REACH Implementation by a Small Chemical Manufacturer: Key Aspects and Requirements

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OUTLINE

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- **TIMETABLE**
- **COST ESTIMATES**
- **IMPLEMENTATION PLAN**
- **OPPORTUNITIES**

REACH INTRODUCTION

REACH is the new European Community (EU) regulation governing the

Registration,

Evaluation,

Authorization and

restriction of **CH**emicals

It came into force on June 1st 2007 and replaces multiple European directives and legislation with a single regulation. All EU members are required to enforce it.

Its primary aim is to protect human health and the environment.

REACH INTRODUCTION

REACH will have major impact on the entire chemicals sector since manufacturers and importers of chemical substances made in or imported into the EU in annual volumes of **1 ton or more** must register them with the European Chemicals Agency (ECHA).

It is estimated that more than **30,000** substances industry-wide will be affected by REACH.

REGISTRATION EXEMPTIONS

REACH includes exemptions for certain groups of substances.

Examples:

- Radioactive substances
- By-products
- Non-dangerous natural substances
- Natural gas, crude oil, coal
- Substances covered by the Plant Protection Products Directive (must be used exclusively)
- Substances covered by the Biocidal Products Directive (must be used exclusively)
- Polymers (Monomers used to produce polymer if >2% present not exempt!)

REGISTRATION

REACH requires manufacturers and importers of chemical substances to obtain information on the physico-chemical, health and environmental properties of their substances and use it to determine how these substances can be used safely. Each manufacturer and importer must submit a registration dossier documenting data and assessments.

If substances are not registered correctly in time, they **cannot** be manufactured, imported or sold.

REGISTRATION

WHO REGISTERS??

- EU manufacturers and importers
- Producers and Importers
- Only Representatives

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EVALUATION PROCESS

Dossier evaluation - ECHA decides whether REGISTRATION information complies with requirements and examines testing proposals made by registrants.

Substance evaluation – ECHA in coordination with the competent authorities of the Member States assesses the risk of substances to human health or the environment and determines the possible need for additional information and/or proposes further testing.

Testing Requirements- A central principal is that animal testing should be minimized and used only as a last resort.

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AUTHORIZATION PROCESS

Companies applying for authorization must demonstrate that any risk associated with uses of a substance is adequately controlled or that the socio-economic benefits of use outweigh potential risk.

RESTRICTION OF **CH**EMICALS

The EU can impose restrictions and prohibit or set conditions for the manufacture, placing on the market or use of certain dangerous substances when unacceptable risks to humans or the environment have been identified.

If an adequate replacement is available, authorization is unlikely.

Most affected:

Carcinogens

PBT's (Persistent, bioaccumulative, and toxic)

vPvB (Very persistent and very bioaccumulative)

ONLY REPRESENTATIVE

A legal entity in the EU appointed by non-EU manufacturers to fulfill the REACH obligations for importers

Requirements:

- Must have sufficient background in practical handling substances and information
- Collects use data
- Submits documentation for pre-registration and registration
- Can work with SIEF to reduce costs
- Maintains updated MSDS's

SIEF AND CONSORTIAS

SIEF- SUBSTANCE INFORMATION EXCHANGE FORUM

- Mandatory membership for all pre-registrants for a substance.
- Established to avoid repetition of work
- Determined after pre-registration
- Proposes a testing program
- Shared costs in testing
- Concerns
  - Protection of confidential information
  - Level of contributions
  - Anti-competitive behavior potential

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REGISTRATION TIMELINE

PRE-REGISTRATION: JUNE 1, 2008- DECEMBER 1, 2008

REGISTRATION: 3 PHASES DEPENDING ON VOLUME IMPORTED

1-100 TONS PER YEAR:	JUNE 1, 2018
100-1000 TONS PER YEAR:	JUNE 1, 2013
1000 TONS PER YEAR:	NOVEMBER 30, 2010

REGISTRATION TIMELINE

PRE-REGISTRATION: JUNE 1, 2008- DECEMBER 1, 2008

Pre-Register all substances with a remote chance of selling into the EU at > 1 ton/year

Relatively simple submission

Information includes:

- Name of substance (EINECS and CAS numbers, IUPAC nomenclature)
- Molecular and structure formula
- Composition of each substance
- Degree of purity
- Percentage of main ingredients
- Spectral data (UV, IR, NMR, MS, HPLC, GC)
- Pre-registrant's name, address, contact person, third party representative
- Tonnage band and envisaged deadline

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REGISTRATION TIMELINE

REGISTRATION:
1-100 TONS PER YEAR: JUNE 1, 2018
Registration Dossier will require test results specified in Annex VII:
1-10 ton/year:
13 Physico-Chemical Properties (ex. MP, BP, Density, VP, FP, Solubility)
5 Toxicological Data (ex. Skin irritation, eye irritation, Ames test, Oral tox)
3 Ecotoxicological Data (ex. Acute Daphnia tox, Algae growth inhibition)
11-100 tons/year:
Above plus Annex VIII Tests
8 additional Toxicological data (ex. In vivo skin irritation, Acute inhalation tox)
5 additional Ecotoxicological data (ex. Acute fish tox, Sludge respiration inhibition test)

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REGISTRATION TIMELINE

REGISTRATION:
100-1000 TONS PER YEAR: JUNE 1, 2013
Registration Dossier will require test results specified in Annex IX:
All of previous tests plus
3 Physico-Chemical Properties (ex. Viscosity, Dissociation constant)
4 Toxicological Data (ex. 28 day repeat dose rat, Pre-natal)
11 Ecotoxicological Data (ex. Long-term fish tox, Fish bioacculation test)

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REGISTRATION TIMELINE

REGISTRATION:
>1000 TONS PER YEAR: NOVEMBER 30, 2010
Registration Dossier will require test results specified in Annex X:
All of previous tests plus
6 Toxicological Data (ex. Developmental tox, Carcinogenicity study)
7 Ecotoxicological Data (ex. Long-term plant tox, Long-term bird tox)

REACH COST ESTIMATES

Industry will be responsible for two thirds of the REACH costs.
Cost estimates will depend on number of members of SIEF/consortia.
COST CALCULATION:
C = F + V where
C = Cost of registration
F = Fixed costs
V = Variable costs

COST ESTIMATE EXAMPLES

SUBSTANCE	TONS/YR	ECHA FEE	TOTAL TEST COST	TEST COSTS	OR FEE	TOTAL	10 YEAR COST PER LB
A	24	$ 3,600.00	$ 260,000.00	$ 260,000.00	$ 7,000.00	$ 270,600.00	**$ 0.51**
B	26	$ 2,000.00	$ 260,000.00	$ 78,000.00	$ 7,000.00	$ 87,000.00	**$ 0.15**
C	27	$ 2,000.00	$ 260,000.00	$ 78,000.00	$ 7,000.00	$ 87,000.00	**$ 0.15**
D	8	$ 740.00	$ 29,000.00	$ 8,700.00	$ 7,000.00	$ 16,440.00	**$ 0.09**
E	11	$ 3,600.00	$ 260,000.00	$ 260,000.00	$ 7,000.00	$ 270,600.00	**$ 1.12**
F	9	$ 1,300.00	$ 29,000.00	$ 29,000.00	$ 7,000.00	$ 37,300.00	**$ 0.19**
G	28	$ 3,600.00	$ 260,000.00	$ 260,000.00	$ 7,000.00	$ 270,600.00	**$ 0.44**
H	7	$ 1,300.00	$ 29,000.00	$ 29,000.00	$ 7,000.00	$ 37,300.00	**$ 0.24**
I	3	$ 1,300.00	$ 29,000.00	$ 29,000.00	$ 7,000.00	$ 37,300.00	**$ 0.57**
TOTAL	143	$ 19,440.00	$ 1,416,000.00	$ 1,031,700.00	$ 63,000.00	$ 1,114,140.00	

Based on 2 suppliers for B, C, and D

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IMPLEMENTATION PLAN

JAN-JUNE 2008

- Gather data on substances exported to EU >1 ton
- Interview Only Representatives and reach agreement

JUNE-NOV 2008

- Submit data for substances to Only Representative
- Inform customers of Only Representative

2009

- SIEF notification will received
- Contact members to establish plan

2009-2018

- Have tests performed
- Revise labels and MSDS's

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BOTTOM LINE

It will cost more to sell into the EU and this law will likely spawn similar laws in other countries.

It is likely many chemicals will be discontinued due to the cost of testing.

Potential Advantages

- Competitors may decide to discontinue sales into the EU
- Potential to obtain information on new customers
- Reduces interest in submitting new substances that may compete

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FOR MORE INFORMATION

EUROPEAN CHEMICALS AGENCY WEBSITE

http://echa.europa.eu/reach_en.asp