Getting Ready for REACH
Advanced Solutions for Compliance

John Phyper, CSO & EVP
Atrion International Inc.
# Getting Ready for REACH – Advanced Solutions for Compliance

<table>
<thead>
<tr>
<th>Introduction – What is REACH?</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Does REACH Mean to the Industry?</td>
</tr>
<tr>
<td>REACH Supply Chain Implications</td>
</tr>
<tr>
<td>REACH Stakeholders</td>
</tr>
<tr>
<td>Requirements of REACH</td>
</tr>
<tr>
<td>REACH-IT</td>
</tr>
<tr>
<td>Atrion’s REACH Solution</td>
</tr>
<tr>
<td>Getting Ready for REACH</td>
</tr>
</tbody>
</table>
Y2K8 for the EH&S World

What is REACH?

R  Registration (notification process)
E  Evaluation (risk screening process)
A  Authorization (use-restrictions process)
CH Chemicals

• Shift from Registration for “New” substances to “Existing” substances.

• Promulgation forecasted between April and June 2007
Aims & Objectives of REACH

- To ensure protection of human health & the environment.
- To ensure sufficient toxicological data is present for high volume chemicals.
- To move the “burden of proof” for safe use of chemicals from Authorities to Industry.
- To stimulate innovation.
- To “level the playing field” with companies importing substances into the EU.
What does REACH mean to Industry?

- The proposed reform has created a need for a scaleable, affordable, and highly usable solution that bridges the gap between the output of a company’s current processes/systems and the deliverables required by REACH.

- **Cost to Industry** – EU Commission estimates it will cost industry between €2.8bn to €5.2bn over 11 years. Testing costs alone are estimated at €2.6bn.

- **Elimination of SME** – Fine and Specialty Chemical sector, predominately composed of SME, will carry a significant burden of the costs.
What does REACH mean to Industry?
What needs to be Registered?

- All imported and manufactured chemicals in the EU (monomers, raw materials, intermediates, products, EINECS substances.)*
- **Intermediates**
  - Non-isolated, On-site isolated, Transported
  - But very limited data requirements
- “USE” is registered along with hazards.

Note- * Still requirements imposed on other materials – e.g. Articles, Polymers, etc., but reduced pending series of rules
What does REACH mean to Industry Register- by whom?

• Importer or manufacturer
  – In effect the primary EU suppliers
• But “user” may register if needed
• Can only be done via an EU resident legal entity
• Overseas companies must use an “Only representative”
• All importers/manufacturers of each substance form a single consortium.
• Estimated 30,000 substances need registration
REACH Supply Chain Implications

- Companies can only purchase substances from a registered supplier.
- Many suppliers may not support low margin products (raw materials) therefore supply chain disruption or cessation.
- Need to confirm that all substances in formulations are registered, (especially imported).
- New need for full disclosure of supplied formulations.
REACH Supply Chain Implications

• Just as you must check with your suppliers that substances (raw materials) will be supported through REACH, your customers will be doing the same with you; for every substance in every formulation.

• Anticipate a raft of questionnaires or queries from both sides of the supply chain.

• **Requirement on Downstream User to notify Upstream suppliers if approved “Use” not covered by SDS.** Supplier then needs to make decision if they will include this use or not.. which triggers additional government submission, etc.. This requirements for some product lines may be ongoing and could impact competitiveness.
REACH Supply Chain Implications

Articles (including Packaging):

- **Registration**: If substance is present in an Article produced/imported in quantity totally >1 tonne/year, substance is intended to be released under normal or foreseeable conditions of Use, AND use is not already Registered – must notify Agency.

- **CSR**: Chemical Safety Report need not consider risk to human health if the end use is Cosmetic or materials intended to come into contact with Food.
Articles (including Packaging):

- **Notification**: If SVHC substance in the Article and >0.1% (w/w) all recipients in the Supply Chain must, as a minimum, advise users of the name of the substance.
Aim/Objectives: Government & Industry collaborating together to determine the best ways to enable compliance with this stringent regulatory framework.
Requirements of REACH

1) **Submission of Pre-Registration Data (minor amount of data) to ECA.** If REACH comes into effect April 2007, pre-registration will be required 18 months later. *Except for new products will require pre-registration immediately.*

2) **Submission of a CSR (Chemical Safety Report) for 10 tonnes of dangerous materials.** The provision of a CSR will occur at the same time as the full registration dossier.

3) **Generation of Extended SDS** which employs Globally Harmonized System of Classification and Labeling (GHS*) & Exposure Scenario’s (ES) & Risk Mgmt Measures (RMM) of Chemicals will be phased in over the 3-11 year period. The actual GHS timing in EU is uncertain, but expected by the first wave of registrations (i.e. 2010).

*Note – Global companies also need to ensure that they are addressing GHS requirements as per country legislation – e.g Japan – as it may be different then the Purple Book.*
4) **Submission of Dossiers**

The timetable for implementing REACH will give industry several years to provide safety data prioritized by both chemical properties and tonnage produced:

<table>
<thead>
<tr>
<th>Date</th>
<th>Type of Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td><em>Carcinogenic, mutagenic or reproductive toxins</em></td>
</tr>
<tr>
<td>2010</td>
<td><em>Produced in quantities above 1000 tonnes</em></td>
</tr>
<tr>
<td>2013</td>
<td><em>Produced in quantities 100-1000 tonnes</em></td>
</tr>
<tr>
<td>2018</td>
<td><em>Produced in quantities 1-100 tonnes</em></td>
</tr>
</tbody>
</table>
## Time Line & Deliverables for REACH

<table>
<thead>
<tr>
<th>Timeline</th>
<th>REACH Action Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>• Conduct IT Gap Analysis&lt;br&gt;• Conduct Pilot Risk Assessments&lt;br&gt;• Review SDS System&lt;br&gt;• Identify Consortium</td>
</tr>
<tr>
<td>2007</td>
<td>• Form Consortiums&lt;br&gt;• Compile Pre-Registration Data&lt;br&gt;• Initiate Risk Assessments&lt;br&gt;• Generate GHS Classification&lt;br&gt;• Assess Impact on the Supply Chain</td>
</tr>
<tr>
<td>2008-2009</td>
<td>• Generate CSR - Chemical Safety Reports&lt;br&gt;• Prepare Registration Dossiers</td>
</tr>
<tr>
<td>2010</td>
<td>• Initiate Registration Dossiers with ECA</td>
</tr>
</tbody>
</table>

## REACH Action Plan Timeline

Are you aware of the impact that REACH legislation will have on your business?

REACH may even resemble “Y2K” or “Y2K8” in the chemical industry for companies who have not adequately prepared.

Since preparing for REACH is a major undertaking, you will need an action plan, and having the right partners, like Atrion, can help.
IUCLID 5 & REACH IT Interfaces

• Currently, EU Commission is planning on having Companies submit Pre Registration data via a new REACH IT system and endpoints for Dossier and information for CSR to a local version of IUCLID 5.

• The local version of IUCLID 5 will allow you to store “your” information, including company specific notes that will not be transferred to the Commission. You will not be allowed access to other companies’ data.

Note - Local Version of IUCLID 5 will also allow you to exchange files with Other Companies as per Substance Information Exchange Fora (SIEF) requirements.
Christel Musset

European Commission, DG JRC
Institute for Health and Consumer Protection (IHCP)
European Chemicals Bureau (ECB)

Workshop on REACH-IT architecture for industry
21 September 2006
RIP2: 2 Main Systems

IUCLID 5 is

• In Industry:
  • The tool for capturing data on chemicals, preparing and submitting dossiers

• In the Agency & in the Member states competent authorities:
  • The central data repository for all dossiers submitted
  • The basis for dossier compliance check and substance evaluation
  • The basis for priority setting, data mining,…

• Accessed centrally by the Agency & the Member states competent authorities personnel
RIP2: 2 Main Systems

REACH-IT is the:

- Central IT system of the future European Chemicals Agency that will support the implementation of the REACH legislation. It includes:
  - A web portal for submission and consultation of information by industry
  - A workflow system for full control of all tasks triggered by REACH
  - Central database of all information necessary to manage the system (REACH-IT database): identification and status of dossiers, decisions etc.
  - A dissemination system for publishing non-confidential data on the Agency website
  - Integration mechanisms with other Agency systems, in particular IUCLID 5, but also payment, reporting systems, e-mails…
REACH IT (CEFIC) – Reference point for Atrion’s Solution

IT systems to support Industry for REACH - 'Work Process picture'

Product Development
- Substance info
- Study / test data

Manufacturing
- Production Volumes

Supply Chain Mgt.
- Trade Products Inventory
- Product Composition

Health, Safety and Environment
- Product Safety
- Maintain Safety Data Sheet
- Product R&D Support
- Product to Market
- Supply Chain Support
- Product Change Mgt.
- Regulatory Monitoring
- Industrial Hygiene
- Occupational Health
- Environmental Care
- Risk Management
- ES / CSA / CSR

Maintain Substance Chemical Information
- Assure Compliance with Legislation

REACH Substance Administration
- Substance Registration, Evaluation, Authorisation, ...

Industry

Agency / MS
• Need to ensure **same data** is used for different purposes, e.g. output of Risk Assessment used for CSR and SDS.

• May need to **leverage data from consortium** (e.g. toxicity data) in Risk Assessments and SDS hence bi-directional flow of information to IUCLID 5.

• Level of work will be greatly influence by # reportable substances x ES/substance – influence decision to do it **manually versus automate**.

• Finally, will need to ensure tightness on rules for **Master/Slave data**.
Integrated, Automated & Auditable

Atrion’s proposed solution for REACH will enable Reporting Companies to:

• Seamlessly **exchange data** between tools for Safety Data Sheets (SDS), Chemicals Safety Reports (CSR) and Risk Assessment Tools.

• **Integrate** easily with Government systems and an organization’s existing ERP

• **Automate** the generation of REACH documents (SDS, CSR) leveraging Atrion’s content

• **Produce Audit** reports for regulatory classifications
Atrion’s REACH Solution

Current IT Infrastructure
- EH&S Management System
- ERP/Materials Management System

Consulting Services

Atrion’s REACH Solution
- Authoring System for SDS, labels, CSR and Authoring Data
- Risk Tools (Environment, Workplace, Consumer) and Risk Content
- Document Manager
- Optimization Tools

REACH-IT Interfaces

Government Database
Atrion will offer a full range of **Consulting Services** that play a key role in supporting our REACH Solution

- Gap Analysis (Regulatory, Business & IT)
- Preparation Work
- Implementation & Training on SDS Systems
- Conducting Risk Assessments
- Generation of new SDS
- Generation & Submission of Pre-Registration data, Chemical Safety Report
Atrion’s Intelligent Authoring® System’s next release will include:

- GHS classification
- Identified usages
- Additional data entry fields
- Form fields and formats to address extended SDS requirements of REACH.
- Redefinition of substances to match IUCLID 5 fields.
- Ability for users to store output of a Risk Assessment pertinent to an SDS (ES/RMM).
KEY ISSUES
• Use of GHS classification will not be universal, e.g., Japan, therefore SDS must address local requirements.
• ES/RMM in SDS may be a nightmare … 25 ES/product may result in a 25 page SDS… In some cases will need to create customers specific SDS. Hence flexibility is key.
• Flexibility…. TGD are not finalized (and even when done may not address business requirements) - hence system must be flexible
Risk Tools/Risk Content

- Atrion will be integrating 3 “basic” Risk Tools: Environment, Workplace, Consumer and potentially 2 advanced tools to address complex needs.

Risk Content:
- Rules to determine critical substances, generate components of CSR
- Integration of Risk Management Measures (RMM) values
- Multilingual, sector or company-specific phrases for Exposure Scenarios & RMM
- Chemical-specific and generic data to initiate Risk assessment tools
Document Manager is a web-based interface database.

**Key Features:**
- Make all hazards communication documents available via an intuitive web-based interface.
- Ability to define privileges for each type of user & restrict access to documents & languages permitted to view/print.
- Multilingual Interface (6 languages)
- In future, can store Chemical Safety Report (CSR) and key sections of substance dossier.
Optimization Tools

The **Optimization Tool** will give users a way to conduct “What if Scenarios” related to their business activities.

**Example:**
If a chemical substitution results in a new authorization requirement...

**How will my business be affected?**
REACH Portal

Atrion’s REACH Solution

Consulting Services

Authoring System for SDS, labels, CSR and Authoring Data

Risk Tools (Environment, Workplace, Consumer) and Risk Content

Document Manager

Optimization Tools

ATRION PORTAL

REACH-IT Interfaces

Product Registration Module

Allow export of data from Atrion Solution

IUCLID 5 (bidirectional)
Dossier/CSR

new REACH IT (unidirectional)
Pre-Registration and C&L
Atrion’s Portal will allow a smooth transfer of information between systems. **Atrion’s customer specific portal** will provide a secure mechanism to update Exposure Scenarios.

- Input of New Use by Customer
- Recalculate RMM using Risk Tools
- Regenerate SDS & CSR
- Validate SDS & CSR
- Resubmit the revised CSR to the government agency.
Atrion’s REACH Solution

Current IT Infrastructure

- EH&S Management System
- ERP/Materials Management System

Consulting Services

Atrion’s REACH Solution

- Authoring System for SDS, labels, CSR and Authoring Data
- Risk Tools (Environment, Workplace, Consumer) and Risk Content
- Document Manager
- Optimization Tools

REACH-IT Interfaces

Government Database
Preparing for REACH is a major undertaking, Atrion suggests performing the activities listed below;


2. Conduct a Product Portfolio Assessment.

3. Create a REACH Project Plan that addresses regulatory, business & IT issues.

Atrion’s Consulting Services Department can help you prepare for these activities.
Conclusion

How can Atrion help you?

- We will assist organizations in becoming “REACH-Ready” by providing solutions that are integrated, automated and auditable.

- With Atrion, you have access to a regulatory partner actively involved in REACH.
Questions? Thank you.

For more information:
Please visit [www.atrionintl.com](http://www.atrionintl.com)
and [www.reachlegislation.com](http://www.reachlegislation.com)