REACH Fact Sheet

REACH is a new European Union regulatory framework for chemicals management. Under REACH (Registration, Evaluation and Authorization of Chemicals), manufacturers and importers of chemicals will be required to submit hazard, use, exposure and risk data for identified uses of substances manufactured or imported in quantities of more than one metric tonne per year.

REACH Philosophy
- Industry assesses, communicates, and manages risk. REACH registration is required for EU market access.
- Manufacturers and importers of substances collect information on substance properties, product applications and exposure to users and the environment and assess and communicate risk management measures within the supply chain.
- Downstream users, e.g., customers, inform suppliers about use and use conditions.
- Substance registration provides evidence to authorities that the supply chain applies the process.
- Specific hazardous chemicals are regulated separately.

Substances
Phase-in substances will be registered by use by each manufacturer or importer legal entity. Products may include multiple substances, and those substances are registered individually and can include multiple uses. Phase-in substances must meet at least one of these criteria:
- Listed in EINECS (European Inventory of Existing Commercial Chemical Substances).
- Having been manufactured in one of the current EU Member states at least once within 15 years before the entry into force of REACH but not placed on the market, e.g., intermediates, R&D substances.
- “No-Longer Polymers” – substances no longer considered polymers exempted from original EINECS reporting rules. New substances notified under the current regulatory requirements (not currently in EINECS), plant protection products and biocidal active substances are considered registered and will be transferred into the new system. Non-phase-in substances will need immediate registration prior to being imported or manufactured after June 2008.

Timing
- REACH entry into force and registration timelines began on June 1, 2007.
- European Chemical Agency (ECHA, the agency created to oversee REACH) must be operational by June 1, 2008.
- Pre-registration of phase-in substances:
  - Within 18 months of entry into force.
  - Submission time window: June 1, 2008 through December 1, 2008.
- Registration deadlines of phase-in substances (must have been pre-registered):
  - VOL 1000 tonnes/yr., CMRs 1 & 2 and R50/53: 100 tonnes/yr. + 3.5 years (by Nov. 30, 2010)
  - VOL 100 tonnes/yr. + 6 years (by May 31, 2013)
  - VOL 1 tonne/yr. + 11 years (by May 31, 2018)

Pre-Registration / Substance Information Exchange Forum (SIEF)
- In pre-registration, manufacturers and importers make known their identity, address and contact person, substance identity, e.g., EINECS number, CAS name and number, and tonnage, which impacts registration date. Downstream use is not included in pre-registration.
- Pre-registrants of the same phase-in substance are brought together in a virtual forum (SIEF), in order to exchange test data against compensation (obligatory data sharing), and determine together additional testing needs, if any.
- Obligatory data sharing aims to avoid duplication of animal testing.
- Substances that are pre-registered may be manufactured, imported and used after REACH has come into force and must be registered according to the phase-in schedule above.

1. CMR 1 & 2: substances classified as carcinogen, mutagen, or reprotoxic category 1 or 2.
2. R50/53: substances very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment.
3. Dow has committed to complete registration by 2015 under Dow's 2015 Sustainability Goals.
Registration

- Registrants collect, submit substance hazard, use and risk information to the Agency (dossier), which includes registrant identity, substance identity, volume data; substance hazard data; testing proposal for generation of additional data, if applicable; uses of the substance; a chemical safety assessment/report (which can include hazard, exposure and risk assessment) for substances of 10 tonnes or more; classification and labeling information; and information about safe handling and use.
- Costs associated with registration include those for substance data generation and/or purchase from SIEF members, dossier generation, and registration fees.
- Downstream users may register specific uses they have not identified to the manufacturer or importer of the substance.
- The Agency assigns a registration number after a dossier completeness check.
- There are reduced registration requirements for isolated intermediates - substances that are consumed or transformed into another substance and are not present in the final manufactured substance. Reduced requirements do not apply to monomers.

Evaluation by Authorities

- Compliance check of registration dossiers and check of testing proposals.
- Substance evaluation and possible request for further information based on risk to human health or the environment.

Authorization

- Authorization includes identification of substances that are banned for general use.
- It also includes authorization of specific uses of such substances banned for general use 1) under defined risk management regimes or 2) based on socio-economic justification.
- Authorization requests should include an analysis of alternatives, a substitution plan when a suitable alternative is available and information about any relevant research and development activities for the application.
- Authorization must be renewed periodically as specified in the authorization decision.

Safety Data Sheet (SDS) and Extended Safety Data Sheet

- As of June 1, 2007, some format changes and content additions apply to SDSs.
- The extended safety data sheet (SDS) will be the primary tool for information transfer in the supply chain.
- Extended SDSs under REACH add relevant exposure scenarios based on chemical safety assessments performed according to registration requirements.
- Extended SDSs must include exposure scenarios only when substances are registered.
- Extended SDSs will be developed for preparations (products that contain multiple substances) as well as individual substances.

Polymers

- Polymers are not exempted from the scope of REACH but are exempted from registration requirements.
- However, monomers as well as any other substances that have been reacted into the polymer backbone must be registered if a polymer produced in or imported into the EU consists of 2% or more by weight of such monomers or other substances and if the volumes of monomers or other substances in reacted form exceed one metric tonne per annum.
- Polymer additives need to be registered if they are manufactured or imported on their own or in compounded form in volumes of one metric tonne or more per annum.

Dow REACH Implementation Steps / Timing for Suppliers / Customer Interaction

Focus on: Pre-registration
- Pre-register substances June 1 – December 1, 2008, and register substances in accordance with deadlines.
- Continue to communicate with suppliers to assure pre-registration and registration of substances in purchased raw materials.
- Publish REACH Product Information Sheets on Dow products at http://reach.dow.com and direct customers to this website, where they can find product-specific responses to their REACH questions from Q4 2007 – Q2 2008
- Work on downstream use identification/exposure scenarios for substance registration. Awaiting standard templates for communication and guidance for a harmonized process throughout industry from CEFIC. Expect to be able to start communication with downstream users via secure web portal later in the second half of 2008.

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