



**International Symposium on Chemicals Management
in the Context of Global Trends
Latest Trends of Chemicals Management in north America,
Europe and Asia**

**Chemicals Management in the European Union and
its application to industrial products**

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1.

Objectives of this Presentation

- ❖ Introduction into the set-up of chemicals management in the European Union
 - Structure of the system
 - Content of the most important acts from an industrial and international trade perspective
- ❖ Description of the main policy drivers which led to the system in its current form
- ❖ Description of the political and technical reasons which led to the new REACH regulation
- ❖ Short personal assessment of the expected developments in the years to come

This presentation is not a technical or legal guidance to RoHS or REACH; however, it provides information where such guidance can be found

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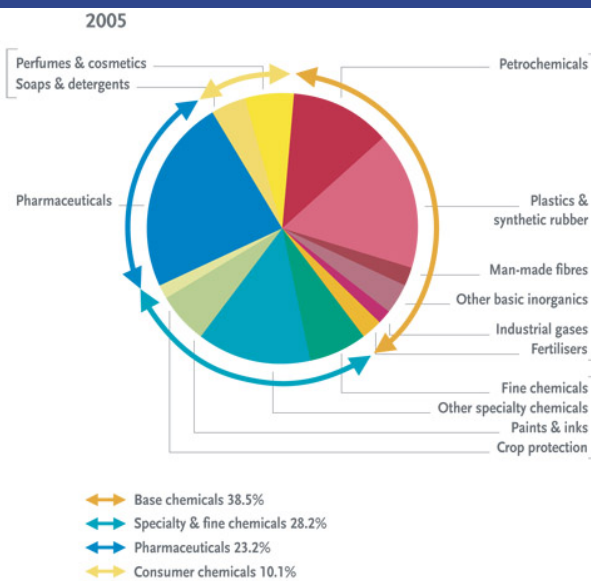
General Outline

1. Introduction to the European context
2. Current legislation for chemicals management in the European Union
 - Structure and general outline of its content
 - The Directive on Restrictions of Hazardous Substances (RoHS) in electrical and electronic products as an example for product legislation
3. The new REACH legislation
4. Outlook – Challenges and future efforts

3.

Context (1)

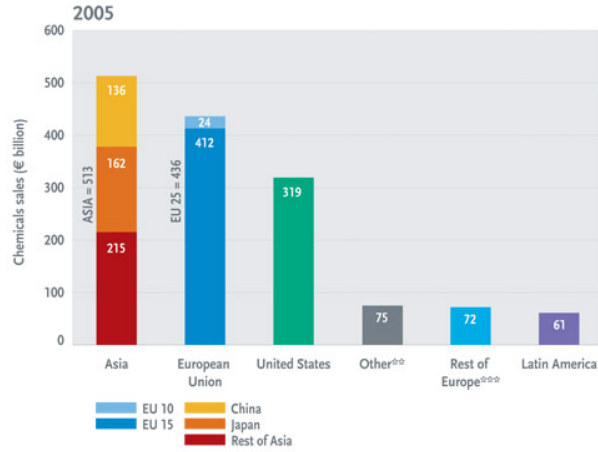
Sectoral breakdown of EU chemical industry



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Context (2)

The production of chemicals in a global perspective



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Context (3)

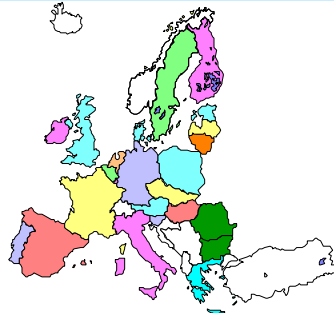
The European Union – A community in the making

27 Member states

2 Candidate countries

several countries requesting membership

more than 20 languages, 500 million inhabitants



6.

Context (4)

Main factors influencing the development of European chemicals legislation

Main objectives of European chemicals legislation

- ❖ Need to harmonise provisions on chemicals of the member states in order to ensure the functioning of the internal market
- ❖ Need to protect public health
originally mainly workers' health
later general population – consumers
nowadays increasing focus on vulnerable groups
- ❖ Increasingly and with a widening scope
protection of the environment – no longer just classical subjects like water and air pollution but items like protection of the ozone layer, climate change, biodiversity

7.

Context (5)

Main factors influencing the development of European chemicals legislation

Important other policy drivers:

- ❖ High rank of concerns on the environment and health in the public debate
A very strong influence of civil society / NGO's
- ❖ Requirement to move from a reactive approach to a precautionary approach
- ❖ Strong call for a life-cycle-approach (integration of consumer of final product and waste management)
- ❖ Strong call for a substitution of hazardous substances in products

8.

Current legislation for chemicals management in the European Union (1)

General Structure of the legislation on chemical substances

Horizontal rules applying to all (industrial) chemicals

- Chemical rules applying to specific product groups (e.g. explosives, cosmetics, detergents, fertilisers, pesticides, biocides, etc.)
- Environmental legislation addressing directly the use of specific chemical substances in certain products (e.g. refrigerants containing ozone depleting substances, restriction of hazardous substances in electrical and electronic products (RoHS), End of life vehicles)

Main challenge: coherence

Large number of government departments involved and wide variety of objectives

Current legislation for chemicals management in the European Union (2) Horizontal rules applying to all chemicals

The Directive on Dangerous Substances (Directive 667/548/EEC) and the Directive of classification labelling of Dangerous Preparations

Main subject: Classification, packaging and labelling of dangerous substances and preparations

These Directives are the key element and foundation of chemical management rules in the EU. The rules of the Dangerous Substances Directive define which substances are to be considered as dangerous, because of which hazards and the classification and labelling provides the basic information for any subsequent risk management.

For substances of special concern harmonised classifications are established which are Legally binding. Harmonised classifications cover at present about 8000 substances and the Directive is under permanent revision to take account of scientific and technical progress.

The two Directives will be replaced by a regulation implementing the **Globally Harmonised System (GHS)** in 2008 (subject to completion of the legislative process)

Current legislation for chemicals management in the European Union (3)

Horizontal rules applying to all chemicals

The Safety Datasheet Directives (Directives 93/112/EEC and 2001/58/EC) and the Directive on the protection of the health and safety of workers from the risks of chemical agents at work (Directive 98/24/EC)

The supplier of a dangerous substance or certain preparation has to provide a safety data which in essence contains all the specified information and hazards, appropriate uses and risk management measures. Safety data sheets are of very high importance for risk management by professional users.

The workplace legislation requires employers to determine whether hazardous substances are present at the workplace and to asses the related risks. He has to do so based on the information in the safety data sheets. The employer has to take all necessary risk reduction measures and he is obliged to take measures for substitution of hazardous by non- or less hazardous substances or to reduce exposure.

Alas empirical studies have shown that many safety data sheets are deficient and of little use. This one of the reasons that risk reduction measures taken by the downstream users of chemicals are frequently not fully up to standards either.

Current legislation for chemicals management in the European Union (4)

Horizontal rules applying to all chemicals

Risk assessment of Existing Substances (Regulation 793/93/EEC) and New Substances (6th and 7th Amendment of Directive 67/548)

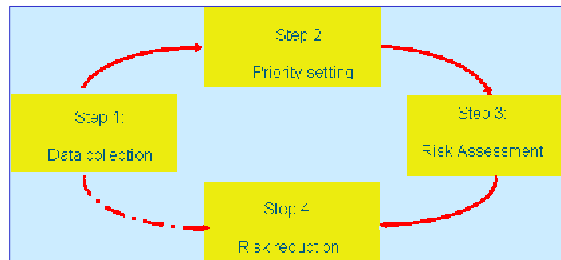
Under the current legislation very different rules apply for “Existing Substances” and “New Substances”. “New” substances (those which entered the market after 1981) need to be notified to the authorities with a fixed set of testing data from very low quantities.

“Existing Substances” are those registered in “EINECS” (European Inventory of Existing Commercial Substances). All substances registered in EINECS can be put on the market unless there are specific restrictions. For most EINECS substances only very limited data on production and toxicity are available

In order to generate more information at least on high volume Existing Substances specific rules for the risk assessment of those substances were introduced in 1993

Current legislation for chemicals management in the European Union (5)
Horizontal rules applying to all chemicals

Existing Substances Regulation (cont.)



The basic structure of the Existing Substances Regulation is simple: Industry submits the data for substances in certain volume brackets, Community authorities take a decision on which substances warrant a Community risk assessment, designated Member States undertake the risk assessments which are then discussed and endorsed on EU level with recommendations how to address the identified risks.

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Current legislation for chemicals management in the European Union (5)
Horizontal rules applying to all chemicals

Existing Substances Regulation (cont.)

In practice, this system worked rather slow. In more than ten years only 141 substances have been prioritised and production and agreement on the respective risk assessments has taken a very long time. Consequently, the results for risk reduction come very late, sometimes too late from a political perspective.

This was one of the main reasons for the reform by means of the new REACH system.

Current legislation for chemicals management in the European Union (6) Horizontal rules applying to all chemicals

The Restrictions of Marketing and Use Directive or „Limitations Directive“ (76/769/EC)

- ❖ This Directive compiles marketing and use restrictions for a wide variety of priority substances, preparations and products (e.g. asbestos, arsenic, certain phthalates, certain brominated flame retardants).
- ❖ The prohibition to put a product on the market is the most severe risk reduction measure existing. It is therefore generally based on a risk assessment and an economic impact assessment.
- ❖ As an exception to this principle carcinogenic, mutagenic and reprotoxic substances are generally prohibited for sale to the general public (with some rare exceptions when no suitable substitute is available)

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Current legislation for chemicals management in the European Union (7) Legislation on specific product groups

Apart from the so-called ‚horizontal legislation‘ which applies in principle to all industries and applications there is quite a number of sector-specific legislation.

The most important areas are:

- . Pharmaceuticals (totally separate)
- . Cosmetics
- . Plant protection products (pesticides)
- . Biocidal products
- . Food contact materials
- . Detergents
- . Explosives

In general this sector-specific legislation is partly based on the horizontal chemical legislation and sets stricter specific rules for the specific product group in consideration of the specific risks of the respective application.

The EU is party to virtually all international chemical conventions, which are then implemented by specific acts of Community law.

Finally, there are substance management provisions in certain acts of Community waste legislation. Most known, the restrictions on the use of heavy metals in vehicles and electrical and electronic products.

Current legislation for chemicals management in the European Union (8)

Legislation on specific product groups The example of the RoHS Directive

- ❖ The Restriction of Hazardous Substances (« RoHS ») in electrical and electronic equipment Directive (2002/95/EC) is an example of environmental legislation influencing directly the use of certain hazardous substances in a group of industrial products
- ❖ Prime objective is to address problems in waste management caused by the presence of hazardous substances in the waste stream
- ❖ Linked to this is the objective to push producers of electrical and electronic articles to design their products in a more environmentally friendly way
- ❖ Restricted are mercury, cadmium, lead, hexavalent chromium and two groups of polybrominated flame retardants; other substances can be added on a proposal from the Commission
- ❖ The Directive requires a substitution of the hazardous materials when technical alternatives are available unless negative effects of the substitution on environment, health or consumer protection outweigh the benefits (compare Article 5);

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Current legislation for chemicals management in the European Union (9)

Legislation on specific product groups The example of the RoHS Directive (cont.)

Practical problems in application of the RoHS Directive

The RoHS Directive can be regarded as the first Directive in Europe which set a general substitution requirement for a wide group of complex industrial products (until then, marketing and use restrictions had a very narrow scope). This caused a number of implementation problems:

- ❖ A high number of derogations has been proven to be necessary, high work load for industry and the European Commission
- ❖ Methodological problems to measure compliance, especially with the concentration limit of 0.1% (0.01% for Cd), this limit applies to « homogeneous material ». A product can consist of many homogenous materials.
- ❖ EU Member States are responsible for the implementation of the RoHS Directive. The rules for compliance are not harmonised and therefore somewhat different, although Member States cooperate.
- ❖ To address the practical problems the Commission is reviewing the RoHS Directive (for further information compare: http://ec.europa.eu/environment/waste/weee_index.htm)

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Current legislation for chemicals management in the European Union (10)

Legislation on specific product groups The example of the RoHS Directive (cont.)

RoHS Directive, conclusions:

- ❖ The Directive addresses an important global waste problem (compare current international discussions on e-waste in the framework of the Basle convention)
- ❖ Basic approach to push producers to consider the full life cycle of their products when they decide to use hazardous substances is generally acknowledged
- ❖ Approach to regulate specific hazardous substances in individual products or product groups is only feasible in some few cases (other examples are « end of life vehicles » or the « batteries directive »).

In future, hazardous substances in products are to be addressed under the new REACH legislation

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The new REACH Regulation (1) Reasons for the new legislation

Problems with the existing system

Current chemicals management system is inefficient

- ❖ Current system is a patchwork developed over time
- ❖ Difficult to identify risks – difficult to address risks:
 - ◆ Lack of information about most substances on the market
 - ◆ Burden of proof on public authorities
 - ◆ No efficient instrument to deal with problematic substances
- ❖ Lack of incentives for innovation
 - ◆ Disproportionately high demands for new substances

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The new REACH regulation (2)

Main features and objectives

❖ Scope:

manufacture, import, placing on market and use of substances:

on their own

in preparations

in articles



❖ Overall aims:

- ◆ Improving health and safety of workers and the general public.
- ◆ Environmental protection – avoiding chemical contamination of air, water, soil and damage to biodiversity
- ◆ Maintaining a competitive/innovative chemicals industry
- ◆ Integration with international efforts (SAICM, GHS, etc)

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The new REACH Regulation

(3) Key Elements (cont.)

❖ One single and coherent system

for new and existing chemicals

❖ Core elements:

- ◆ Registration of substances ≥ 1 tonne/yr (staggered deadlines)
- ◆ Information in the supply chain
- ◆ Evaluation of some substances by Member States
- ◆ Authorisation only for substances of very high concern
- ◆ Restrictions - the safety net
- ◆ European Chemicals Agency to manage system

❖ Focus on priorities:

- ◆ high volumes (as a proxy for potential risk)
- ◆ greatest concern (substances & uses with highest risk)

❖ Shift of responsibilities:

from public authorities towards industry

The new REACH regulation

(4) Key elements as regards the scope

⇒ *REACH applies to the manufacturing, import, placing on the market and use of substances*

- However, as in the current legislation there are **exemptions** for certain:
 - Substances (e.g. ores, certain common natural substances)
 - Uses of substances (mainly those regulated by special legislation)
- In comparison to the current legislation **reduced obligations** for R&D (research, product and process related research and development (PPORD)), polymers and intermediates
- Note that substance definition includes metals, as has been the case in the EU for the last decades

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The new REACH regulation (5)

Registration: obligations of Manufacturers/Importers

- **Registration requirement** for substances ≥ 1 tonne per year (per manufacturer/importer, in practice over a three year average)
 - **Imports:** registration to be effected by EU-importer or the “only representative” of the non-EU company
 - **Chemical Safety Report (CSR)** for all substances ≥ 10 t per year; CSRs document the hazard and classification of the substance, potential exposures of humans and the environment during the life cycle of the substances are described in ‘exposure scenarios’ for all foreseen uses, CSRs contain a risk assessment and risk management measures for these uses
- ⇒ *In the absence of available information, **tests** may have to be conducted*
- ⇒ *Data sharing (obligatory for vertebrate tests)*
 - ⇒ *Substance Information Exchange Fora (SIEFs) in order to limit duplication of testing*

The new REACH regulation (6) Registration: obligations of Manufacturers/Importers (cont.)

■ Timetable:

◆ Non phase-in substances:

- ◆ A 67/548/EEC notification for a 'new substance' in the current system automatically becomes a registration
- ◆ When not already notified by the company:
registration required before production or import can take place (= new substances under REACH)

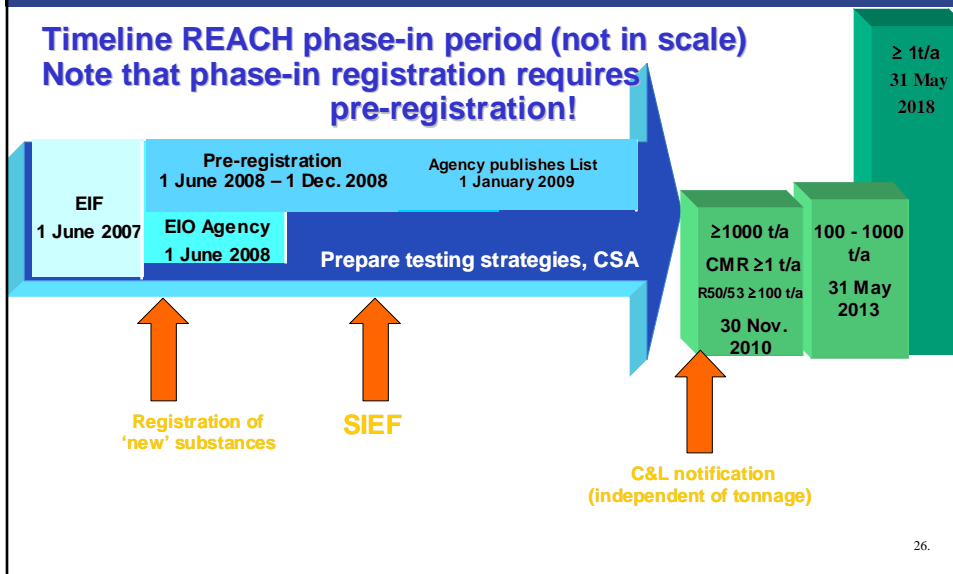
◆ Phase-in (of former 'existing') substances:

benefit from transition periods if pre-registered

- ◆ Pre-registration: 1 June 2008 – 30 November 2008
(except where newly manufactured / imported)
 - ◆ Identify substance, manufacturer, tonnage band/deadline
 - ◆ European Chemicals Agency will publish list
- ◆ Registration: Transition period depending on the tonnage band

The new REACH regulation (7) Registration: Timelines

Timeline REACH phase-in period (not in scale)
Note that phase-in registration requires pre-registration!



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The new REACH regulation (8) Downstream User Rights and Obligations

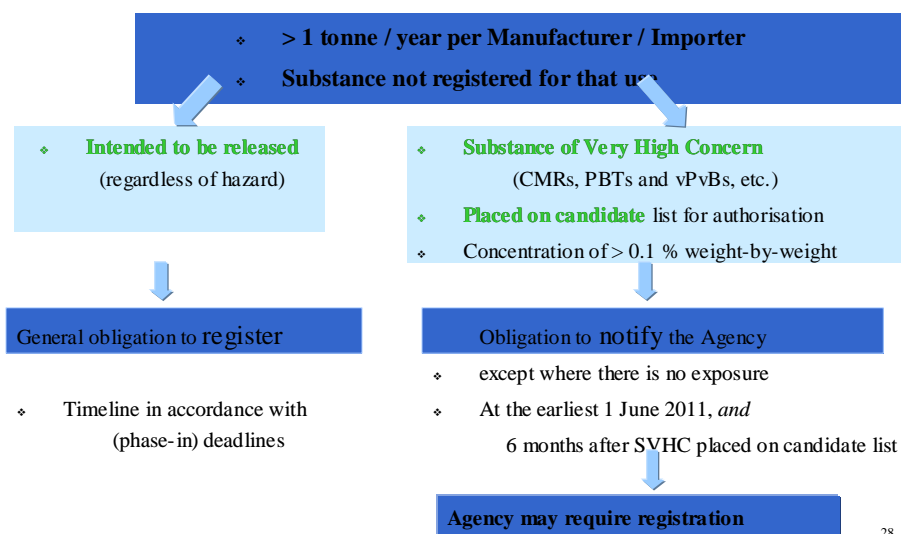
One of the main differences between the current system and REACH is the integration of Downstream Users. Downstream Users are users of chemical substances that are neither manufactured nor imported by the company itself.

- CSRs and Safety Data sheets usually have to address uses of the chemicals by the Downstream Users. Therefore, Downstream Users have to make their uses known to manufacturers/importers. However, to enable the suppliers to prepare the corresponding exposure scenario and support of the use they need to provide the relevant data
- Downstream Users are entitled carry out their own CSA (e.g. for confidentiality reasons)

⇒ In case input chemical is directly imported from outside the EU without “only representative” of the exporting manufacturer:
The Downstream User is regarded as importer and has the registration obligations!

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The new REACH regulation (9) Substances in Articles (Article 7)



28.

The new REACH regulation (10) Authorisation/Restriction

■ **Authorisation:**

for Substances of Very High Concern (“SVHC”, essentially CMR category 1 and 2, PBT, vPvB substances)

- Identification of SVHC (compare Art 58 of REACH Regulation)
- “Sunset date” after which manufacturing and use is only allowed when covered by an authorisation
- Uses or use categories can be exempted from authorisation if the risk is adequately controlled (i.e. if no emissions are expected)

Note: although the number of SVHC is relatively high, authorisation will be a

long term process as a strict priority setting will be needed

■ **Restriction:**

only minor changes compared to existing system (Directive 76/769/EEC)

- In addition to “marketing & use”, now also manufacturing covered

The new REACH regulation (11) Authorisation and Substitution (Art. 62)

A manufacturer applying for authorisation of a SVHC needs to provide an analysis of the alternatives “considering their risks and the technical and economic feasibility of substitution”

- ❖ If the mandatory “Analysis of alternatives” finds suitable alternatives, the application must also include a substitution plan with timetable
- ❖ When no such alternatives are found, the application must provide information on any relevant R&D activities, if appropriate
- ❖ During a review, the Commission may require a substitution plan when it decides that there are suitable alternatives available
- ❖ PBT substances cannot invoke the “adequate control route”
- ❖ By 1 June 2013, the Commission to consider whether to exclude Endocrine Disruptive Substances from the scope of the “adequate control route”

The new REACH regulation (12) Imminent implementing goals of the Commission

- ❖ Intensify the preparation to implement REACH smoothly:
 - ◆ Drafting the Technical Guidance Documents,
 - ◆ Preparing the necessary software tools (IUCLID 5 and REACH IT),
 - ◆ Setting up ECHA: the Chemicals Agency in Helsinki

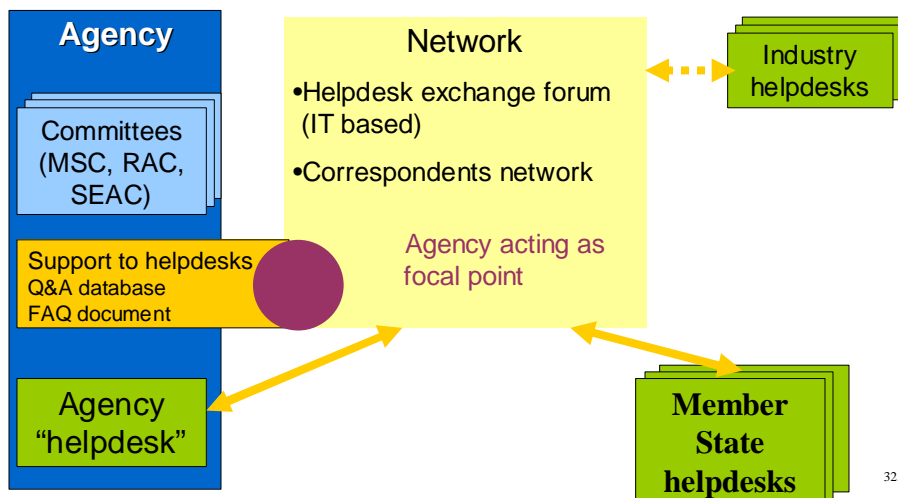
➔ Important:

- to provide key elements of the guidance by entry into force
- to make REACH workable for SMEs
- to get the Agency operational on time

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The new REACH regulation (13) Network of helpdesks

trade associations, industry organisations, experts



32.

The new REACH regulation (14)

Points of immediate relevance for non-EU companies

- **Pre-registration required for (phase-in) registration:**
Your EU-importer or your “only representative” must participate in the SIEF
- **Avoid uncoordinated testing:**
Testing can only be carried out once agreed in the SIEF
For higher volumes: Before testing can start, Agency must approve testing proposal
- **Agency helpdesk takes up questions from outside the EU**
- **Substances intended to be released from articles:**
Also fall under obligation to register

The new REACH regulation (15)

Conclusions from a policy perspective

REACH builds largely on the existing system of European chemicals legislation. It is not a revolution. Virtually all elements have been applied in parts of the chemical legislation before.

The main differences are:

- Much more information is to be collected on existing substances
- New requirement of registration of substances as a pre-condition for placing them on the market (Article 5: No data, no market)
- Strong involvement of downstream users
- A further step in addressing chemical substances in articles.

None of these ideas are new, neither in the European nor in the international debate.

The challenges are implementation and cost.

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Outlook

Challenges and further efforts

- ❖ REACH defines to a large extent the work programme for chemicals management in Europe for the next decade;
- ❖ GHS will be a complement to REACH; adoption of the legislative proposal imminent; start of the legislative discussions expected for first semester 2007
- ❖ Growing importance of regulatory convergence and of the work of international bodies (eg OECD, SAICM) as globalisation of the industry will continue
- ❖ International co-operation strongly desirable in emerging issues (e.g. nanotechnology)

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Further Information

Further information is available on the following internet pages of the Commission:

1. **Policy Information and Text of the Legislation**

Environment Directorate General:

<http://ec.europa.eu/environment/chemicals/index.htm>

Enterprise Directorate General

http://ec.europa.eu/enterprise/chemicals/index_en.htm

2. **Technical information** (technical guidance documents, risk assessments):

European Chemicals Bureau

<http://ecb.jrc.it/>



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European Commission

Thank you!

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