

REACH in brief

The essentials of the EU chemicals reform

REACH, which stands for the **R**egistration, **E**valuation, **A**uthorisation and restriction of **C**hemicals, will undergo its 2nd Reading vote on 13 December in Strasbourg. The vote is likely to be a formality, since the main political groups in the Parliament agreed – at a meeting behind closed doors with the European Commission and Council in early December - on a compromise deal. This is expected to be ratified by member states on 18 December at the Environment Council. According to its present timetable, REACH will come into force on 1 June 2007.

The problem

Over 90% of all chemicals on the European market today have never been tested for their effects on health and the environment.

- Almost all the approximately 104,000 chemicals known today were first produced before 1981. These "existing" substances, as they are called, have never been adequately tested to see how dangerous they are. Better data is available on the 3,500 "new" substances which have come onto the market since 1981.
- For most chemicals, we know very little: whether, for example, they damage genes, cause allergies, accumulate in the food chain or are carcinogenic. *"Even with mass-produced chemicals which are produced in thousands of tonnes every year,"* the German environment ministry has established, *"there is in 80 per cent of cases no sufficient reliable information on the dangers involved."*¹

Chemicals are everywhere - including where they shouldn't be.

- Chemicals are contained in many products we come into contact with in daily life: paints, plastics, cosmetics, carpets, furniture, wallpaper, textiles, toys, cars, packaging, rubber goods, cleaning agents, etc.
- But they also end up where they shouldn't - in our blood, in unborn children and in breast milk; in animals, plants, waters, soils and the atmosphere.

There is a cocktail of chemicals in our bodies.

- Hundreds of different man-made chemicals can be found in the blood of the average European person, and in the breast milk of European women. Hazardous chemicals such as brominated flame retardants, phthalates or synthetic musks have been found even in the blood of umbilical cords of unborn children. Not only are the dangers of many of these substances unknown, the combined effect of this "chemical cocktail" is unknown.

Chemicals damage our health.

- Many chemicals are linked to avoidable kinds of cancer, allergies and fertility disorders. The number of chronic illnesses registered by the World Health Organisation, especially cancer, is increasing alarmingly. Male infertility in particular has been increasing in highly industrialised

regions. In Europe 15% of all couples are now involuntarily childless. Every seventh child suffers from asthma.

→ Of particular cause for alarm are chemicals which have a hormone-mimicking effect ("environmental hormones") and can cause great damage in the early stages of development.

Chemicals turn the natural environment into a dump for toxins.

→ Chemicals accumulate in the environment in soils, rivers, animals and plants, and thus in the food chain. Persistent non-degradable toxins which damage hormones have even been found in the blood of polar bears in the Arctic, thousands of miles from chemical factories.

Current controls on chemicals are not effective and offer no protection.

→ Ignorance about the dangers of chemicals has not been eliminated in over 20 years. In the last 12 years, not even the 140 priority substances of the over 100,000 existing substances have been able to be comprehensively tested, because even testing the most dangerous substances is beyond the authorities.

Chemical corporations have a free hand to produce without responsibility.

→ Until now it is up to government authorities - not the producer of an "existing" chemical - to prove if it is dangerous or not.

The intent of REACH

After years of debate, the European Commission in October 2003 proposed the REACH regulation.

The original aim for a new chemicals policy was to:

- close the gaps in knowledge on the hazardousness of chemicals
- protect people and the environment from dangerous chemicals
- detect, limit and if need be remove hazardous substances from circulation
- transfer responsibility for substances away from the authorities and onto chemical manufacturers ("reversing the burden of proof", so that in future the authorities no longer have to prove that a chemical is dangerous; the onus will be on manufacturers to prove it is not)
- only allow chemicals onto the market if specific data on them are made available (on a principle of "no data - no market")
- ensure that there is adequate information on all chemicals and that this information is communicated to all who come into contact with the chemicals - from users to final consumers
- foster innovation of new, safer substances
- simplify the law on chemicals; in having 140 articles on roughly 213 pages, REACH replaces over 40 items of EU legislation on chemicals.

REACH – down but not out

The main political groups in the European Parliament agreed in early to support a compromise on REACH which **strongly favours chemicals corporations**. Major elements of earlier proposals have been deleted or watered down.

Despite the aggressive lobby of the chemicals industry to weaken REACH, **a framework to substitute some of the most hazardous chemicals with safer alternative has emerged intact**. This precautionary approach gives REACH the potential to eliminate hazardous substances from everyday products.

The loopholes

- Loopholes in **REACH will allow companies to continue importing, producing and using many hazardous substances associated with cancer, birth defects, reproductive illnesses and hormonal imbalances, even when safer alternatives exist.** They may gain authorisation for these “very high concern” chemicals, because producers say that these substances can be “adequately controlled” and that there exist “safe thresholds”, such that we can carry these chemicals in our bodies without ill effect. This “adequate control” approach for authorisation is inherently flawed given the unknown effects of chemicals in combination, on vulnerable hormone functions and on the development of children from the earliest stages of life. In addition, the nature of “effect threshold” is open to subjective interpretation, as it depends on numerous factors (type of test, conditions selected, organism exposed, timing of exposure...).
- Deadlines for substituting very high concern chemicals will be decided on a case-by-case basis. This leaves the system vulnerable to pressure for delay by chemical producers.
- REACH applies to some 30,000 of the over 100,000 chemicals known, that is, only to substances made in volumes above one tonne per year. This means that REACH will apply to less than a third of known chemicals. In this respect, it has lower requirements than the current regulation on “new” chemicals, which applies to substances produced in volumes above 10 kilos a year.
- Of the 30,000 substances covered by REACH, companies will have to supply only “available” data on 17,500 of them (those produced in volumes between one and 10 tonnes per year per producer), unless certain criteria is met. The producers will not, for example, have to identify a substance as acutely toxic or say whether it decomposes in the environment. The rudimentary information required will thus not suffice to enable a substance to be classified as hazardous or not. Neither will companies have to provide a chemical safety report for these substances, outlining the human health, physicochemical, environment hazard assessment as well as persistent and bioaccumulative assessment .
- Companies will not have to provide data on exposure for these 17,500 substances (60% of all chemicals under REACH). That is, information about how much of a substance enters the environment, where it will be released, or how people will come into contact with it will remain secret.
 - Polymers have been exempted from registration. These include, for example, nonylphenol ethoxylates, a substance which decomposes in the environment, disrupts the hormonal system and causes feminisation of fish.
- The decision on whether to include endocrine disruptors among ‘very high concern’ substances – which would only be authorised if justified by socio-economic cost benefits and lack of alternatives - has been postponed for six years.
- The chemicals industry lobby has won significant concessions on confidentiality, which will allow it to keep secret the full composition of chemicals, their use, production tonnage and from and to whom they buy and sell substances.

REACH - the potential for change

About 1,500 substances are estimated to fall into the category of ‘chemicals of very high concern’. These chemicals will be subject for special authorisation requirements. Specifically,

- Substitution will be mandatory for chemicals that are persistent or bioaccumulative, wherever safer alternatives are possible. These substances will only be authorised if there are no alternatives and according to an analysis of their socio-economic costs and benefits.
- A company will be required to submit a substitution plan for a chemical of very high concern when it can itself identify a safer alternative. This of course leaves room for a company to ignore safer alternatives.

Other positive points:

- REACH will set goals to promote alternatives to animal testing, such as data sharing, avoiding duplicate tests, using in vitro tests. Every three years, the European Commission will have to examine new testing methods and legislative proposals to further reduce animal testing.

REACH benefits versus burden

- The European Commission estimates (under its most conservative assumptions) that if chemical-related diseases are reduced by 10% then the cumulative benefits to society would be 50 billion euros over 10 years. Another Commission study indicates that REACH could bring extra benefits worth up to 95 billion euros over 25 years. This figure includes improved use of sewage sludge, savings on drinking water purification, and cleaner water. A requirement for companies to substitute the most hazardous chemicals with safer alternatives has been the advice of medical associations, consumer groups and innovative businesses across Europe (www.substitutionworks.com).
- The European Commission estimates registration costs for the chemical industry to be 2.3 billion euros over 11 years, equal to just 0.05% of the sector's annual sales. The total cost of REACH (for both chemical producers and downstream users) is estimated at between 2.8 and 5.2 billion euros. The weakening of the proposal will probably result in costs lower than estimated.
- REACH places fewer requirements on chemical producers than the German chemical industry's own **voluntary commitments of 1997**. Then, it committed to provide data about a substance's acute hazardousness to humans, environmental degradability, and toxicity for aquatic life.
- REACH gives manufacturers and importers up to **11 years** to register and supply the necessary data on substances in the 1 to 100 tonnes range (six years for 100-1,000 tonnes; three-and-a-half years for over 1,000 tonnes).

The future of REACH and chemical safety

- In order to guarantee that the REACH reform will protect human health and the environment policy-makers will need to remain committed to implementing the substitution pathway opened up by the new chemicals legislation.
- The new EU chemicals agency will need to be closely monitored to ensure that it is not manipulated by vested interests. At the earliest opportunity, lawmakers should increase the scope of the legislation to strengthen the weakened registration requirements and to close the adequate control loopholes for other substances of very high concern.
- Decision-makers should not neglect to strengthen REACH at the following agreed opportunities:
 - After 12 years (or 7 years for certain problematic substances), to require Chemical Safety Reports for low volume chemicals (1 to 10 tonnes)
 - After six years to require substitution for hormone disrupting chemicals.

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