

ES-3: How Does the REACH Program Affect NC Manufacturers and Exporters?

Joseph Plamondon – Bergeson & Campbell

REACH: A New Approach to Chemical Regulation

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Registration, Evaluation, Authorization and Restriction of Chemicals

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- REACH seeks to improve the protection of human health and the environment from risks posed by chemicals
- Under REACH, European Union (EU) manufacturers and importers of substances will be required to:
 - Gather information on the properties of substances; and
 - Register the substances/information with the new European Chemicals Agency (ECHA)
- The regulation, including its various appendices, comprises about 280 pages
- REACH guidance documents -- thousands of pages

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History of REACH

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- European Commission (EC) issues "White Paper" February 2001 -- "Strategy for a Future Chemicals Policy"
- REACH proposed by the EC October 2003
- European Parliament's (EP) first reading completed November 2005
- Common position reached by Council of Ministers June 2006
- Heavy negotiations in November 2006 resulted in a compromise agreement, which was approved by the EP on December 13 and the Council on December 18
- REACH entered into force on June 1, 2007; ECHA became operational June 1, 2008
- Initial Critical Phase: pre-registration June 1, 2008, to December 1, 2008

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Outline of Presentation

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- The traditional regulatory framework for industrial chemicals
- General comments on risk assessment and data generation
- Pre-registration and registration under REACH
- Authorization and restriction of substances of very high concern (SVHC)
- Complex issues involving implementation of REACH

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Traditional Regulatory Framework for Industrial Chemicals

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- Global chemical control laws, including the Toxic Substances Control Act (TSCA) in the U.S. and the European Community Directive 67/548 -- 6th and 7th amendments
- Common features:
 - Grandfathered inventory of existing chemical substances (TSCA Inventory and the European Inventory of Existing Chemical Substances (EINECS))
 - Mechanism for adding substances to the existing inventory -- premanufacture notifications (PMN)
 - Grandfathered substances not reviewed

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Regulation of Grandfathered Substances

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- TSCA -- Sections 4 (testing), 6 (regulation), and 8 (information gathering)
- REACH
 - Registration and review of all non-exempt substances
 - A new model for chemical regulations
 - Implementation issues will arise as the regulation matures

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Principles of Risk Assessment

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- Risk = f (hazard x exposure)
 - Hazard is the inherent toxicity of chemicals to humans and the environment
 - Exposure is the extent to which humans or the environment are exposed to chemicals

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Hazard and Risk Assessment Tools

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- Traditional methods of assessing toxicity rely on animal testing
- REACH seeks to minimize animal testing -- the three R's:
 - Reduction (of numbers of animals tested)
 - Replacement (of animals in testing)
 - Refinement (of protocols)

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Alternatives to Animal Testing

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- *In vitro* testing
- Read-across methodology
- Computer modeling
 - U.S. Environmental Protection Agency's (EPA) voluntary sustainable futures program for PMN submissions
 - Models include hazard and exposure, humans, and the environment

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REACH Guidance Documents and Registration

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- REACH guidance documents -- e.g., nomenclature and substance identification; substances released from articles; monomers and polymers
- 2008 -- Pre-registration from June 1, 2008; if not pre-registered must be registered by June 1, 2008
- November 2010 -- Deadline for first phase of registration for high volume (>1,000 metric ton/year) and high risk substances
- June 2013 -- Deadline for moderate volume substances (>100 metric ton/year)
- June 2018 -- Deadline for substances at or above one metric ton/year

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Registration

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- Substance and company specific -- One Substance, One Registration
- For EU companies only
- Non-EU manufacturers, formulators, and article producers whose product is imported into the EU can appoint an "Only Representative"
- Registration dossiers submitted to the new ECHA in Helsinki

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Pre-Registration

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- Applies to "phase-in" substances only -- existing chemicals (EINECS); substances manufactured in the EU after May 31, 1992, but not placed on the market; no longer polymers
- Six-month pre-registration period from June 1, 2008, to December 1, 2008
- Not required under REACH but necessary to obtain the benefits of the phase-in period

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Registration Requirements

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- Technical dossier must contain:
 - Identity of manufacturer/importer
 - Identity of substance (International Union of Pure and Applied Chemistry (IUPAC) name, trade names, EINECS number, Chemical Abstracts Service registry number (CASRN))
 - Manufacturing/use information
 - Classification and labeling
 - Guidance for safe use from safety data sheet (SDS)
 - Study summaries
 - Chemical safety report (CSR) for >10 metric ton/year substances

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Evaluation

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- Carried out by the ECHA
- Assesses testing proposals
- Goal of minimizing animal testing
- Compliance check -- focus on technical dossier and CSR
- The ECHA and Member States set prioritization criteria

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Authorization

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- Applies only to SVHCs
- Substances for which there is evidence of probable harmful effects on humans or the environment may not be used unless authorized
 - Carcinogens, mutagens or toxic for reproduction (CMR), persistent, bioaccumulative and toxic (PBT), and very persistent and very bioaccumulative (vPvB) substances
 - Goal is to find suitable replacements for dangerous substances
 - Required vs. informed substitution

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Complex Implementation Issues

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- Registration of monomers in polymers and related confidentiality issues including proprietary supplier information
- Chemical nomenclature
- Cost of compliance
- Cost of funding the ECHA

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How Are Polymers Named?

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- Nomenclature primarily based on monomers used to manufacture them
- The two percent rule
- Example: the following are considered to be the same polymer for regulatory purposes
 - 90% Methyl methacrylate/10% butyl acrylate and
 - 10% Methyl methacrylate/90% butyl acrylate and
 - 50% Methyl methacrylate/49% butyl acrylate/1% ethyl acrylate

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How Are Polymers Named (cont'd)

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- Polymers of butyl acrylate (BA)/methyl methacrylate (MMA) are described for regulatory purposes as: 2-Propenoic acid, 2-methyl-, methyl ester, polymer with butyl 2-propenoate; CASRN 25852-37-3 (random copolymer)
- Other chemical identities may be used to describe block and graft copolymers

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Regulatory Definitions of Polymers

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- Basic definition from the EC (both pre- and post-REACH)
 - Must contain a sequence of at least three monomer units, which are covalently bound to at least one other monomer unit or other reactant
 - Over 50% of the substance must consist of polymer molecules
 - The amount of polymer molecules presenting the same molecular weight must be less than 50%

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Registration of Polymers and Monomers Under REACH

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- Polymers are exempt from registration and evaluation
- No longer polymers are not exempt
- Monomers in reacted form are subject to registration and evaluation
 - Provided that the monomer comprises over 2% of the polymer; and
 - The total quantity of the monomer makes up one metric ton or more per year
- Recent lawsuit challenges the need to register monomers that are not actually present other than in reacted form in polymers imported into EU countries

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Examples of Monomer Notifications

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- Consider the following hypothetical acrylate-based polymer
 - 50% BA/40% MMA/6% EA/2.5% PM1/1.5% PM1 -- What is reportable if import volume is 20 metric tons/year?
 - Registrant must know which monomers are present in the polymer
 - Registrant must know how much of each monomer is present in the polymer
 - Impact of polymer design and protection of confidential information

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How to Protect Confidential Information -- Exporters to EU Countries

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- Discontinue supply
- Establish corporate entity in the EU
- Provide customer with confidential chemical identity information
- Meet pre-registration and registration requirements through an Only Representative

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Chemical Nomenclature

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- IUPAC names primarily used under REACH
- CAS naming conventions/CASRNs used under TSCA
- Complex naming issues
- Company naming practices
- One substance, one registration
- Importance of consistency for Substance Information Exchange Forum (SIEF), consortia formation

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Cost Considerations

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- Operational costs for ECHA
 - Fees received to date much lower than expected
- Company burden -- gathering information; costs of compliance (data generation and administrative); business decisions including impact on products currently offered in EU countries
- A company perspective

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