



Environment fact sheet:

REACH

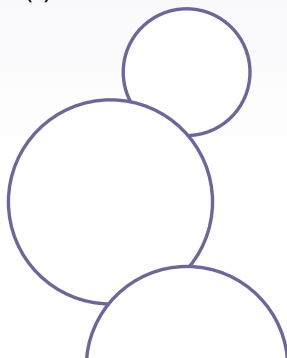
— a new chemicals policy for the EU



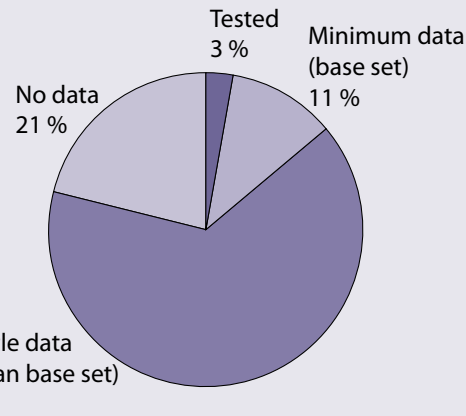
- Modern society needs chemicals, and the EU chemicals industry is an important sector for the EU's economy. But the production and wide-spread use of substances may pose risks to human health and the environment.
- The number of incidents of allergies, asthma, certain types of cancer, and reproductive disorders in Europe is increasing. It is suspected that chemicals are contributing to this trend, but we need more information.
- We know very little about our chemicals: for 99 % we don't have enough information about effects, uses and how they need to be handled to be safe.
- The proposed new EU chemicals policy, REACH, will require producers and importers of chemicals to register them along with the information needed to use them safely.
- REACH will provide a high level of protection of human health and the environment. At the same time, it will enhance the competitiveness of the EU chemicals industry by fostering innovation and ensuring high safety standards for its products.

Potential negative effects of chemicals

- The number of incidents of allergies, asthma, certain types of cancer, and reproductive disorders, including low sperm counts, are on the increase in Europe. Chemicals may be one of the causes.
- Some chemicals have endocrine-disrupting properties, which means they mimic or inhibit hormones. In some animals, such as frogs, birds, fish and molluscs, they have produced infertility and gender changes.
- In 2004, the environmental campaign group WWF tested the blood of government ministers from 13 EU Member States for chemicals that can negatively affect human health and wildlife. WWF found on average 37 out of the 103 tested substances in the ministers' blood ⁽³⁾.
- Some chemicals can travel long distances. High levels of toxic chemicals have been found in Inuit and polar bears. Chemicals can also accumulate in mothers' milk.
- Two studies commissioned by the European trade unions' association ETUC show that a third of all recognised occupational diseases in Europe are related to exposure to chemicals. The benefits of REACH for occupational skin and respirator diseases could range from EUR 21 to 160 billion in the next 30 years. ⁽⁴⁾.
- According to the EU Agency for Safety and Health at Work, occupational skin diseases alone result in the loss of 3 million working days each year, valued at EUR 600 million ⁽⁵⁾.



Information about high-volume chemicals



Fact 1: We need chemicals and a strong industry

Today, chemicals are the basis of most of our products. They can make them soft or firm, washable or degradable, transparent or colourful, whatever the specific need. Since 1930, global production of chemicals has risen from 1 million tonnes to over 400 million tonnes annually.

The chemicals industry is important to the EU economy. The chemicals sector is the third-largest manufacturing industry in the EU, encompassing 31 000 companies that employ 1.9 million people. Internationally, the EU is the leading chemicals-producing area. In 2004, it accounted for 33 % (EUR 580 billion) of global sales (EUR 1 736 billion) ⁽¹⁾.

Fact 2: Chemicals can pose risks, but information is sketchy

Chemicals can have hazardous properties. They can be irritant, toxic and corrosive; and they can cause cancer, mutations and reproductive problems. The problem is that we know very little about the vast majority of the chemicals we use.

In the EU, more than 100 106 chemicals were reported to be on the market in 1981, which was the first and only time that the chemicals used in the EU were listed.

For 99 % of chemicals (by volume), information on properties, uses and risks is sketchy. Chemicals produced in high volumes (above 1 000 tonnes per year) have been examined more closely. Still, there are no data for about 21 % of those, and another 65 % come with insufficient data ⁽²⁾.

⁽¹⁾ 'Fact and figures — The European chemical industry in a worldwide perspective', January 2005, CEFIC (European Chemical Industry Council) (<http://www.cefic.org/factsandfigures/>).

⁽²⁾ 'Public availability of data on EU high production volume chemicals', European Chemicals Bureau, Joint Research Centre, European Commission (<http://ecb.jrc.it/Data-Availability-Documents/datavail.doc>).

⁽³⁾ 'Bad blood? A Survey of chemicals in the blood of European ministers', WWF, October 2004 (<http://www.worldwildlife.org/toxics/pubs/badblood.pdf>).

⁽⁴⁾ 'The impact of REACH on occupational health', School of Health and Related Research (University of Sheffield, UK), September 2005 and 'Skin sensitisers', *Facts*, Issue 40, European Agency for Safety and Health at Work, June 2003.

⁽⁵⁾ <http://agency.osha.eu.int/publications/factsheets/40/en/index.htm>

Fact 3: Current legislation does not provide the necessary level of protection

Current EU legislation on chemicals makes a distinction between:

- chemicals put on the market **after** 1981, so-called 'new substances' (around 4 000 until now); and
- chemicals put on the market **before** 1981, so-called 'existing substances' (100 106 substances).

To avoid risks, new substances must be tested and notified to the authorities before they can be marketed.

With regard to the 100 106 existing substances, public authorities are in charge of identifying the hazardous among them, prioritising those used in highest volumes for risk assessment and, where needed, developing risk management measures. This is a complex procedure that depends on information from industry. Since 1993, the European Commission and Member States have prioritised 141 high-volume chemicals, but the procedure has so far been finalised for only 39 substances.

This system is unable to produce the level of protection that is needed. Most chemicals continue to be used without safety information. In addition, the system discourages the introduction of new and possibly safer chemicals, as it is easier to continue to use existing substances than to introduce new ones which have to be tested and notified.

EU citizens are concerned. In a recent survey, the impact of chemicals used in everyday products came fifth in a list of 15 environmental issues of concern. When asked about which issue they feel they lack information, citizens cited chemicals first ⁽⁶⁾.

Fact 4: We need REACH to be able to use chemicals safely

On 29 October 2003, the European Commission presented a proposal for a new EU regulatory system for chemicals: REACH, which stands for Registration, Evaluation and Authorisation of CHemicals. REACH places responsibility for the safety of chemicals on manufacturers and seeks to produce the information on chemicals that has been lacking so far.

Registration: Under REACH, each producer and importer of chemicals in volumes of 1 tonne or more per year and per producer/importer — around 30 000 substances — will have to register them with a new EU Chemicals Agency, submitting information on properties, uses and safe ways of handling them. They can use existing data and share data. The producers and importers will also have to pass the safety information on to 'downstream users' — manufacturers that use these chemicals in their production processes — so that they know how to use the substances without creating risks for their workers, the end consumers and the environment. The Agency will make non-confidential information available to the public.

Evaluation: Through evaluation, public authorities will look in more detail at registration dossiers and at substances of concern. They can request more information if necessary. At this stage, they will also scrutinise all proposals for animal testing to limit it to the absolute minimum. REACH makes data-sharing on animal test results compulsory and prescribes the use of alternative methods wherever possible.

Authorisation: Use-specific authorisation will be required for chemicals that cause cancer, mutations or problems with reproduction, or that accumulate in our bodies and the environment. Authorisation will be granted only to

Making the most of REACH: What will it bring?

- A high level of protection from the risks that chemicals may pose to human health and the environment, through the generation and dissemination of information on chemicals, in particular safety information.
- A sustainable and competitive EU chemicals industry that can innovate more easily and whose products meet high safety standards. This will increase consumer confidence, reduce liability risks and improve workers' health. Downstream users will enjoy much of the same benefits and know more about the chemicals they use.
- Compliance with the global commitment agreed at the 2002 World Summit on Sustainable Development in Johannesburg 'to achieve, by 2020, that chemicals are used and produced in ways that lead to a minimisation of significant adverse effects on human health and the environment'.



⁽⁶⁾ 'The attitudes of European citizens toward the environment', Special Eurobarometer 217 / Wave 62.1, conducted in November 2004, published in April 2005 (<http://europa.eu.int/comm/environment/barometer/index.htm>).

State of play in January 2006

The adoption of the proposed REACH Regulation involves the Council of Ministers and the European Parliament (co-decision procedure). In first reading, the Parliament proposed amendments on 17 November 2005. The Council reached a political agreement on 13 December 2005, taking into account many of the Parliament amendments.

The proposed changes do not alter the basic structure of REACH. They lower information requirements for substances in the 1 to 10 tonne range and increase them for substances of highest risk, providing an incentive to substitute them. For SMEs, they reduce the administrative burden and costs.

It is expected that the Parliament and Council will reach final agreement in second reading, which is scheduled for the second half of 2006. In that case, REACH could enter into force in 2007. The new European Chemicals Agency will be fully operational 12 months later.

In the meantime, the European Commission is producing, in consultation with stakeholders, technical guidance documents and computerised tools based on practical trials of REACH. It is also developing an 'interim strategy' with Member States and industry to prepare for a smooth transition.

companies that can show that the risks are adequately controlled or if social and economic benefits outweigh the risks where there are no suitable alternative substances or technologies. This will encourage substitution — the replacement of such dangerous chemicals with safer alternatives.

Restrictions: The Commission will continue to be able to restrict the use of certain dangerous substances at EU level, but REACH will introduce clearer procedures and allow for decisions to be taken more quickly than is currently the case. The provisions for restrictions will act as a safety net.

Fact 5: REACH is the result of a comprehensive consultation process

REACH is the result of a comprehensive drafting and consultation process run jointly by the Commission's Environment and Enterprise Directorates-General.

When EU environment ministers came together in 1998 on the UK town of Chester, they agreed to ask the European Commission to review the current policy on chemicals. The result was a decision to reform it. The development of REACH included a White Paper in February 2001 and thousands of meetings with stakeholders (industry, foreign trade partners and retail, consumers', environmental and animal welfare groups). In 2003, an Internet-based consultation on a first draft of the proposal was conducted, which attracted over 6 000 comments. Based on these comments, the proposal was streamlined and expected costs were cut by 80 %.

Fact 6: The costs under REACH are manageable

The Commission has conducted an extended impact assessment on REACH. Macroeconomic effects in terms of GDP are expected to be limited, and REACH is expected to yield business benefits including improvements in innovation, competitiveness and workers' safety, as well as significant health cost savings.

The costs of registration, including the necessary testing, are estimated at EUR 2.3 billion over the 11 years that it will take to register all the substances covered by REACH. The total costs, including those to downstream users, are estimated at EUR 2.8 billion to EUR 5.2 billion, depending on the extent to which registration costs will increase prices of chemicals and on the costs of substituting chemicals that will be withdrawn (an estimated 1–2 %).

If REACH succeeds in reducing chemical-related diseases by only 10 %, the health benefits are estimated at EUR 50 billion over 30 years.

Further reading

European Commission REACH web sites:

DG Environment: www.europa.eu.int/comm/environment/chemicals/reach.htm

DG Enterprise and Industry: www.europa.eu.int/comm/enterprise/reach/index_en.htm

Decision-making process in the Council and the Parliament

www.europa.eu.int/prelex/detail_dossier_real.cfm?CL=en&DosId=186450

Information on the interim strategy

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

CEFIC (European Chemical Industry Council)

www.cefic.be/Templates/shwStory.asp?NID=29&HID=441

WWF (World Wildlife Fund)

www.panda.org/campaign/detox/the_problem/
www.worldwildlife.org/toxics/index.cfm

Greenpeace

eu.greenpeace.org/issues/chem.html

February 2006