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REACH CHEMICALS REGULATION

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REACH REGULATION 1907/2006 TEXT

Title I	General Issues
Title II	Registration of Substances
Title III	Data Sharing
Title IV	Information in the Supply Chain
Title V	Downstream Users
Title VI	Evaluation
Title VII	Authorisation
Title VIII	Restrictions
Title IX	Fees and Charges
Title X	Agency
Title XI	Classification and Labelling Inventory
Title XII	Information
Title XIII	Competent Authorities
Title XIV	Enforcement
Title XV	Transitional and Final Provisions

AIMS AND OBJECTIVES

Aim and scope

A.1.1

"The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."

The European Court of Justice is the final arbiter of European Community law.

When interpreting REACH it will probably look first at the purpose "to ensure a high level of protection of public health and the environment", and try to give effect to that purpose.



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AIMS AND OBJECTIVES

Producer Responsibility

A 1.3

"This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle."

Many systems of chemicals regulation internationally have failed because regulators have been unable to work through a big backlog of substances or chemicals to assess.

REACH tries to reverse that process by making those who place substances on the market carry the primary responsibility for ensuring that they do not damage human health or the environment.

SCOPE – A.2

EXCLUDED from the Scope of REACH:

- **radioactive substances**
- **some substances in customs storage or transit**
- **non-isolated intermediates (defined at A 3.15(a))**
- **dangerous substances in carriage by road, rail, inland waterway, sea or air**
- **waste, as defined in EU Directive 2006/12/EC**
- **specific, discretionary defence exemptions**

SCOPE – A.2

LIMITED or QUALIFIED APPLICATION TO –

- medicinal products for human or veterinary use
- food or feeding stuffs
- other limited categories of substances

REDUCED OBLIGATIONS FOR –

- research and development (Product and Process Oriented Research and Development 'PPORD')
- polymers (defined at A 3.5)
- intermediates (defined at A 3.15)

ANNEXES IV, V : Exemptions from obligation to Register

HOW REACH IS DIFFERENT

- **Scope**
- **Treatment of existing chemicals**
- **Producer Responsibility**
- **No data, no market**
- **Authorisation/substitution assumptions**

MAIN OBLIGATIONS I

REGISTRATION :

Title II:

Registration of substances over 1 tonne per year

A5 'No data, no market' –if a substance needs Registration, and it has not been registered, it cannot be put on the EU market

A6 Registration of substances, on own or in preparations

A7 Substances in articles (1 tonne p.a., intended release)

MAIN OBLIGATIONS I

EVALUATION :

Title VI:

A40 -> New European Chemicals Agency and EU Member State authorities check Registration dossiers, and select some for evaluation

MAIN OBLIGATIONS I

AUTHORISATION/SUBSTITUTION :

Title VII

A55 -> Substances of Very High Concern 'SVHCs' are subject to stricter controls and pressure to substitute with safer alternatives. Applies particularly to carcinogens, mutagens, reprotoxins, endocrine disruptors and substances of equivalent concern

MAIN OBLIGATIONS I

RESTRICTIONS ON MARKETING AND USE :

Title VIII

**A67 -> Directive 76/769/EEC replaced and re-enacted.
Restrictions can be introduced on the manufacturing,
marketing and use of dangerous substances and
preparations – for example asbestos**

KEY DATES

- **Publication in Official Journal** **30 December 2006**
- **Entry into Force** **1 June 2007**
- **Pre-registration** **1 June 2008 –
1 December 2008**
- **Registration deadlines (A. 23):**
- **CMRs over 1 tonne; R50/53 over 100 tonnes;**
- **Phase in substances over 1,000 tonnes** **1 December 2010**
- **Phase in substances over 100 tonnes** **1 June 2013**
- **Phase in substances over 1 tonne** **1 June 2018**

MAIN DEFINITIONS A.3

- **Substance**: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- **Preparation**: means a mixture or solution composed of two or more substances;
- **Article**: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

MAIN DEFINITIONS A 3 CONTD.

- **Manufacturing**: means production or extraction of substances in the natural state;
- **Manufacturer**: means any natural or legal person established within the Community who manufactures a substance within the Community;
- **Import**: means the physical introduction into the customs territory of the Community;
- **Importer**: means any natural or legal person established within the Community who is responsible for import;
- **Downstream user**: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;

Purpose of Pre-Registration

- **Potential Registrants needing benefit of Registration have a phase-in timetable under Article 23**
- **Must pre-register substances under Article 28 with EINECS or CAS number and brief details**
- **Chemicals Agency to release pre-registration details December 2008**
- **Pre-registration applies to "potential registrants" – Manufacturers, Importers, Sole Representatives**
- **Establishes Substance Information Exchange Fora 'SIEFs' for data showing:**
 - **mandatory exchange of vertebrate tests**
 - **optional data exchange for other tests**

IMPLICATIONS OF PRE-REGISTRATION

- Essential to take advantage of phase-in timetable
- If missed, obligation will be individual Registration without phase-in timetable from 1 December 2008
- Allows Chemicals Agency to assess the scale of the Registration task
- Will determine which Substance Information Exchange Forum 'SIEF' is relevant
- Very short timescales for all that needs to be done!

PRE-REGISTRATION PRIORITIES

Manufacturer of substances?

Pre-registration?

Importer of substances?

Pre-registration?

Substances "intended to be released" from imported articles?

Pre-registration?

Check whether supplier will pre-register

- **substances in preparations of own specification**
- **substances key to your business**
- **substances with few suppliers**

SUBSTANCE INFORMATION EXCHANGE FORA 'SIEFS'

- **Article 29**
- **Force companies to co-operate and to share basic information, studies on substances – SIEF membership required of all potential registrants of phase-in substances**
- **Purpose is to facilitate Registration, require the exchange of exchange information, avoid duplication, avoid need for repeated animal testing on same substances**
- **Background is idea of 'One Substance, One Registration'**
- **Does not protect SIEF members from the full application of EU Competition Law.**

CONSORTIA

- **Governed by consortium agreement between a group of those handling the same substance – legal aspects of agreement and procedures are important.**
- **Not required by REACH text itself, but a practical response to share e.g. costs of studies, management of Registration, joint approach to substance identification, classification and labelling.**
- **Competition issues – N.B. RECITAL 48 – EU Competition Law still applies, whatever it says in REACH.**

ALLOYS AND SPECIAL PREPARATIONS

REACH is designed to deal with SUBSTANCES

- Its predecessor, the Dangerous Preparations Directive, dealt with **PREPARATIONS**.
- **REACH** assumes, as does **DPD**, that preparations are simple mixtures of substances.
- How valid is this for **GLASSES, ALLOYS, ELASTOMERS, CERAMICS, CEMENTS** and **CONCRETES**?
No clear answer, so have become known as 'Special Preparations'

WHAT ARE SPECIAL PREPARATIONS?

In which the substances are bound chemically
(as opposed to physical dispersion)

- Substances react to form SPECIAL mixtures
- They form "Matrix" structures, from which the constituents cannot be physically separated. This is the form in which most people/consumers will encounter chemical substances.

The challenge is to find ways of treating these SPs, which satisfy both the demands of credible regulation and sound science.

Q. 1

As processors and distributors of Nickel alloys, Stainless steels and Titanium alloys, 1, Do we have to register all elements over 1000 kg/year as these are locked into fairly inert alloys

A. Presently REACH only properly recognises the constituent substances in alloys and applies Registration requirements to them, but c.f. developing guidance, UN GHS, EIMAG work. Consider also definition of downstream user in A3.13 – different from ‘distributor’

Q 2

- 2. The markets we serve are mainly aerospace, petrochemical, thermal process and power generation. Do these require registration?
- A. Substances require Registration, not markets, with only limited exceptions see Annex IV and V. Some relevant substances (e.g. coal, oil, coke if not chemically modified, are exempt from Registration).

Q 3.

- 3. “We have several locations throughout Europe all of which import and export these alloys, do they all need to register separately or can we centralise the registration on one location?”
- A. Legal entity has obligations of Importer etc, so if multiple legal entities within a group each import, each will take on those obligations – many groups will find it worth revising their purchasing arrangements as a result

Q.4

- 4. Will REACH be enforced across Europe or do you believe only the UK will comply?
- A. REACH is more an expression of producer responsibility than a set of rules principally enforced by the regulators. As Cathy Phillips points out, the real issue is business continuity, and the real pressure will be from your customers.

ALLOYS AND SPECIAL PREPARATIONS

Recital 31

Alloys definition A 3.41

Annex I General Provisions for Assessing Substances and Preparing Chemical Safety Reports: Para 0.11 –

"When assessing the risk of the use of one or more substances incorporated into a special preparation (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account"

Compare with impending changes once GHS system on Classification and Labelling is adopted

POLYMERS AND REACH

- Polymers are not subject to Registration, BUT
- Registration requirement may be added in future (A.138.2)
- Monomers require Registration if –
 - not already Registered, and
 - polymer contains > 2% (w/w) of such monomers; and
 - total of monomer(s) is over 1 tonne per year
- Polymers are subject to Authorisation –
 - particularly relevant to SVHCs as additives etc?

POLYMERS

Article 2.9: The provisions of Titles II and VI shall not apply to polymers

Article 138.2: The Commission may present legislative proposals as soon as a practicable and cost-effective way of selecting polymers for registration on the basis of sound technical and valid criteria can be established, and after publishing a report on the following:

- (a) the risks posed by polymers in comparison with other substances;**
- (b) the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other.**

REACH REVIEWS

- Important reviews of the operation of the REACH Regulation are set out in detail in Article 138. They include –
- CSR/CSA Reviews by 2014 and 2019
- Polymers proposals "as soon as practicable"
- Review of Registration of low volume tonnage information requirements
- Review of Annexes I, IV and V by 1 June 2008
- Review of Annex XIII by 1 December 2008 on criteria for PBTs
- Review of legislative overlaps with other EU law by 1 June 2012
- Review of endocrine disruptors by 1 June 2013
- Review of Scope of A.33 on dangerous substances by 1 June 2019
- Review of testing requirements of Section 8.7 of Annex VIII by 1 June 2019



REACH AND THE SUPPLY CHAIN – INFORMATION FLOWS

PRACTICAL MESSAGES

- Early preparation of inventory of substances highly important : that is where customers will start
- Early discussions up and down supply chain essential – downstream users will start asking 'what substances are in my products?' – suppliers must help provide answers
- Pre-registration checking before 1 June 2008 essential – it is going to be a busy time – early preparation will help!
- Identification of likely information bottlenecks advised – how much is known about substances in products, articles, components, preparations.
- Multiple suppliers and component supplies will take longer to reach – for example if they are in China.



Substances withdrawn from market

- **May be for legal reasons, or commercial or practical reasons**
- **Whatever the reasons, it will be necessary to plan for and anticipate substances withdrawal**
- **Customer information is essential – they need to know if substances will be reviewed, included or substituted**



OVERSEAS SUPPLIERS TO THE EU

- Consider the present problems with the supply of some toys from China to Western Markets
- REACH could raise similar issues and problems
- Understand what EU customers will need in order to comply, and plan to meet these requirements
- Expect a shift away from suppliers unable or unwilling to help their EU customers comply with REACH

GLOBALLY HARMONISED SYSTEM 'GHS'

GLOBALLY HARMONISED SYSTEM 'GHS' FOR THE CLASSIFICATION AND LABELLING OF CHEMICALS

- **Current system of classification based in Directive 67/548/EEC on classification, packaging and labelling of dangerous chemical substances; and Directive 1999/45/EC on dangerous preparations and the Safety Data Sheet Directive 91/155/EEC**
- **European Commission pledged to make REACH compatible with GHS**
- **Important implications for Special Preparations, Alloys, firms trading chemical substances in several jurisdictions**
- **EU legislative proposals already out for consultation, adjustments to REACH and RIPs expected**

CLASSIFICATION AND LABELLING IN THE EU AT PRESENT

DIRECTIVE 67/548/EEC ANNEXES I, V, VI, III, VIII	DIRECTIVE 1999/45/EC ANNEXES I, II, III
FURTHER INFORMATION:	
http://ecb.jrc.it/classification-labelling	

GHS (GLOBALLY HARMONISED SYSTEM)

- (a) To enhance the protection of human health and the environment by providing an internationally comprehensible system for hazard communication**
- (b) To provide a recognised framework for countries without an existing system**
- (c) To reduce the need for testing and evaluation of chemicals**
- (d) To facilitate international trade in chemicals whose hazards have been properly assessed and identified on an international basis**

UN GHS

- **Classification system which provides uniform criteria and hazard information at global level for all sectors**
- **Implementation agreed at WSSD in Johannesburg 2002**
- **Non-binding scheme**
- **Living document, updates every 2 years**
- **Commitment to implement: AIM IS IMPLEMENTATION BY 2008**



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PROBABLE IMPLICATIONS OF GHS IN THE EU

- **Reformulation of products to eliminate certain ingredients**
- **Warning labels for currently exempt products**
- **More stringent shipment labelling and transport precautions**
- **More stringent chemical storage, handling and disposal**
- **(M)SDS changes**

REACH AND THE GHS

- **REACH does not include CRITERIA for C&L**
- **Globally Harmonised Classification and labelling system will be introduced in parallel with REACH**
- **REACH Pre-Registration, Registration and Authorisation will be based on GHS Classification not on present Classification and labelling of dangerous substances in Directive 67/548/EC**

Advantages of REACH compliance

1. Business Continuity
2. Supplier advantage
3. Favourable comparison with non-compliant suppliers
4. New uses for new information, e.g. about substances characteristics, weight, substitutes
5. Last, and least, regulatory compliance

Further information: HSE

- UK REACH CA Helpdesk
 - www.hse.gov.uk/reach/helpdesk.htm
 - E-mail: UKREACHCA@hse.gsi.gov.uk
 - Tel. 0845-408-9575
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- e.g. new guidance on Basics of REACH, REACH Timeline, Pre-Registration and Exemptions

Further information: ECHA

- http://echa.europa.eu/reach_en.html
- e.g. January-February 2008 new guidance on Registration, Intermediates, PPORD, Downstream Users

Further information: EIMAG and Eurometaux

- EIMAG – European Industry Metallic Alloys Group
- Eurofer, Eurocopper, Euronickel etc
- Eurometaux www.eurometaux.org
- **See especially REACH Metals Gateway**

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