REACH Implementation: An Approach for Industry

REACH entered into force 1 June 2007, and EU Parliament's President, Mr. Josep Borrel has called REACH "one of the most complex texts in the history of the EU." Industry's deadlines for submitting information extend over 11 years; however, near-term effort is needed to apply the internal resources and information exchange required to effectively meet the requirements.

A systematic approach to meeting REACH requirements & applying available resources:

1. **Inventory substances, including contained in preparations & in articles**:
   - Identify substances in products and articles by reviewing safety data sheets (SDS), risk management plans, health and safety plans, spill control plans, permits, & other sources.
   - Identify substances & groups of substances to be registered together (RIP 3.10 substance guidance).
   - Use the European Chemical Substances Information System (ESIS) to identify: notified substances that are considered already registered for REACH by finding them in the European List of New Chemical Substances (ELINCS); "phase-in" substances listed in the EINECS (European Inventory of Existing Commercial chemical Substances); or in the database of NLP (No-Longer Polymers).
   - Classify substances for REACH requirements, as: a substance that occurs in nature; a preparation; a monomer residual in polymer; a transported isolated intermediate; in product and process oriented research and development (PPORD); in scientific research & development.
2. **Exclude chemicals that are outside the scope of REACH or exempt**
   (Article 2 & distributed throughout REACH Articles; also see Annex IV & V for registration exemptions).
   - Document the basis for each exemption, & any scheduled exemption reconsideration dates.
3. **Identify the supply chain for each substance, preparation, & article**:
   - Identify company's role under REACH (e.g., manufacturer, importer, downstream user).
   - Document suppliers for each substance and each article, which is intended to release a substance.
   - Determine if the supplier is within the EU or non-EU, and if the material might be discontinued.
   - Determine all on-site and known downstream users identified uses for each substance & for each preparation or article containing the substance.
4. **Establish internal co-operation & communication**:
   - REACH will impact many departments: marketing; sales; purchasing; customer service; health & safety; environmental; production; research & development; legal counsel; & regulatory affairs.
   - Management commitment & a single REACH coordinator will simplify efforts.
   - Coordinate pre-registration, registration, & notifications submitted by each legal entity in company.
5. **Assemble & exchange chemical information**:
   - Use the ESIS to identify known information about substances, including from the Classification and Labelling (C&L) database that includes risk and safety phrases, and IUCLID Chemical Data Sheets.
   - Document internal environmental and safety & health procedures, safety data sheets, & environmental management system information known for each substance.
   - Clearly identify company proprietary, confidential, or sensitive data, and define the terms of use.
   - Identify other interested parties by using the ESIS to access EU Producers/Importers lists in databases of HPVCs (High Production Volume Chemicals) & LPVCs (Low Production Volume Chemicals).

[**Maintain this information as products and formulations change**.]

Internal resources needed to meet REACH requirements:

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- Support and commitment from management
- REACH Coordinator assigned to be responsible to direct and coordinate all activities.
- Cooperation between departments holding the needed information (research & development, purchasing, production, IT, marketing & sales, environment, and health & safety).
- Cooperation between all EU-based legal entities is required since each entity must make separate notifications, pre-registrations, and registrations under REACH.

External resources available to assist in meeting REACH requirements:

- Information sharing and on-going dialogue with suppliers & DU companies to identify common issues.
- Substance Information Exchange Forums (SIEFs) may provide valuable information, especially on high production volume chemicals.
- Trade associations may offer basic agreements on effective risk management measures and standardized phases for use throughout an industry, between industry sectors using the same chemical, and between countries.
- For non-EU enterprises, identify an "only representative" or importer based in the EU to register substances. An only representative may allow the manufacturer to avoid disclosing sensitive information to an importer, and the importer is then considered a downstream user.

Role of Actor in Supply Chain	**Type of Information Required from Industry**
Manufacturer or importer – submit data to ECHA	❑ Dossier: identify substance & its intrinsic properties ❑ Chemical safety assessment (CSA) & safety report (CSR) -- exposure scenarios
Distributor or **Re-importer** – pass information on	❑ Safety Data Sheet (SDS) in Member State's language ❑ Extended SDS (ESDS) -- include exposure scenarios for substance>10 tonnes/year
Downstream user – receive information	❑ SDS or ESDS ❑ Registration, authorisation, restrictions, & info. on risk mgmt. -- with first delivery of registered substances after EIF
Consumer – receive information	❑ Instructions on safe uses of article & proper disposal, including within 45 days of request

References:

- Final REACH Legislation as Published in the Official Journal of the European Union (850 pages) http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2006:396:SOM:EN:HTML
- REACH in Brief (February 2007) – an excellent overview of REACH requirements http://ecb.jrc.it/documents/REACH/REACH_in_brief_0207.pdf
- Guidance for Identification and Naming Substances (RIP 3.10) (June 2007) http://ecb.jrc.it/documents/REACH/RIP_FINAL_REPORTS/RIP_3.10_SUBSTANCE_IDENTITY/substance_id_en.pdf
- European Chemical Substances Information System (ESIS) http://ecb.jrc.it/esis/

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