Bill of Materials” and “Bill of Substance” to generate regulatory compositions and automate compliance checks
 - Not used for 2006 IUR – data not verified at that time; used SAP manufacturing data - verified with manufacturing
 - Implementing Substance Volume Tracking and SAP REACH module to facilitate REACH compliance

- Company D (formulator)
 - 2006 IUR - Used SAP manufacturing and commercial import data
 - Verified with select internal compliance teams
 - Internal formulation database used for constituents of imported finished products
 - 2011 IUR using a sharing automated process for volume tracking, implemented for REACH, along with formulation database

Issues for Consideration

- Data quality
 - Trusted source (garbage in; garbage out)
 - Traceable; referenced
 - Appropriate methods used to generate data
 - Comprehensive – provides what you need in form you need it
- Data ownership
 - External
 - Right to refer vs. Right to own
 - Especially important for high value studies
 - Internal
 - Reliance on another organization's data to meet your needs
- Data storage, retrieval and retention important
 - IT systems change
 - Subject matter experts transfer or retire – maintain proper documentation
 - Your company has a records management policy
- Means for maintaining data
 - Change of suppliers, multiple suppliers – is it really the same?

Opinions about the Future

- In the future we will need mechanisms to understand the complete material balance of chemicals throughout the value chain
- Impurity profiles will be more important
- For enterprises handling more than a few materials an IT solution is **critical** and will become more so
- Exposure and use data will become as **critical** as hazard information
- CBI status will be harder to claim and maintain
- It isn't going to get any easier