



DATE

Open Solution to Reporting and Effectively Using TSCA Information

Industry Experience with REACH

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_experience the commitment™

Discussion Topics

- Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
- Reach IT
- Lessons Learned
- Managed Toxic Substances Phase II

REACH

- Streamlines legislative framework on chemicals within European Union
 - Unifies requirements for “existing” and “new” chemicals into 1 system
 - Gives European Chemicals Agency (ECHA) authority to restrict or ban the use of substances of very high concern
 - Premise – Industry understands best how chemicals are used
 - Industry required to document that chemicals can be used safely
- Mandates electronic submission of Registrations & Notifications

REACH

Registration

- Manufacturer or importer assesses hazards & if required exposures
- Assessments documented in CSR

Evaluation

- ECHA and CA's of MS's evaluate testing proposals, dossiers and substances

Safe use of chemicals

Tools

- Communication of information in the supply chain via SDS
- SDS information consistent with CSR, attach Exposure Scenario Summary

Substance Information

- REACH-IT central database
- Updated as necessary

Public

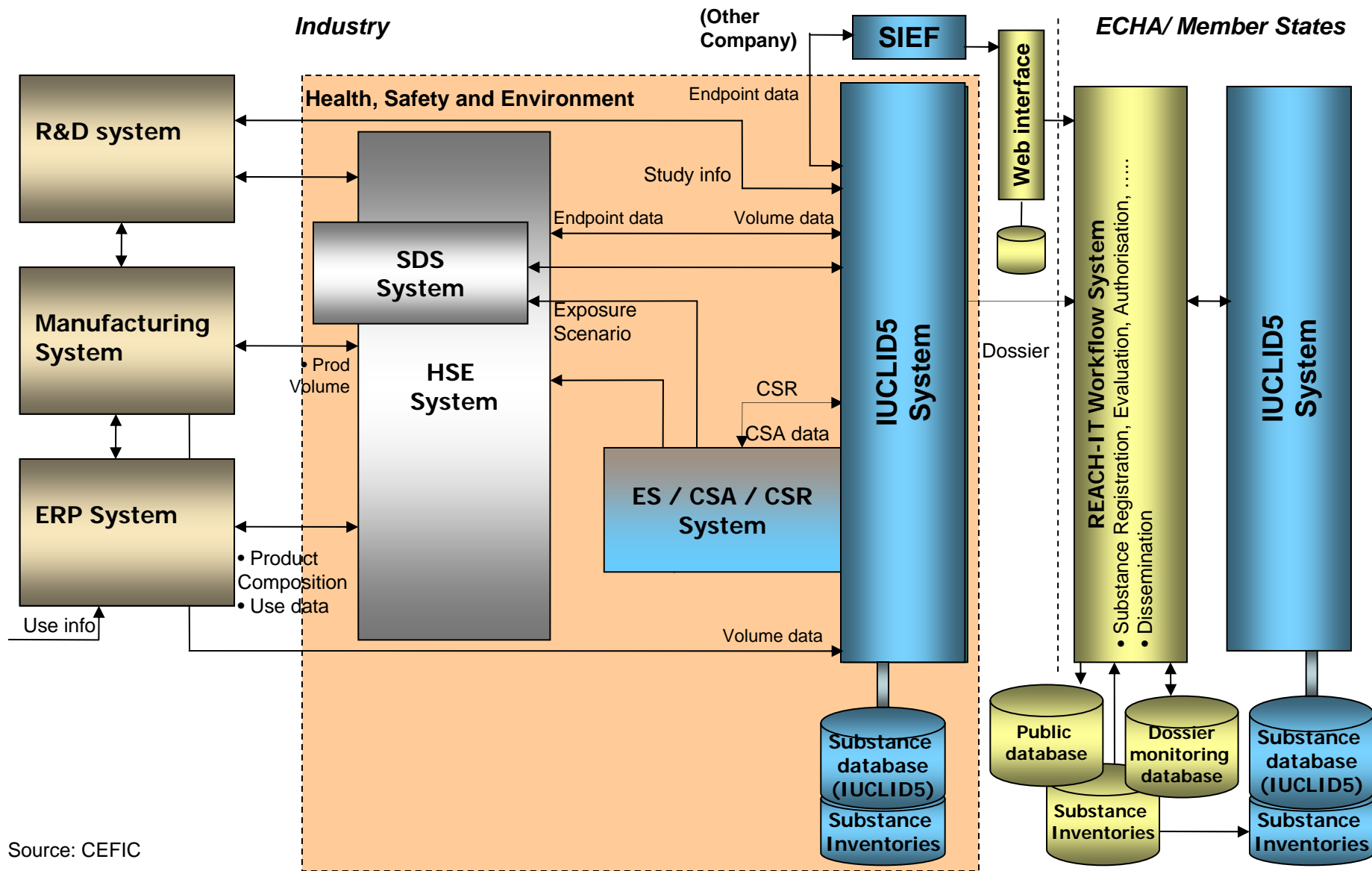
Authorization

- Manufacturer/importer, downstream user applies for authorization for SVHC
- Agency prepares the authorization decision
- Commission makes the decision
- Objective to substitute SVHC

Safety Net: Restrictions & Bans

CSR = Chemical Safety Report; CA = Competent Authority; MS = Member State; SVHC = Substance of Very High Concern; SDS = Safety Data Sheet; RMM = Risk Management Measures

Example Industry IT for REACH





Lessons Learned – Regulatory Process

- Guidance not developed prior to entry into force
- A more narrow scope of impacted Substances in Phase 1 would allow for leveraging of learning's in subsequent phases
- Level of “start up issues” for Substance Information Exchange Forums (SIEF) was underestimated
- Implementing GHS into the CLP Regulation at the same time as REACH created a more significant burden than originally anticipated

Lessons Learned - REACH-IT

IUCLID5

- Implementation of the OECD Harmonized Templates for study results provides common utility to share data
- Well documented XML schema enables:
 - Sharing of information across industry and increases consistency of information in joint submissions
 - Electronic submission of registrations/notifications to ECHA
- Electronic submissions enable sophisticated validation/completeness checking and increases submission quality
- Technology supports easy deployment



Lessons Learned - REACH-IT

IUCLID5

- Timing of updates
 - Latest version released in February 2010 caused manual data entry on substances already registered and for substances “in-progress”
 - Plug-in to integrate exposure based Chemical Safety Assessment data into IUCLID5 is not completed
 - CSR generation tool can not generate Exposure Assessment and Risk Characterization chapters of the Chemical Safety Report
- Lack of tools to support the communication of consistent substance registration data to Safety Data Sheet systems

Managed Toxic Substances Phase II

- New OPPT architecture that:
 - Leverages Central Data Exchange, Substance Registry System, Facility Registration System
 - Accepts electronic submissions
 - Stores all data in central, harmonized database
 - Facilitates OPPT internal business processes/workflow
 - Supports quick, efficient publication of information to public