Draft Chemicals Regulation

Briefing Note – August 2003

In May 2003 the European Commission published its long-awaited draft chemicals legislation.

The new Regulation proposes a complete overhaul of the regulatory system, which will impact right across the chemicals value chain.

ERM has been tracking development of the legislation, and helping our clients to assess how it will impact on their business.

Introduction

In May 2003, following five years work by the Commission, including publication of a white paper in February 2001, the EU published its 1200 page draft chemicals legislation for internet consultation.

Although the closing date for consultation responses was in early July, sufficient time remains for influencing the final form of the Regulation as the legislation makes its way through the EU co-decision procedure.

What issues are driving the changes?

- The existing regulatory regime is fragmented and leaves significant gaps.
- The complex system for registering new chemicals promotes a lack of innovation to seek alternatives.
- Insufficient capacity in Member States to assess the risks posed by chemicals.
- Other jurisdictions are moving ahead with more stringent chemical test regimes, particularly the US.
- Growing public concerns over the health and environmental risks posed by chemicals.
- Desire for the industry to improve its public image.

Key elements of the draft proposals

- A general *Duty of Care* will be placed on all actors in the value chain to ensure that products do not adversely affect human health and the environment - this represents a significant departure from the previous system by shifting the *burden of proof* from public authorities and onto producers and downstream users.
- The REACH system (**R**egistration, **E**valuation, **A**uthorization of **CH**emicals) - REACH will completely reform the current regulatory system for managing chemicals within the EU.
- Establishment of a New European Chemicals Agency to manage REACH.

How will it affect your business?

The proposals contain both opportunities and threats to producers and downstream chemical users, including:

- An opportunity to show safety of products and allay public concerns.
- The overall principles of the legislation fit well with sustainable development goals.
- There is a strong emphasis on building consortia and improving communications with all actors in the chemicals value chain.
- For many substances, there will be significant costs associated with fulfilling informational requirements.
- Concerns over intellectual property rights on test data.

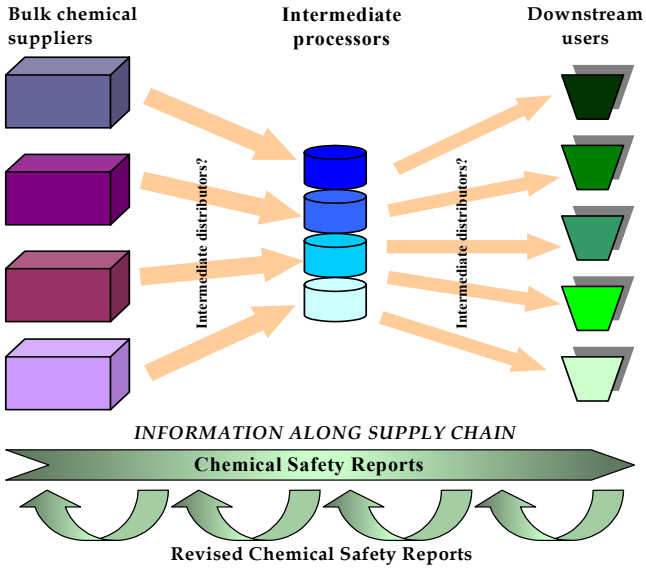
What will be required under REACH?

The stringency of REACH requirements increases according to production volume and hazard potential of the product, as shown below:

	Production volume	Information requirements
Registration	> 1 tonne/yr	Hazard assessment. Exposure data and risk assessment.
Evaluation	> 100 tonnes/yr + others where concern is raised	Long-term exposure testing programs for all products placed on the market.
Authorization	Any substance giving rise to "very high concern".	Producers required to prove that product use will result in minimal exposure or that the social/economic benefits outweigh associated risks.

How will requirements impact along the value chain?

Chemical Safety Reports, as required under the general *Duty of Care* and REACH, will necessitate information to flow in both directions along the chemicals the value chain (shown below):



What are the practical implications?

The following are a few examples of how these requirements may work in practice:

Example 1 **A producer of bulk chemicals**
Requirements: ***Registration*** dossier for products + some 'intermediates'; communicate exposure assessments with downstream user; refine assessments based on feedback; fulfil ***Evaluation*** requirements for HPV chemicals; seek ***Authorisation*** for any substances of "very high concern".

Example 2 **A multi-national textile/clothing company**
Requirements: Assess chemical use in production & undertake exposure assessments; assess exposure and fate of chemicals in finished 'articles'; compile risk assessments.

Example 3 **A global pharmaceutical manufacturer**
Requirements: Limited *Registration* requirements for isolated intermediates + other potential requirements to undertake exposure and risk assessments.

What will it cost?

The European Commission, Member States governments and industry associations have all made various cost assessments, some of which suggest significant financial impacts for industry. However, an in-depth review of test costs by ERM suggests these estimates may be exaggerated, because of pessimistic assessments of the number and nature of tests required.

ERMs services

ERMs Corporate Advisory Service has a long history of tracking and managing emerging EH&S regulatory issues for *Fortune 500* companies, including:

- analysing requirements of emerging legislation.
- undertaking *Business Impact Assessments*.
- reviewing current practices/compiling gap analyses.
- assessing key stakeholder responses.
- benchmarking competitor's management of issues.

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