**EDUCATIONAL MATERIAL**

on the New European Chemicals Policy REACH

# REGISTRATION EVALUATION AUTHORIZATION AND RESTRICTION OF CHEMICALS

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# INTRODUCTION

## Our daily chemistry

Our house, our living-room, bathroom, kitchen and bedroom all contain a world of synthetic chemistry of which we know little or nothing about, although it is an integral part of our daily life. Innocent objects beyond any suspicion, shoes, mattresses, sofas, towels, shampoos, carpets, the TV, etc., often contain chemical substances with toxic properties that might be suspicious for carcinogenicity, allergenicity or corrosive behavior and of which most of us are not at all aware.

The chemical world in which we live includes all spaces in which we work, move around, entertain ourselves, etc. For example, chemical substances with well-known harmful effects can be detected in the dust of most homes[1], while these or other substances can also be found in our food or even in breast milk and in our blood[2]. As consumers we unfortunately don't know that some of the substances we use in our daily environment interfere with our hormone system causing phenomena such as "feminization" and reduced fertility[3]. These are the so-called 'endocrine disruptors', the object of a relatively newly developing medical science worldwide, which has not managed yet to effectively influence the current legislation towards a better protection of human health.

[1] *Consuming chemicals: Hazardous chemicals in house dust as an indicator of chemicals exposure in the home. Greenpeace, May 2003*
*http://www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/5679.pdf*

[2] *Chemical Check Up: An analysis of chemicals in the blood of Members of the European Parliament,21 April 2004, WWF DETOX campaign: Brussels Belgium*
*http://www.panda.org/downloads/europe/checkupmain.pdf*

*Contamination: the next generation. Results of the family contamination survey. October 2004, WWF UK, London*
*http://www.wwf.org.uk/filelibrary/pdf/family_biomonitoring.pdf*

[3] *Endocrine Disrupters, Environmental Health and Policies P. Nicolopoulou-Stamati, L.Hens, C.V.Howard, Environmental Science and Technology Library, 2001*

In practice, the laws in force to regulate our "chemical culture" allow for the accumulation of several chemicals in the environment. Several of these are expected to burden humanity for many years since they will come back to us through the food chain or the interaction of our body with the surrounding environment, as the toxic heritage of DDT and PCBs has shown. Polychlorinated Biphenyls (PCBs), after having circulated for approximately five decades in the market, were finally banned in 1996 and are supposed to be eliminated by 2010. This will happen 80 years after the first serious indications of how highly hazardous the related chemical DDT was.

Another serious problem that needs to be tackled is the lack of adequate knowledge: very little is known about the millions of different chemicals synthesized by man but also for the approximately 100.000 chemicals produced for commercial uses that exist today in the European market (figure based on the **European Inventory of Existing Commercial Chemical Substances - EINECS** 1981) This lack of meaningful information may hide many problems for human health and the environment, as the increase in production during the last 70 years has been exponential, from 1 million tons worldwide in 1930 to 400 million tons after 2000. Such ignorance gives rise to many types of injustice. Injustice towards workers and consumers, whose health is put under risk due to lack of proper precautions in using the chemicals but also towards enterprises and businesses that produce, use or provide the market with safe or safer substances.

In the existing framework of ambiguity, lack of proper information and clear rules, many chemical businesses - mainly 'downstream users' e.g. those who use a substance either on its own or in an intermediate stage of production - are often not aware about the harmful properties of the substances they get from their distributors and also do not know what to do to improve the situation. More transparency, as well as a stronger and clearer legislation is urgently needed in order to allow downstream users to undertake the responsibility *vis-à-vis* their clients and build a long-term relationship based on trust.
It is therefore imperative to replace ignorance - the main trait of our present chemical culture - with knowledge and proper management.
This is essential, not only for European societies, but also for those of developing countries and countries with economies in transition where the biggest growth in global sales of chemi-

cals - most of them produced in developed countries, including Europe - is expected to happen over the next decade(s).

Aiming at establishing a more uniform, transparent and safer management of chemicals in the European Union, a new legislation, known by its acronym **REACH** (**R**egistration, **E**valuation and **A**uthorisation of **Ch**emicals) was designed. It entered into force on June 1st 2007.

**Chemicals that will be considered as unacceptable, in terms of the hazard they pose on human safety and environmental health, are to be identified and gradually substituted by safer alternatives, implementing the precautionary principle**[4].


[4] *This principle was enshrined at the 1992 Rio Conference on the Environment and Development, during which the Rio Declaration was adopted, whose principle 15 states that: "in order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".*

## Green and Sustainable Chemistry

REACH substitution's provision is in line with the philosophy of "green chemistry", conventionally described in the 12 principles developed by Anastas (from the USA EPA) and Warner in 1998[5], that encourages the design of products and processes able to reduce or eliminate the use and generation of hazardous substances but also with the concept of Sustainable Chemistry, coined on the wake of important global events focusing on Sustainable Development.

At the United Nations Conference on Environment and Development, held in Rio de Janeiro in 1992, about 170 nations agreed that the protection of the environment and social and economic development are fundamental to sustainable development[6]. To achieve sustainable development they adopted the Rio Declaration on Environment and Development and the Agenda 21, which is the comprehensive blueprint of action for the 21st century to be taken globally, nationally and locally in every area in which humans impact on the environment.

Chapter 19 of Agenda 21 also provides targets for the environmentally sound management of toxic chemicals, including prevention of illegal international traffic in toxic and dangerous products. The full implementation of Agenda 21 was strongly reaffirmed at the World Summit on Sustainable Development (WSSD) held in Johannesburg, South Africa from 26 August to 4 September 2002. The participants agreed to minimize the significant negative impact from chemicals by 2020. The declaration of WSSD also deemed it necessary for sustainable development to establish sound management of chemicals over their whole life cycle. Since then, several international fora have discussed sustainable chemistry.

[5] *http://www.epa.gov/greenchemistry/pubs/principles.html and Green Chemistry: Theory and Practice, Paul Anastas and John Warner, Oxford University Press, New York, 1998.*

[6] *The concept came into general usage following publication of the 1987 report of the Brundtland Commission formally, the World Commission on Environment and Development. Set up by the United Nations General Assembly, the Brundtland Commission coined what was to become the most often-quoted definition of sustainable development as development that "meets the needs of the present generation without compromising the ability of future generations to meet their own needs." The field of sustainable development can be conceptually broken into three constituent parts: environmental sustainability, economic sustainability, social-political sustainability.*

The concept of Sustainable Chemistry offers an arena of innovation, which not only calls for the preservation of resources, but also for a new development process in the chemical industry. Sustainable Chemistry aspires to raise the stake of less dangerous chemicals as well as the production of environmentally high-quality products from preferable renewably resources. This reduces emissions and excessive consumption of resources like energy and materials. The principle of Sustainable Chemistry comprises important elements in areas like environment, economy and society. Sustainable Chemistry deals with the whole life cycle of intrinsically safe chemicals and products, including their production, processing, use and disposal.

Intrinsically safe chemicals and products are characterized by low toxicity to the environment and human health and low persistence and accumulation potential. Thereby, human health and the environment are protected from step one and socio-economic follow-up costs are avoided. Additionally, production of sustainable chemicals and articles contributes to economic profit for innovative enterprises and thereby presents an opportunity for competitive advantage compared to production and marketing practiced according to old-fashioned concepts.

Besides enhancing the functioning of Europe's internal market and creating a level playing field for the management of chemicals in Europe, a proper application and enforcement of the new REACH legislation could be indeed an excellent occasion to foster innovation and preparing new market opportunities i.e. increase the competitiveness of the European chemical industry.


**Figure 1**
*Chemicals: a great variety of chemicals exists in the market but there is lack of adequate information about their effects on human health and the environment.*

# 1 THE CONTROL OF CHEMICALS AT INTERNATIONAL AND EUROPEAN LEVEL

## 1.1. International Actions on Hazardous Chemicals

After the Second World War industrial countries started to regulate the production, marketing and commercial use of chemicals. A number of very dangerous or hazardous chemicals were restricted while measures were taken to avoid their release in the environment. But only in the last 30 years have more vigorous legislative efforts have been undertaken to ban or restrict the use of very dangerous ones.

In 1975 two actions were initiated by the **United Nations Environmental Programme** (UNEP): The International Registry of Potentially Toxic Chemicals (IRPTC) and the International Occupational Safety and Health Hazard Alert System (IOSHHAS). In 1985 another programme, the International Programme on Chemical Safety (IPCS), was launched by UNEP, in cooperation with the World Health Organisation (WHO) and the International Labour Organisation (ILO) to establish the scientific basis for safe use of chemicals, and to strengthen national capacities for chemical safety.

More recently, the **Strategic Approach to International Chemicals Management** (SAICM) was adopted by the International Conference on Chemicals Management (ICCM) on 6 February 2006. SAICM **is an international policy framework to foster the sound management of chemicals** and supports the achievement of the goal agreed at the 2002 Johannesburg World Summit on Sustainable Development of ensuring that, by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.

The **World Health Organization** (WHO) also initiated programmes for the study of toxic substances. One of these, Monographs on the Evaluation of Carcinogenic Risk to Humans (**International Agency for Research on Cancer, IARC/WHO**) was directed at identifying environmental factors that can increase the risk of human cancer (including chemicals, complex mixtures, occupational exposures, physical and biological agents, and lifestyle factors) so that National health agencies could use this infor-

mation as scientific support for their actions to prevent exposure to potential carcinogens.

The **Organization for Economic Co-operation and Development** (OECD) coordinated in 1978 a programme among industrial countries in order to improve the control of chemicals and contribute to the protection of humans and the environment from exposure to hazardous chemicals, the so called: "Assessment of Potential Environmental Effects of Chemicals and Guidelines for Anticipating the Effect of Chemicals on Man and the Environment, Special Programme on the Control of Chemicals". Later on, with similar objectives in mind, OECD also promoted its "Mutual Acceptance of Data and Recommendations on Test Guidelines and Principles of Good Laboratory Practice" (1981), which is considered very important for testing samples and using modern analytical techniques to generate valid and high quality test data and also introduced (1982) the "Minimum Pre-Marketing Set of Data" (toxicological and safety tests) for commercial chemical products among industrial countries.

Several countries, including some EU Members (Germany, Sweden, Denmark) but also other 'heavy' chemical producers, such as the USA, Canada and Japan, have developed programmes for gathering data on chemical hazards and systems for protecting the environment, workers and consumers from dangerous or hazardous chemicals.

## 1.2. European Actions on Chemicals

A Community Chemical legislation has been in existence since 1967 (Directive 67/548/EEC) when it was recognized that provisions related to the classification, packaging and labeling of substances on the market, in particular dangerous industrial chemicals, should be harmonized throughout the Community in order to eliminate the barriers to trade that national provisions in the Member States could represent. Since its adoption in 1967, Council Directive 67/548/EEC has constantly been updated in order to take into account scientific and technical progress to make sure a high level of protection of man and the environment, as well as the correct functioning of the internal market is guaranteed. One of the most important amendments was the so called "6th Amendment" of the Directive in 1979, which introduced the protection of the environment from the dangerous effects of substances as well as a notification system for "new" substances which, consequently, required the establishment of the list of "existing" substances, called EINECS. This development was part of the EU response to the US legislation known as TOSCA (Toxic Substances Control Act)[7]. EINECS was established as the **E**uropean **In**ventory of **E**xisting Com-mercial **C**hemical **S**ubstances and lists all substances that were reported to be on the market on or before 18 September 1981. The substances placed on the market for the first time after this target date are considered "new" and are added to ELINCS, the **E**uropean **LI**st of **N**otified **C**hemical **S**ubstances. Another important step was the 7th amendment of the Directive in 1992, which required the principles of risk assessment for "new" substances. It further introduced the "sole representative" in the notification system, and added the **Safety Data Sheet** as a hazard communication facility for the professional user.

In the 1980s a Community Action Programme underlined the need for a legislative instrument, which would provide a comprehensive structure for the evaluation of the risks posed by "existing" chemicals. In particular, the Action Programme stated that such a legislative instrument "will establish a procedure for treating priority lists of chemicals for immediate attention, as well as setting out the means for gathering information, requir-

[7] *http://www.epa.gov/lawsregs/laws/tsca.html*

ing testing and evaluating the risks to people and the environment". Consequently, the European Commission proposed a series of legal instruments, which were aimed at meeting the objectives outlined in the Action Programme. One of these instruments was the Existing Substances Regulation (EEC) 793/93 which was adopted by the European Council on 23 March 1993 and came into force on 4 June 1993. It applies to any manufacturer or importer who produces or imports an existing substance in quantities exceeding 10 tones a year.

Throughout these developments the relevant Community chemical legislation came to cover four main sections:

**A. DATA COLLECTION**
(for existing chemicals and new ones)

**B. CLASSIFICATION AND LABELLING**
(harmonization of labels and classification of toxicity danger)

**C. DATA ASSESSMENT**
(existing chemicals, protection of workers)

**D. RISK MANAGEMENT**
(during marketing, use, export, import, consumer protection, etc).

Moreover, the chemical policy focus was shifted from measures directed to control "downstream" impacts of hazardous chemicals on workplaces (where exposure is at its highest), consumers and the environment, to "upstream" reduction of potential exposure and prevention.
It is in this framework that, for example, the Integrated Pollution, Prevention and Control Directive (**IPPC Directive 96/61/EC**) was adopted. This is about minimizing pollution from various industrial sources in the EU, covering around 50.000 installations which are subject to environmental permit from the relevant authorities of EU countries. The implementation of IPPC forces large plants to adopt a comprehensive approach to pollution prevention concerning hazardous chemicals.

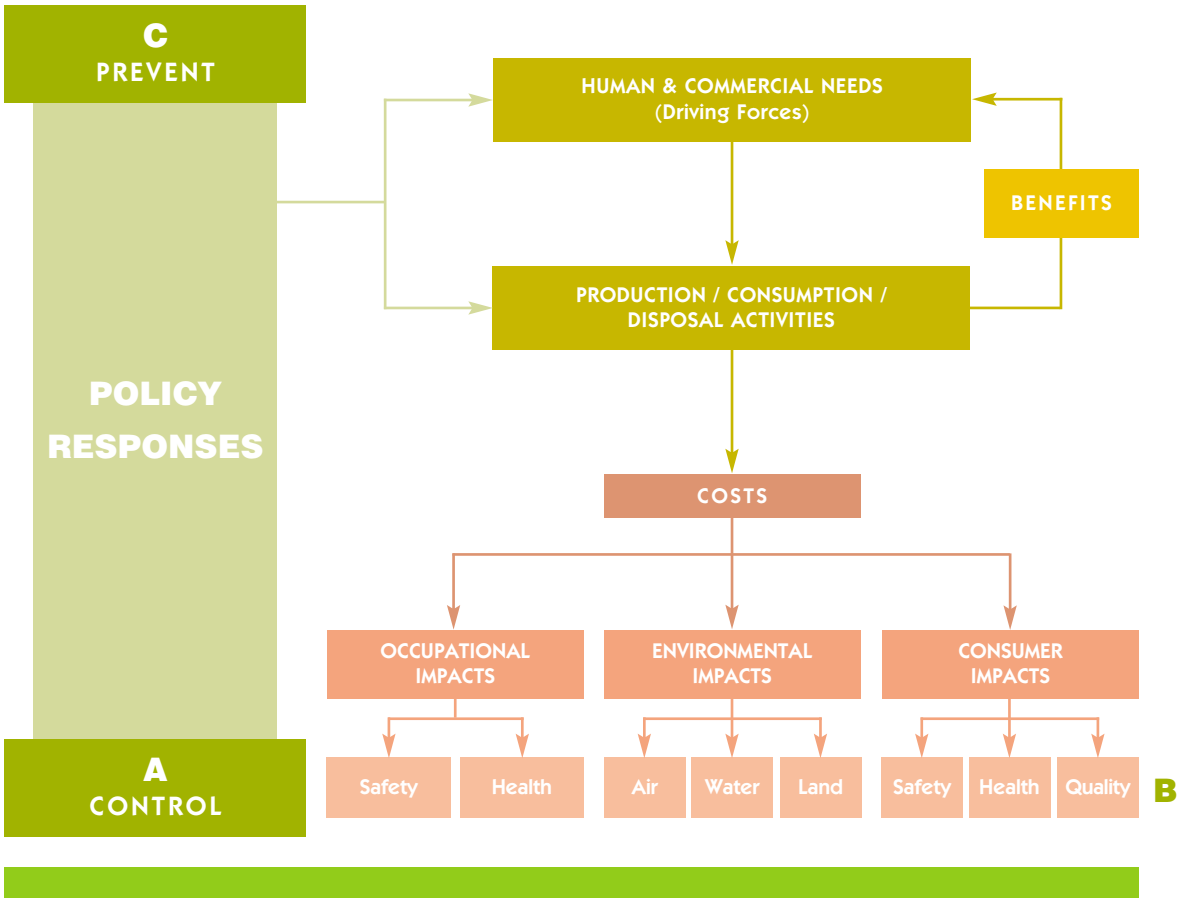
Furthermore, the EU is being guided in its legislation by various international environmental treaties (Stockholm Convention on Persistent Organic Pollutants - POPs, long-range transboundary air pollution, Basel Convention, Kyoto Protocol, Montreal Protocol, etc) which are considered integral part of its legislation.

The European Union from the beginning of its formation was interested in regulating the health and safety aspects of chemical substances. The chemicals, plastics and rubber industries are among the larges in the EU (Europe produces 31% of the world's chemicals). The over 60.000 chemical industries in Europe employ almost 3.5 million people and account for 12% of the manufacturing industry's added value. Furthermore, the chemical sector represents 2/3 of the entire manufacturing trade surplus of the EU.

**Figure 2.**

*A framework analysis of the EU policy concerning the impact of hazardous chemicals. The policy was to move from chemical legislation associated with difficulties of co-ordination among departments ("A") to policies which are related to more difficult problems ("B"). Policies at "C" focus on the "upstream" sources of chemicals via the integrated prevention of exposures that cause adverse effects on health and safety and environmental pollution.*

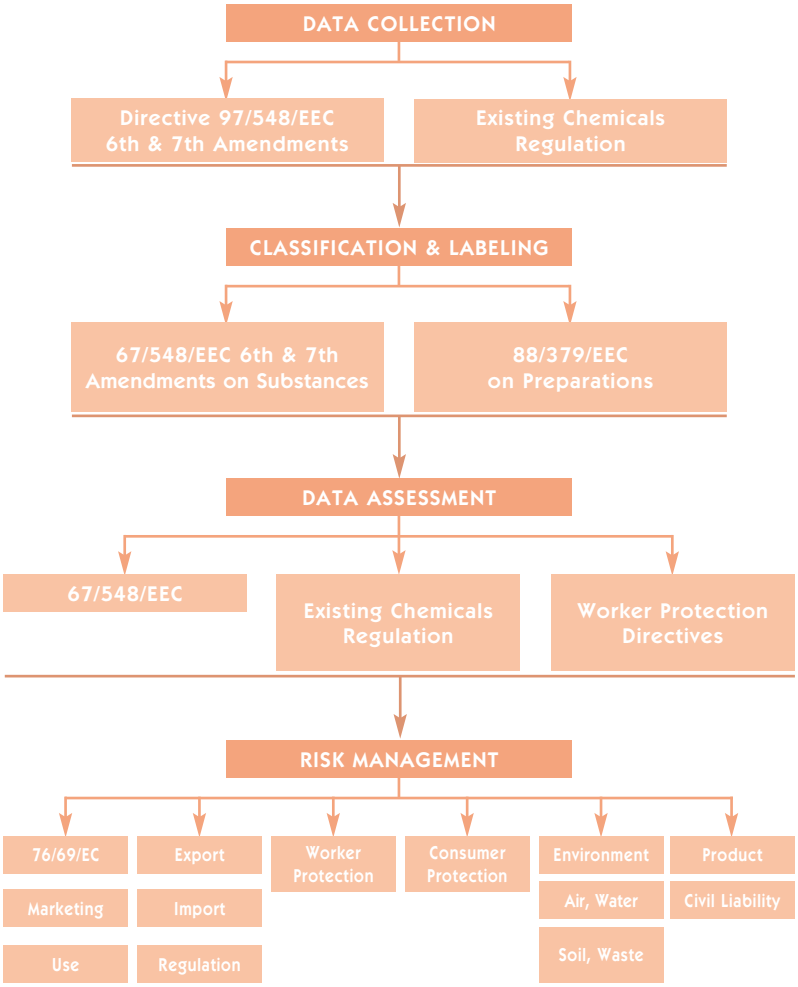
(Source: European Environment Agency).



In the last 30 years the EU introduced numerous Directives and amendments for the classification and labeling, the collection of information on chemicals hazards, and the management of various risks presented by hazardous chemicals. A diagram of the most important elements of the EU legislation on chemicals is presented in Figure 3.

**Figure 3.**

*Control of Chemicals in the European Union (Source: CEC, 1994).*



# 2

## **THE PROBLEM:** DATA COLLECTION ON HAZARDOUS CHEMICALS IN EU

Until recently chemical substances have been treated differently in the European Community depending on when they were introduced in the market. "New" substances (introduced after 1981) were required to be tested about their toxicity and physico-chemical properties and notified before being marketed in volumes above 10 kg. For higher volumes more in-depth testing focusing on long-term and chronic effects had to be provided. On the basis of this information, they were assessed on their risks to human health (toxicity) and the environment (ecotoxicity).

However, there have been no corresponding requirements for chemicals deemed to be on the European Community market between 1 January 1971 and 18 September 1981 (the "existing" chemicals) and listed in the EINECS, more than 100.000 existing substances, counting for almost 99% of the chemicals' volume on the market.

In order to bring a better control in the chemical substances scene, a set of inventories was created. Apart from the existing chemical list EINECS the other inventories had focused on new, high production volume chemicals, low production volume chemicals and priority chemicals. The list of chemicals was further subdivided and completed by adding the existing and new, high production volume chemicals and the priority chemicals:

a. **European Inventory of Existing Commercial Chemical Substances (EINECS):** 100,204 substances (until 1981)
b. **European List of Notified Chemical Substances (ELINCS):** 3,827 substances (new chemicals from 1981 to 2006)
c. **High Production Volume Chemicals (HPVC):** HPVCs data requirements: name of substance, produced and imported

quantities, classification and labeling information under 7/548 and reasonably foreseeable uses. Also data in the following areas: physico-chemical properties, information related to chemical fate and pathways in the environment and toxicological and ecotoxicological properties (environmental fate, ecotoxicity, acute toxicity, chronic toxicity, mutagenicity, developmental/reproductive toxicity)

d. **Low Production Volume Chemicals (LPVC):** 7.829 substances (until 2006, with production volume exceeding 10 tons/ year but not greater than 1,000 tons/year. LPVCs data requirements include only the first part of those of HPVCs.

e. **Priority List of Chemicals:** 141 substances (1994-2006) with potential hazardous properties and high volume production. The European Chemicals Bureau (ECB) selected the priority list for urgent collection of data.

The initial effort of the European Community to test and assess most of the hazardous existing (1981) and new (after 1981) chemicals did not work effectively, since risk assessments require comprehensive information and data on toxicity and ecotoxicology. Starting in 1994 with 4 priority lists containing 141 chemical compounds the data collection and risk assessment was very slow. Yet at the same time certain chemicals had caused serious damage to human health and the environment, because information on their adverse impacts was not available. On the total of 141 chemicals 69 (for 72 substances) have final reports, and 67 (for 70 substances) only summaries (by the EU Scientific Advisory Committee on Toxicology and Ecotoxicology).

Overall information available on the toxicity and exposure data showed that:

- 75% of chemical substances in use (existing) do not have adequate toxicity data,
- 50-75% of priority chemicals (HPVC) do not have adequate ecotoxicity data (ecotoxicology tests are experimentally very difficult and it takes a long time to assess risk in the various ecosystems)

- some marketed chemicals in use in various products have inadequate toxicity data on fertility, carcinogenic potential, endocrine disruption and other adverse effects to humans
- for a large number of marketed chemicals there is inadequate data or information on their distribution, fate and concentration in the environment, their presence in consumer products and their impacts on ecosystems

**It is clarified that the EINECS list includes:**

- **Industrial chemicals,**
- **Substances produced from natural products** by chemical modification or purification (metals, minerals, cement, refined oil and gas and their products)
- **Substances produced from animals** and plants (lanolin, turpentine, rosin oil and resin acids)
- **Food additives**
- **Ingredients of active substances** of pesticides, medicaments (aspirin, paracetamol) and cosmetic products
- **Monomers**
- **Natural polymers** (natural rubber and starch)
- **Some waste** and by-products, including some products of processed coal (coke and coal tar pitch).

**The EINECS does not include:**

- **Synthetic polymers** (these are registered in EINECS under their building blocks, monomers)
- **Impurities as such**
- **Intentional mixtures**
- **Medical products, cosmetic products**
- **Pesticides** as intentional mixtures
- **Food**
- **Feedstuffs**

- **Alloys** (stainless steel) however it includes most individual components of alloys
- **Most naturally occurring raw materials** (coal and most ores).

All substances not on the EINECS list are required by the 6th and the 7th Amendments to Directive 67/548/EEC to be notified and assessed prior to receiving permission to be marketed.

# 3

# THE SOLUTION? "NO DATA NO MARKET": REACH, THE NEW CHEMICALS POLICY IN THE EU

REACH represents a broad and radical EU Chemicals' Policy rethinking in an effort to overhaul the drawbacks of the current system in relation to the production and use of chemical substances, in line with sustainable development principles as well as competitiveness concerns. In fact the EU is the largest chemicals producing region in the world and its chemical industry is the biggest, on a global scale, representing more than 30% of the global sales, generating work and wealth for most of the European countries and its competitiveness and productivity is vital for Europe's future economic situation. On the other hand this increases the responsibility of the EU not only for its own citizens but also for the entire planet where its chemicals are used.

This is particularly evident from projections showing that the most growth in global sales over the next decade is likely to happen in developing countries and countries with economies in transition. Today, consumption of chemicals is far higher in OECD countries than in countries with less developed economies. A person living in Europe or the US consumes chemicals worth over 1,500 Euro/year, while a person living in India or Africa spends some 50 Euro on chemicals annually. Thus the chemical industry sees an enormous potential in the developing world.

Moreover, the chemicals industry in the OECD is shifting production from basic high-volume chemicals to more sophisticated and high value-added products. The chemicals industry in richer countries is therefore expected to become more high-tech while industry in developing countries will account for an increasing part of the production of basic high-volume chemicals as globalization and deregulation of trade will make it possible for chemical corporations in OECD countries to move into developing country' markets.

## 3.1. The REACH process

### 3.1.1. THE WAY TOWARDS THE OFFICIAL EC PROPOSAL ON THE NEW CHEMICALS POLICY

REACH has been created through a long process of stakeholder debate and discussions within the European Commission, Member State Governments and the European Parliament. Following the concerns expressed initially by environmental NGOs and then by Member States and scientists during the Informal Environmental Council (April 1998), about the limited information on marketed chemicals (especially those existing before 1981), the Commission launched a review of the EU policy in this field. A Report was prepared on the functioning of the four main current chemicals regulatory instruments and it was followed by a stakeholders' debate (February 1999). The Environmental Council (June 1999), concluded that there was a need for a new approach to chemicals regulation, and called on the Commission "to submit the policy document outlining a new chemicals strategy, at the latest by the end of the year 2000" (Council document 11265/1999).

The Commission prepared a **White Paper** [8] (produced under co-responsibility between the Commission's Directorates General for Environment and Enterprise), which recognized the current problems and the need for a new strategy in the field of risk assessment of chemicals and the competitiveness of the Chemical Industry in the EU (13 February 2001). The White Paper recognized that:

**a.** There is restricted knowledge about the dangerous and hazardous chemicals in the EU market. This lack of data makes it difficult to assess risks and to make informed decisions about their control.

**b.** The risk assessment process in place (toxicity, ecotoxicity etc.) is much too slow. In 10 years there were only around 140 chemical substances which were assessed.

[8] *"White Papers" published by the European Commission are documents containing proposals for European Union policy, strategy and action in a specific area. They sometimes follow a green paper released to launch a public consultation process.*

**c.** Financial and scientific resources focus too much on the assessment of "new" substances which make up less than 1% of the total volume of chemicals on the global market and not enough on "existing" substances (the list of approximately 100.000 chemicals in the market until 1981). This results in stifling innovation in new chemicals production and the competitiveness of the EU Chemical Industry.

After studying various possible alternatives the Commission came to the decision to set a new comprehensive system for **R**egistration, **E**valuation and **A**uthorization of **CH**emicals (**REACH**) and to change the pace of risk assessment of existing chemicals.

The overriding goal of the new chemical strategy outlined in the White Paper was to achieve an appropriate balance between environmental, economic and social priorities which are consistent with the Commission's policy on Sustainable Development. At the same time the White Paper aimed to enhance the competitiveness of the important EU chemical industry.

On 29/10/2003, the full REACH proposal was published by the European Commission having as broad objectives:

**a.** to develop a new integrated and coherent chemicals' policy reflecting the precautionary principle and the principle of sustainable development.

**b.** to improve the safety of humans and the protection of the environment during application and use of chemicals.

**c.** to modernize the regulatory framework in order to encourage innovation, competitiveness and the efficient working of the internal market.

From this point the debate moved to the European Parliament and Council, the two bodies that, on the basis of the co-decision procedure, are responsible for the adoption of the new Regulation.

In order for the proposal to become law, the Council and the Parliament had to approve each other's amendments and agree upon a final text in identical terms. If the two institutions had agreed on identical amendments after the first reading (or

vote), the proposal could have become law. This was not the case and there was a second reading in each institution, where each considered the other's amendments. According to the provisions for adopting new legislation the EU Parliament must conduct its second reading within three months of the Council delivering its common position (or else the Council's amendments are deemed to have been accepted), though this time period can be extended by Parliament if it chooses to do so. If the institutions are unable to reach agreement after the second reading (which was the case for REACH), a conciliation committee is set up with an equal number of members from the Parliament and the Council. The committee attempts to negotiate a compromise text which must then be approved by both institutions. Both the Parliament and the Council have the power to reject a proposal either at the second reading or following conciliation, causing the proposal to fail. The Commission may also withdraw its proposal at any time.

### 3.1.2. THE ADOPTION PROCESS

The adoption process of the new chemicals' legislation has been a very long and demanding one. Because of its wide implications in terms of competitiveness and innovation on the one hand, and its aims for a safer environment and human health protection on the other, the proposed legislation went through various phases of intense lobbying and negotiations (for the key steps of the process please see Table A) among the relevant stakeholders.

Due to the strong lobbying and argumentation to influence the final text of REACH carried out by the powerful European chemical industry - the big producers of chemicals rather than the downstream users - but also by other countries with a strong chemical industry (United States, Japan, South Africa etc.) some of the original EC proposals included in the White Paper and the Official Proposal and considered as fundamental for the protection of human safety and environmental health by European civil society organizations and NGOs have been weakened.

Throughout the process leading to the final approval of the new REACH Regulation these organizations - including environmental, consumers, women, animals protection associa-

tions - have fought hard to protect the rights of European citizens for a healthier future.

They have called, in particular, for the following four main points to be safeguarded in the REACH legislation in order to deliver a meaningful minimum level of protection to citizens and the environment:

**1. PLAY IT SAFE:** by requiring substitution of hazardous chemicals, such as those causing cancer, affecting DNA or the reproductive system (CMR) or those that build up in our bodies and the environment or interfere with the hormone system (PBT) with safer alternatives, whenever they exist. They backed the European Parliament provisions emerging from the 1st Reading stating that a continued use (Authorisation) of the most hazardous chemicals should:

- only be granted if no safer alternatives are available and the use is essential to society
- be time-limited to a maximum of five years in order to foster innovation and the development of safer alternatives
- take into account the analysis of alternatives and a concrete substitution plan to be submitted by the applicant as well as substitution information provided by third parties

**2. INFORMATION IMPROVES TRUST:** by asking for the provision of sufficient safety information to identify dangerous chemicals and safer alternatives. Transparent safety and use (exposure) information via the Registration process is essential to enable companies and the authorities to take informed decisions on the safe management of chemicals and identify safer alternatives. In line with European Council proposals, scientific organizations and NGOs supported the idea that under REACH, companies should:

- provide information on long-term effects, including reproductive toxicity, at higher tonnage bands (>10tpa)
- provide good quality use and exposure information (scenarios)
- define risk management measures as required in the Chemical Safety Report from 1 tpa onwards (this had

been proposed by the European Parliament), otherwise the safety information would not result in any practical improvements

**3. A LEGAL GUARANTEE** to ensure the "Duty of Care" e.g the chemical industry's responsibility for the safety of their products, independently from the production volume. As proposed by the European Parliament during its first reading chemical manufacturers, importers and users should be made responsible, on the basis of clear legal provisions codifying existing voluntary commitments by industry, for the safety of their products and guarantee that these products do not negatively affect human health or the environment.

**4. TRANSPARENCY AND THE RIGHT TO KNOW:** Securing transparency for consumer products establishing a "right to know" for citizens. Sufficient, publicly available information is needed to allow chemical users and consumers to make informed choices. Information must be handed down the supply chain to enable retailers and consumers to find out about hazardous chemicals in products. In particular it is considered essential that:

- Citizens have the right to ask about substances present in EU-made and imported products they buy; all articles which contain chemicals of very high concern need to be labeled (as proposed by the European Parliament).
- The list of non-confidential information in REACH needs to be extended to all information relevant for the environment and human health, in line with the Aarhus Convention (access to information).
- Industry should always be obliged to give transparent justifications when applying for information to be kept confidential.

After three years of hard lobbying the REACH Regulation was adopted in a conciliation procedure that implied a series of negotiations between the Council and the European Parliament.

Several European NGOs and other stakeholders, including the Greens in the European Parliament, while recognizing the importance of such a piece of law for an improved, better coordinat-

ed future management of chemicals in the EU, expressed some doubts on the full efficacy of the final compromise package in offering much greater protection to EU citizens from hazardous chemicals, especially since mandatory substitution of substances of high concern in consumer products, where a safer alternative exists, was not ensured.

Table A summarizes the various steps followed in the 6 year period (2001-2006) for the introduction and adoption of REACH.

| DATE | RESPONSIBLE BODY | TYPE OF ACTION |
|---|---|---|
| 13/02/2001 | European Commission | White Paper setting out the strategy for a future Community Policy for Chemicals |
| 29/10/2003 | European Commission | Adoption of the Commission's original proposal on REACH COM(03) 644 (01) and COM(03) 644 (02) amending Directive 67/548/EEC and communication to both the European Parliament and the European Council in November 2003 |
| 17/11/2005 | European Parliament | Adoption of the First Reading Opinion: the work in the European Parliament was led by the Committee on Environment, Public Health & Food safety with the assistance of nine other parliamentary committees |
| 13/12/2005 | European Council | The Council reaches a Political Agreement for a Common Position |
| 27/06/2006 | Environment Council | Adoption of the Common Position serving as the basis of discussion during the Second Reading in the European Parliament |
| 12/07/2006 | European Commission | Adoption of a Communication on the Common Position (COM (2006) 375) and submission to the European Parliament and Council allowing the Second Reading to commence |
| 13/12/2006 | European Parliament | Adoption of REACH at the Second Reading |
| 18/12/2006 | Environment Council | Formal adoption of REACH. The text of the law was published on 30 December 2006 in the official Journal of the European Union L 396 and entered into force on 1st June 2007 |

Given that the whole chemical sector in the EU is heavily regulated (numerous Directives and regulations for its operation, environmental protection, workers protection, safe products for consumers, etc) the big challenge for the future will be to ensure a smooth transition from the old legislation to the New Chemicals Policy- the REACH regime. But it is equally important to make sure that the existing legislation and its amendments be fully and correctly implemented by all Member States.

# 4

# THE NEW REGULATION REACH

## 4.1. What are the most important changes introduced by REACH?

The new Regulation REACH will replace over 40 existing Directives and Regulations creating a single, integrated system for both of what are currently described as "existing" and "new" substances. Substances are now described as **non-phase-in** substances (i.e. those not produced or marketed prior to the entry into force of REACH) and **phase-in** substances (those substances listed in the EINECS, or those that have been manufactured in the Community, but not placed on its market in the last 15 years, or the so-called "no longer polymers" of Directive 67/548).

The main differences between the old system and REACH are summarized below:

| OLD SYSTEM | REACH |
|---|---|
| **1.** System controlled by public authorities | **1.** System controlled by industry |
| **2.** Focus on Risk Assessment of substances | **2.** Focus on Risk Management of substances |
| **3.** Comprehensive assessment of substances | **3.** Targeted and use-specific assessment of substances |
| **4.** Evaluate effects of chemicals | **4.** Evaluate exposure to chemicals |
| **5.** Tests for all chemicals | **5.** Selective tests (including QSARs) |

## ANALYTICAL COMPARISONS OF THE OLD SYSTEM AND REACH

**A.** The old system did not work efficiently and **gaps in our knowledge** on chemicals were not filled but increased exponentially. REACH is expected to close that gap, at least for chemicals produced in volumes higher than 1 ton/year

**B.** In the old system the "**burden of proof**" was placed on the **authorities** (they needed to prove that the use of a chemical was unsafe before they could impose restrictions). REACH puts the "**burden of proof**" **on industry** which has to demonstrate that the chemical can be used safely, and how. The actors of the supply chain will be obliged to ensure the safety of the chemical.

**C.** The old system applied **notification requirements** for "new substances" at a production level of **10 kg** (at least one animal test), at 1 ton (a series of tests had to be undertaken). REACH simplifies that. **Registration** will be required when production/import reaches **1 ton** (animal testing minimized).

**D.** In the old system it was relatively **costly to introduce a new substance** on the market. It encouraged the continued use of "existing", tested or untested chemicals (inhibition of innovation). REACH will **encourage innovation** on safer substances with **lower registration costs** for new substances and the need to consider **safer substitutes**.

**E.** The old system obliged public authorities to perform comprehensive **risk assessments** that were slow and cumbersome. REACH puts the **responsibility on industry** for assessing the safety of chemicals for **specific identified uses**, before the production and marketing. Authorities will concentrate on issues of serious concern with chemicals that are known to be dangerous.

**F.** The old legislation required the manufacturers and importers of chemicals to provide information, but did not impose similar obligations on downstream users (industrial users and formulators) unless the substance had to be classified and a safety data sheet had to be supplied with it further down the supply chain. **REACH brings downstream users into the system**. They are required to consider the safety of their uses of substances, based primarily on information from their suppliers and to apply appropriate risk management measures.

## 4.2. The main steps envisaged by the new REACH policy

### 4.2.1. REGISTRATION

This is, perhaps, the main element of the new system REACH that is based on the "**No data no market**" principle, i.e. that only chemicals about which information is provided will be able to be imported and made available on the EU market in the near future.

The main points of the Registration process are the following:

**a. Chemicals manufactured or imported in quantities of more than 1 ton per year** and per manufacturer/importer will have to be registered in a central database.

**b. Some groups of substances do not need to be registered.** These include polymers and some chemicals regulated under other EU legislation. However, the registration of polymers may be reviewed at a later stage. A "light" registration is required for certain isolated intermediates as long as they are being manufactured under strictly controlled conditions.

**c. Registration would include information** on properties, uses, and safe ways of handling the chemicals in the work environment and by consumers.

**d. The information required for each chemical follows the "proportionality principle": it will be proportional to production volumes and the risk** that the chemical substance poses to environmental and human health and safety.

**e. Safety information on each chemical will be passed down the supply chain.** The aim is to inform the people handling the chemical in their own production processes, or when other products are manufactured using it, so that it can be used in a safe and responsible way.

**f.** The most important part of this process is that it requires manufacturers and importers to **generate data on the substances they manufacture or import, to use this data to assess the risks** related to these substances and to **develop and recommend appropriate risk management measures.**



ECHA For this purpose the EU has established a new Agency, called **European Chemicals Agency (ECHA)**, (in Helsinki, Finland), which will manage the central chemicals database. ECHA will receive the registration dossiers and it will be responsible for provid-

ing non-confidential information to the public. It is anticipated that with the new registration procedure, almost 80% of all registered chemical substances would require no further action by the manufacturers or importers (some chemicals might have problems because of lack of data on their risks).

### 4.2.2. EVALUATION

The evaluation process is of two different types: (a) Evaluation of the dossier and (b) evaluation of the substance:

**Firstly, evaluation of the dossier has to be carried out to check** its compliance with registration requirements and to **assess all animal testing proposals.** The purpose of this compulsory evaluation is to minimize animal testing and costs for the industry to the necessary minimum. REACH requires the sharing of data obtained from these tests among industries and encourages the use of alternative sources of information on chemicals.

**Secondly, an evaluation of the chemical substance follows**. ECHA, in co-ordination with Competent Authorities of Member States may clarify suspicions of risks to human health or the environment by requesting further information from industry.

In order to promote a consistent approach the Agency will, in co-operation with the Member States, develop guidance on the prioritization of substances for further evaluation and it will publish a Community rolling action plan on its website identifying the Member State who shall carry out the evaluation of those priority substances.

For both types of evaluation (dossier and substance), the outcome will be studied by ECHA and there might be cases requesting further information or clarification from industry. ECHA would take the final decision for further information if all Member States agreed, whereas in case of disagreement, the European Commission would take the decision.

### 4.2.3. AUTHORIZATION

This section is deals with **certain chemical substances of very high concern** (in terms of health, safety, environmental pol-

lution) and which **require special authorization** for their use and their placing on the market. Chemical substances of very high concern include:

**a.** Carcinogens, mutagens and toxic to reproduction (CMRs), category 1 and 2[9]

**b.** Persistent chemicals with low biodegradation rates, substances which accumulate in living organisms and the environment and highly toxic substances (PBTs).

**c.** Substances which are very persistent and very bio-accumulative (vPvBs)

**d.** Substances which, on the basis of scientific evidence, have the potential for very adverse effects on humans and the environment, equivalent to those above, on a case-by-case basis, such as endocrine disruptors.

For these chemical substances the new system would pose strict controls and in cases of use **authorization** would be granted under certain conditions. If they could not be adequately controlled, the Commission would look at the level of risk, whether the use of these chemicals is socially and economically important and if there are substitutes. Based on these factors the Commission would decide whether a chemical substance would be authorized. Also, the Commission will be able to **introduce restrictions** on substances that need to be managed at an EU-wide level and to ensure that the risks they pose are "acceptable".

### 4.2.4. RESTRICTION

The restriction procedure enables, regulation, Community wide, of the conditions for the manufacture, placing on the market or use of certain substances where there is an unacceptable

[9] ***Category 1:*** *substances known to be carcinogenic to humans. There is sufficient evidence to establish a causal association between human exposure to the substance and the development of cancer.*

***Category 2:*** *substances that should be regarded as if they are carcinogenic to humans, for which there is sufficient evidence, based on long-term animal studies and other relevant information, to provide a strong presumption that human exposure may result in the development of cancer.*

risk to health or the environment or the prohibition of any of these activities, if necessary. Restriction provisions act, therefore, as a safety net.

Proposals for restrictions are prepared by Member States or by the Agency on behalf of the Commission in the form of a structured Dossier showing that there is a risk to human health or the environment that needs to be addressed at Community level and identifying the most appropriate set of risk reduction measures.

Interested parties have the opportunity to comment and the Agency will provide opinions on any proposed restriction.

Existing restrictions set out in Directive 76/769/EEC (such as the ban on asbestos and restrictions on the use of certain azo-dyes) are carried over in a consolidated version into the REACH Regulation.

# 5 THE DIVISION OF RESPONSIBILITIES IN REACH

## 5.1. Responsibilities of Industry: Manufacturers and Importers

The new system REACH distributes the various responsibilities for a more efficient implementation of the four sections of the new system on concerned actors, **Industry, the European Chemicals Agency, the relevant Authorities of the Member States and the European Commission.**

### REGISTRATION

- Collection and submission of data in line with relevant Annexes and within the deadlines on chemicals produced in more than 1 ton/year
- Assessment of risks and identification of risk management measures
- Keeping registration updated
- Proposing testing schemes
- Where chemical safety assessments are performed according to the registration requirements, relevant exposure scenarios shall be annexed to the safety data sheet (SDS) and shall be thus passed down the supply chain.

### EVALUATION

- Provision of further information, if required so by the Agency and Member States

### AUTHORIZATION

- Submission of application dossier

### RESTRICTION

- Comment on relevant dossiers and the suggested restrictions
- Realization of a socio-economic analysis or provision of information which can contribute to one of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions

## 5.2. Responsibilities of Downstream Users

### REGISTRATION

- Make the use known and provide sufficient information to allow the manufacturer, importer or other downstream user who has supplied the substance to prepare an exposure scenario, or if appropriate a use and exposure category, for a specific use in the chemical safety assessment.
- Assessing the risks arising from the own uses of substances, if those are not covered by a safety data sheet received from the suppliers, unless the downstream user concerned takes more protective measures than those recommended by his supplier or unless his supplier was not required to assess those risks or provide him/her with information on those risks.
- Prepare a chemical safety report for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him/her in a safety data sheet or for any use his/her supplier advises against.
- Report to the Agency certain basic information if their use is outside the conditions of the exposure scenario detailed in the safety data sheet communicated by their original manufacturer or importer and to keep such reported information up-to-date

### EVALUATION

- Provide further information if required so by ECHA and Member States

### AUTHORIZATION

- Downstream users benefiting from an authorization granted to their supplier should inform the Agency of their use of the substance

## 5.3. Responsibilities of the European Chemicals Agency (ECHA)

### REGISTRATION

- Provide advice and assistance to manufacturers and importers
- Receive the registration dossiers and carry out compliance checks
- Handle requests for exemptions from the registration requirement for product and process oriented research and development
- Facilitate the sharing of animal testing data at the pre-registration stage by enabling the formation of the Substance Information Exchange Forums (SIEFs)[10]
- Maintain the database with information on all registered substances, the classification and labeling inventory and the harmonized classification and labeling list and to provide information to the public

### EVALUATION

- To co-ordinate the substance evaluation process and take decisions resulting from evaluations
- To co-ordinate the work of Member State authorities
- To develop evaluation criteria
- To take decisions on requesting more information (from manufacturers) on chemicals if all Member States agree

### AUTHORIZATION

- Publish applications on its website
- Recommend priorities
- Support the Commission in decision making providing expert opinions



[10] *For phase-in substances, potential registrants shall pre-register information to the Agency with the aim of identifying other potential registrants of the same substance and the available information. All potential registrants of the same substance will be participants of a Substance Information Exchange Forum (SIEF). Within a SIEF all reasonable steps shall be undertaken to reach agreements on the sharing of available information and on who will perform new tests on behalf of other SIEF participants. Manufacturers and importers have to take part in the pre-registration of phase-in substances to be able to benefit from the phase-in deadlines for registration, thus to continue with their manufacture or import while they are preparing their registration.*

## 5.4. Responsibilities of Member States' Authorities

### RESTRICTION

- Provide expert opinions and comments
- Publish the Member State restriction proposals and its Committee draft opinions on the internet

### REGISTRATION

- Enforce the REACH regulation through a system of official controls and other activities as appropriate to the circumstances

### EVALUATION

- Develop in cooperation with the Agency criteria for prioritising substances on a risk-based approach with a view to further evaluation
- Review individual dossiers
- Prepare rolling plans for substance evaluations and carry them out
- Prepare draft decisions on further information requirements

### AUTHORIZATION

- Submit proposals (and prepare dossiers) for substances that are considered to pose risks (carcinogens, mutagens, harmful to reproduction, persistent)

### RESTRICTIONS

- Submit proposals and prepare dossiers for substances that may pose a risk to human health or the environment, or are not adequately controlled and need to be addressed

## 5.5. Responsibilities of the European Commission

### REGISTRATION

- Review exemptions to the requirement to register for substances contained in Annexes IV and V, within 12 months after the entry into force of the Regulation

### EVALUATION

- Take decisions on requesting more information from industry, if Member States do not all agree on certain chemicals

### AUTHORIZATION

- Take decisions on priority setting (step 1) and on granting authorizations (step 2)
- Set the length of the authorization review period after a certain time, on a case-by-case basis

### RESTRICTION

- Take decisions on restrictions of production, marketing and use of dangerous chemicals

# 6 PROSPECTS OF THE REACH SYSTEM: QUESTIONS AND ANSWERS

## 6.1. Registration

The Commission has prepared a series of questions and answers concerning the three steps of REACH to make the system better understood. We summarize herewith those we consider interesting for educational purposes.
The full text is available at:

*http://www.lifesciences.at/ download.asp?id=1459*

### How many substances have to be registered?

The new REACH system is expected to process around 30.000 phase-in chemical substances (excluding intermediates) plus a number of "non-phase-in" substances on a phased basis over a period of 11 years (ending 2018) starting with those chemicals produced in highest volumes and marketed for commercial use.

Of the 100.000 existing substances listed in the EINECS inventory only those manufactured or imported in volumes starting at 1 ton need to be registered. Substances listed in the HPV-LPV list might give a good indication of existing substances marketed in volumes at or above 10 tons per year that will need to be registered.

Manufacturers and importers of substances listed in EINECS will have to pre-register their substances from 12 to 18 months after entry into force of REACH and the Agency will make publicly available the list of all pre-registered substances within 19 months of entry into force.

The Commission's schedule for chemical registration is according to volume:

**a.** Substances produced in more than 1000 ton/year (within 3 years 2007-2010)

**b.** Also, carcinogenic/mutagenic/toxic to reproduction substances must be registered within 3 years

**c.** Substances with a production volume of more than 100 ton/year but less than 1000 ton/year (within 6 years 2007-2013),

**d.** Substances with production volume of between 1 and 100 ton/year within 11 years (2018).

Manufacturers and importers of chemicals (from the existing list) must compile information on each chemical produced. New chemicals will be registered as they are introduced in the market. The Commission believes that after 11 years, by the year 2018, all existing chemicals (produced in more than 1 ton/year) will have been dealt with (there will be a dossier) and the system will continue to operate for new chemicals only. Registration data will be collected by the Agency.

Concerned with the importance of securing environmental and human health safety through stringent requirements for all registered substances European NGOs and Trade Unions (under the coordination of the European Trade Union Institute, ETUI) actively lobbied so that substances manufactured or imported at 1-10 ton/year could have a similar treatment as substances from 10 ton/year upwards.

They argued that, from the 30.000 substances to be registered **around 20.000 are in the range 1-10 tons/year, i.e. more than 66% of the total** (4.600 chemicals are the estimated chemicals in the range 10-100 tons, 2.800 in the range of 100-1000 tons and 2.600 more than 1.000 tons).

In the end, this demand was not accepted and so REACH now requires that the technical report accompanying the substances manufactured or imported in volumes between 1-10 tons/year includes information on the identity, properties or classification of the substance but not a chemical safety reports, which is required for substances of the higher tonnages. This means that there will be no chemical safety report for 20.000 chemicals registered under REACH, although, as European NGOs and Trade Unions argued, the obligation for these additional safety reports would add only marginally to the total costs of registration, while increasing the safety of workers significantly and it would improve the 98/24/EC Directive (assessment of risks to workers' health by chemicals).

## Which substances are exempted from Registration in the REACH system?

**a.** Substances manufactured or imported in **volumes < 1 ton** (NB: there is no such volume-based exemption for authorization, restriction or the classification and labeling inventory).

**b.** Substances described in **Article 2 (1,2,3)** of the REACH text: radioactive substances, non-isolated intermediates (chemicals used to make other chemicals and never separated from the mixture), wastes, substances under customs supervision and, if the Member States so choose, substances necessary for defense purposes.

**c.** Substances exempted from the **present legislation** (Existing Substance Regulation, Reg. 793/93) with the addition of cellulose pulp as listed in Annex IV of the REACH text.

**d.** A number of **classes of substances** (Annex V of the REACH text) are exempted from registration unless they are chemically modified. In addition, a number of basic elemental substances for which the hazards and risks are well known are also exempted.

**e. Polymers** should be exempted from registration and evaluation until those that need to be registered due to the risks posed to human health or the environment can be selected in a practicable and cost-efficient way on the basis of sound technical and valid scientific criteria.

**f. Substances** (i.e used in medicinal products for human or veterinary use, in food or feeding stuffs) and **preparations**[11] in the finished state (medicinal products for human or veterinary use, cosmetic products, medical devices which are invasive or used in direct physical contact with the human body, food or feeding stuffs etc.), **covered by other EU legislation**.

**g. Isolated intermediates** will have to be registered, but with simplified information requirements (isolated means that substances have been separated from other substances).

**h. Substances in articles**, e.g. shoes, textiles, toys, etc. must be registered only if both the following conditions are met:

[11] *mixtures or solutions composed of two or more substances*

(a) the substance is present in those articles in quantities totalling over 1 ton per producer or importer per year;

(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

In addition, all substances of very high concern (on a list of candidate substances for authorization that will be produced by the Agency) present in articles above a concentration limit of 0.1% weight by weight and present at more than 1 ton per year must be notified to the Agency except where exposure to humans and environment can be excluded during normal conditions of use, including disposal. In such case safety instructions should be provided. Information will also be made available to consumers on request. As a safety net, the Agency can require Registration of a substance in an article at any time when it considers that its release poses risk to human health or the environment.

### What about preparations of chemicals?

Registration under REACH is only for substances, not preparations or articles. The substances in preparations and articles are potentially subject to Registration. However, if all or certain parts of a Chemical Safety Report are relevant for other substances, it can be used for those other substances., e.g., if an exposure scenario (ES) covers the risks of all dangerous substances (at or above 10 tonnes per year) in a preparation, such a exposure scenario can be used for all those substances.

### How will substances for product and process orientated research and development (PPORD) be dealt with?

PPORD substances are exempted from registration requirements for a period of 5 years. This exemption is for manufacturers and importers doing research, either by themselves or with listed customers. Downstream Users requirements don't apply because the supplier is not required to make a CSR and would not be supplied to others in the supply chain for commercial purposes.

The PPORD exemption applies to Downstream Users using a substance for PPORD and where risks to human health and the environment are adequately controlled. However, if the substance is used in quantities bigger than 1 ton per user per year then the Downstream Users must report this to the Agency.

## What are the differences between Chemical Safety Reports (CSR) and Safety Data Sheets (SDS)?

**Chemical Safety Reports** are documents through which industry can demonstrate that it can use chemicals safely. Manufacturers and importers must prepare CSRs for substances in volumes at or above 10tons/year. CSRs document the hazards and classification of a substance and the assessment as to whether the substance is PBT or vPvB. They also describe exposure scenarios for specific uses of substances that are classified as dangerous or are PBT or vPvB substances. Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends to control, exposures to humans and the environment. Exposure scenarios must include the appropriate risk management measures and operational conditions that, when properly implemented, ensure that the risks from the uses of the substance are adequately controlled. Exposure scenarios need to be developed to cover all "identified uses" which are the manufacturers' or importers' own uses and they need to be annexed to the Safety Data Sheets supplied to downstream users and distributors. Downstream users may require their suppliers to address their use in the chemical safety report (called an identified use). If they decide to protect information on their use from their manufacturer or importer and this use is not covered in the exposure scenario annexed to the SDS and in total they use 1 tonne or more of the substance, they have to prepare their own CSR. If they use less than 1 ton of the substance they should consider the use(s) of the substance and identify and apply any necessary risk management measures.

**Safety Data Sheets** are summaries of information on the properties of substances and the safe means of using them. They are a long-established and primary tool of transmitting safety information down the supply chain for all dangerous substances. REACH will take over the current safety data sheet requirements contained in Directive 91/155/EEC. Furthermore, by establishing more data and requirements for SDS to be provided for PBT or vPvB substances and preparations containing them, as well as triggering information exchange in the chemical product chain, REACH is expected to improve the quality of SDSs. In particular, the exposure scenarios derived from chemical safety reports are to be annexed to SDSs in order to facilitate the application of appropriate risk management measures.

New information on hazardous properties and information that challenges the quality of risk management measures in the SDSs shall be passed up the supply chain

## Which laboratories or institutions in which countries could be recognized or designated to supply their testing data or information?

REACH is not intended as a testing programme. New testing should only be a last resort and available information should be used wherever possible. The registrant will have to make decisions as to what is reasonable information for use in a Registration. Guidance on information requirements will be developed.

The new system REACH places responsibility on industry to provide adequate information. No specific laboratories will be recognized or designated under the provisions of REACH. New toxicological or ecotoxicological tests and analyses need to be carried out in accordance with Good Laboratory Practice (GLP)[10] or other international standards recognized by the Commission or the Agency.

[10] *Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, agrochemicals, veterinary medicines, industrial chemicals, cosmetics, food and feed additives and biocides. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments (OECD).*

## 6.2. Evaluation

The evaluation process will ensure that reliable and useful data is provided and made available to the relevant bodies by ECHA. Evaluation may lead authorities to the conclusion that action needs to be taken under the restrictions or authorization procedures in REACH, or that information needs to be passed on to other authorities responsible for relevant legislation.

### Where is the boundary between registration (completeness check) and dossier evaluation?

Registration includes a "completeness check", which is only an automated check of the availability of all required information in the dossier and it does not constitute any check on quality.

Dossier evaluation will be a substantial quality check of selected elements of the Registration dossier(s) of at least 5% of the dossiers registered in each tonnage band and the evaluation of all testing proposals for tests listed in the relevant Annexes of the REACH test (Annex IX and X).

It should be noted that registrants are not obliged to have carried out all tests before the registration deadline, they only need to submit a testing proposal for carrying out the tests. After they have received the green light from the Agency they will be given a new deadline for submitting the test data.

### What are the reasons for thorough evaluation of a substance?

Substance evaluation can be performed when there are reasons to believe that a substance may present a risk to human health or to the environment. Reasons for this action can be structural similarities (or QSAR studies) with other dangerous substances. Also, ECHA, after looking at all the Registration dossiers submitted for the same substance, could take into account any available information on dangerous properties. ECHA will develop criteria to assist industry and authorities with prioritization of substance evaluation. A competent authority from the Member States will be designated in each case to carry out an evaluation based on rolling plans. An evaluation outcome may be that the registrant(s) have to provide additional information.

## 6.3. Authorization

### What does it mean when a substance needs "authorization"?

Authorization is needed for substances of very high concern. These substances can be used and put on the market only with special permission. The identification of the different groups of substances that may be subjected to authorization is clearly defined. For the carcinogenic, mutagenic or toxic to reproduction (CMR) category 1 and 2 substances, the criteria have long been established in the present legislation (Directive 67/548). For persistent (like persistent organochlorines), bioaccumulating and toxic (PBT) and very persistent, very bioaccumulating (vPvB) substances, the criteria are included in Annex XIII of the REACH text. For any other substances there must be scientific evidence of probable serious effects to humans or the environment which give rise to an equivalent level of concern as CMRs category 1 and 2, PBTs or vPvBs.

ECHA will grant authorization permits. Authorisation will be granted for substances if the risks they are associated with can be adequately controlled or for those chemicals where valid social and economic reasons support their use, especially if there are no alternatives.

### Can applications for Authorization be submitted together?

Grouping of applications for Authorization is allowed by the Regulation. Groups can be of: manufacturers, importers and downstream users substances and uses or any combination of these groups. This is to enable costs to be minimized and the process of application to be advanced rapidly.

### How will "substances of equivalent concern" be identified and agreed ?

All substances will be identified through an open process and the decision to include the substance in Annex XIV will finally be taken by the Commission in accordance with the Comitology procedure[13]. Dossiers to identify a substance for the authoriza-

[13] *Most EU regulation in not enacted as legislation by the Council and Parliament but as implementation measures under the executive duties of the Commission. Such regulation can be adopted when the Council has conferred executive powers on the Commission and after an Implementation Committee, composed of policy experts from the Member States, has given its opinion on or approved the Commission's proposed measures. The Committee procedures are commonly referred to as "comitology".*

tion procedure will be prepared either by a Member State or by the Agency if asked for by the Commission. All dossiers will be published and will be open for comments by interested parties. Substances identified as having any of the listed properties of very high concern will be included on a candidate list published by the Agency within which the Agency indicates the substances that are on its work programme. The Agency then recommends substances to the Commission for inclusion in Annex XIV. Priority will normally be given to substances with PBT or vPvB properties with wide dispersive use or in high volumes. These substances may then finally be included in Annex XIV.

## How are substances of very high concern produced in small volumes treated under REACH?

Any substance identified as being of very high concern may be considered for Authorization, independently of its volume. However, if a particular substance has never been registered in the EU due to its very low production volume (less than 1 ton/year) and has never has been tested otherwise, then its hazardous properties may not be known and it is therefore not likely to be a priority for subjection to Authorization.
The safety net is provided by the competent authorities of Member States: if they identify substances with potentially very high concern properties, they can draw attention to them and suggest that they be subject to Authorization.
Authorization will also have a prioritization approach based, amongst other criteria, on volume, meaning that in many instances low volume substances will not be selected for Authorization at an early stage.

## What is substitution?

If companies cannot adequately control the risks posed by substances of very high concern they need to examine ways of **substituting** them or changing processes so that the risk can be controlled. A plan for substituting the substance shall include a timetable for proposed actions by the applicant. In addition, the analysis of alternatives should show, if appropriate, any action the applicant is taking to work towards a substitute for their product, the Research and Development (R&D) work towards this goal and the likely timescale for it.
PBTs, vPvBs and CMR substances (category 1 and 2) for which

a safe level cannot be defined, cannot be authorized based on adequate control of risks.
If suitable alternative substances or technologies are not available an authorization may still be granted if it is shown that the related socio-economic benefits outweigh the risks to human health or the environment arising from the use of the specific substances.
If suitable substitutes are not currently available the applicant may provide information about any relevant R&D. The assessment whether a suitable alternative is available must take into account both the technical and economic feasibility of substitution for the applicant.

## 6.4. Classification and Labeling

### Why is the United Nations Global Harmonized System (GHS)[14] not included in the REACH proposals?

GHS was not formally adopted by the UN at the time of the drafting and agreement of the REACH Regulation in the Commission. The Commission has adopted a proposal for a Regulation to implement GHS that aligns the EU system of classification, labeling and packaging substances and mixtures to the UN Globally Harmonized System. It is expected to facilitate global trade and harmonized communication of hazard information of chemicals and to promote regulatory efficiency. It will complement the new REACH Regulation on the registration, evaluation, authorization and restriction of chemicals.



[14] *The "Globally Harmonized System of Classification and Labeling of Chemicals (GHS)" addresses classification of chemicals by types of hazard and proposes harmonized hazard communication elements, including labels and safety data sheets. It aims at ensuring that information on physical hazards and toxicity from chemicals is available in order to enhance the protection of human health and the environment during the handling, transport and use of these chemicals. The GHS also provides a basis for harmonization of rules and regulations on chemicals at national, regional and worldwide level, an important factor also for trade facilitation.*

## 6.5. ECHA and Competent Authorities

### Accessibility to ECHA databases and available information. How will the permissions management work?

A procedure is established where confidential information is to be made available to interested parties after their request directly to the European Chemical Agency, unless the information is commercially sensitive.

## 6.6. Enforcement

### What types of enforcement mechanisms has the Commission considered when developing REACH?

It is expected that actors down the supply chain, in particular in smaller enterprises, have a competence in risk management (this is required by the current legislation) but not necessarily in risk assessment. This is also the case for inspectors.

The know-how regarding the hazards and potential risks of chemicals generally lies with the manufacturers and importers and with the national agencies/authorities.

The **exposure scenarios** are the conditions of use, including risk management measures, which, when implemented, can ensure safe handling and use of the substance. It is therefore built up of elements which the local risk managers down the supply chain understand and can apply. They are also enforceable by inspectors as they are formulated in risk management terms, not requiring any deep knowledge of toxicology from the inspector. Inspectors, therefore, will be able to check if the exposure scenario listed in the CSR/SDS or the CSR developed by the downstream user is in fact implemented.

The national agencies have full access to this information and they can check if the emissions generated by applying the exposure scenarios are sufficiently low. This concept is more easily enforceable and provides better protection than does the current legislation.

# 7

# REACH IMPLEMENTATION PROJECTS (RIPS)

**Another body, closer to research, the European Chemicals Bureau (ECB) has the responsibility of developing methodologies, tools and technical guidance needed for REACH through a number of REACH Implementation Projects (RIPs).**

The aim of the REACH Implementation Projects (RIP's) is to ensure an efficient implementation of the future legislation through the development of guidance and IT-tools for the Agency, industry and the authorities. The RIPs include 7 main areas and a number of sub-subjects, which are outlined below. The activities are coordinated closely with the main stakeholders i.e. Member States, Industry, NGOs.

The 7 individual implementation projects are:

**RIP 1 - REACH Process Description: Development of a detailed description of the REACH processes**

Aim / Objectives: To achieve a better stakeholder understanding of the REACH procedures and to provide a basis for the detailed work in the other RIP projects.

**RIP 2 - REACH-IT: Development of the IT system set up to support REACH implementation (http://ecb.jrc.it/reach-it/)**

Aim / Objectives: To ensure that the REACH processes in ECHA, the Members States Competent Authorities, the Industry, the Commission and other affected stakeholders are supported (and partially enabled) by (an) appropriate IT system(s) and corresponding interfaces.

This includes the following objectives:

- The REACH workflow is automated by an IT system;
- The REACH dossier submission is mainly organised through an IT system;

- The REACH dossier creation and management is supported by a new version 5 of IUCLID, already well introduced in the stakeholder community in its version 4;
- Non-confidential REACH data are published on a REACH dissemination website;
- Future corrective and evolutive maintenance of the REACH-IT and IUCLID 5 systems are taken over by the most appropriate organisations;
- Future first-level support (helpdesk) is run by the most appropriate organisation.

Additional objectives:

- The IUCLID 5 system must also be able to accommodate non-REACH requirements.

### RIP 3 - Guidance Documents: **Development of guidance documents for industry (http://ecb.jrc.it/reach/rip/)**

Aim / Objectives: To develop in time before entry into force of the REACH legislation the appropriate guidance documents and tools for industry in order to facilitate a smooth implementation of the legislation.

### RIP 4 - Guidance Documents: **Development of guidance documents for authorities (http://ecb.jrc.it/reach/rip/)**

Aim / Objectives: To develop in time before entry into force of the REACH legislation the appropriate guidance documents and tools for the authorities in order to facilitate a smooth implementation of the legislation.

### RIP 5/6 - Setting up the Agency

To establish the European Chemicals Agency within 18 months of entry into force of REACH, ensuring that it can effectively, efficiently, and transparently carry out the tasks allocated to it.

### **Overall Guidance Package** (http://echa.europa.eu/reach_en.html)

Aim / Objectives: To facilitate the accessibility to the guidance developed under the RIP 1, 2, 3 and 4 a web application has been developed. This REACH Guidance Website contains:

- a brief description of REACH,
- the Technical Guidance Documents for the implementation of REACH developed within the RIPs),

- a tool for helping industry to figure out their obligations under REACH and guiding them through the guidance developed to fulfil these obligations.

This Overall Guidance Package is available on the European Chemicals Agency (ECHA) website: http://echa.europa.eu/reach_en.html.

### IT TOOLS: REACH-IT and IUCLID 5

**The REACH-IT system** is a central system running in the data centre of ECHA. It enables all stakeholders (ECHA, European Commission, Member State Competent Authorities, industry, NGOs, general public) to submit (mostly industry), retrieve, exchange, evaluate, further treat (mostly authorities) and view (general public) information on chemical substances.

REACH-IT consists of three main parts:

**1. The industry homepage** is addressed mainly to manufacturers, importers, and downstream users. This is the place where, amongst others, a company can pre-register or make inquiries on substances, submit Registrations, download invoices and view the status of submitted registrations and payments. In addition, it will allow online preparation of certain types of dossiers, e.g. PPORD notification, C&L notification, downstream user notification - users will have their private workspace where they can prepare dossiers.

**2. The Authorities workflow** is addressed to the Agency and Member States Competent Authorities staff. This part of REACH-IT supports the communication between the ECHA and the Member States Competent Authorities and enables them to fulfil their tasks under Registration, evaluation, Authorization, restriction and classification and labelling of substances.

**3. The dissemination website** is addressed to the general public and makes available all non-confidential data on chemicals (e.g. physicochemical data, the results of toxicological and ecotoxicological studies, the classification and labeling inventory) as well as the information on the status of those chemicals.

**IUCLID** (**I**nternational **U**niform **C**hemica**L** **I**nformation **D**atabase) is a software application that can be used by anyone (especially chemical industry companies and government authorities) to capture, store, maintain and exchange data on intrinsic and hazard properties of chemical substances.

IUCLID is maintained under the responsibility of the Toxicology and Chemical Substances (TCS), commonly known as European Chemicals Bureau (ECB) within the Institute for Health and Consumer Protection (IHCP) of the Joint Research Centre (JRC) of the European Commission based in Ispra, Italy, and is distributed free of charge.

In 2003, when it became clear that the REACH proposal would be adopted sooner or later by the European Union, the European Commission decided to completely overhaul IUCLID4 (the previous version) and to create a new version, IUCLID5, which will be used by chemical industry companies affected by REACH to fulfil their data submission obligations.

In particular IUCLID5 enables to prepare a Registration dossier as well as to prepare other types of dossiers (PPORD dossiers, C&L notifications, notifications of substances in articles, DU reports and Annex XV dossiers).

IUCLID5 is built using internationally harmonized formats for reporting data on chemicals that were prepared and accepted by many national and international regulatory authorities within the OECD.

The use of IUCLID by industry can be twofold:

- Any company can use its local IUCLID5 installation to collect, store and maintain relevant data on its substances. Once all the data necessary for a dossier (be it a Registration dossier, a notification of C&L or of substances in article, a DU report, etc.) are included into IUCLID, the user can automatically create its dossier for submission to the European Chemicals Agency. This way, the data which has been stored once in IUCLID, can be used in several types of dossier, or when an update of a dossier is requested.
- When the company decides to submit the dossier, it will do it via the Industry homepage of REACH IT where it will use the appropriate functionality to submit the dossier file.

IUCLID5 is provided free of charge to all stakeholders (companies, Member States, individuals, universities, research organizations etc).

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# ACRONYMS

**CEC:** Commission for Environmental Cooperation

**CMRs:** Carcinogen, mutagen and toxic to reproduction

**DDT:** Dichloro-Diphenyl-Trichloroethane

**DU:** Downstream Users

**ECB:** European Chemicals Bureau

**ECHA:** European Chemicals Agency

**EINECS:** European Inventory of Existing Commercial Chemical Substances

**ELINCS:** European List of Notified Chemical Substances

**EPA:** Environmental Protection Agency

**ES:** Exposure Scenarios

**ETUI:** European Trade Union Institute

**EU:** European Union

**GHS:** United Nations Global Harmonized System

**HPVC:** High Production Volume Chemicals

**IARC:** International Agency for Research on Cancer

**IHCP:** Institute for Health and Consumer Protection

**ILO:** International Labour Organization

**IOSHHAS:** International Occupational Safety and Health Hazard Alert System

**IPPC Directive:** Intergrated Pollution, Prevention and Control Directive

**IRPTC:** International Registry of Potentially Toxic Chemicals

**IUCLID:** International Uniform Chemical Information Database

**LPVC:** Low Production Volume Chemicals

**MIO-ECSDE:** Mediterranean Information Office for Environment

**NGO:** Non Governmental Organization

**OECD:** Organization for Economic Co-Operation and Development

**PBT:** Persistent, Bioaccumulative and Toxic

**PCBs:** Polychlorinated Biphenyls

**POPs:** Persistent Organic Pollutants

**PPORD:** Product and Process Oriented Research and Development

**R&D:** Research & Development

**REACH:** Registration, Evaluation and Authorization of Chemicals

**RIPs:** Reach Implementation Projects

**SDS:** Safety Data Sheet

**SIEFs:** Substance Information Exchange Forums

**TCS:** Toxicology and Chemical Substances

**TOSCA:** Toxic Substances Control Act

**UNEP:** United Nations Environmental Programme

**vPvB:** very Persistent and very Bioaccumulative

**WHO:** World Health Organization

**WSSD:** World Summit on Sustainable Development

Mediterranean Information Office for Environment, Culture and Sustainable Development

Commission of the European Union DG Environment

National and Kapodistrian University of Athens, Department of Chemistry

Association of Greek Chemists