

How to make REACH work

An MEP's guide

GREENPEACE

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THE BASICS

REACH has the potential to create a safe and competitive chemicals industry

The new European chemicals legislation is intended to give the public greater protection from intentionally produced chemicals. It is the biggest and most important regulation in twenty years.

REACH (Registration, Evaluation and Authorisation of Chemicals) will completely change the way chemicals are controlled. It will pass through the European Parliament during 2004 and 2005, and should become law in 2006. When it comes into force, chemical companies will, for the first time, have to provide basic health and environmental safety data on the chemicals they produce. (Currently only chemicals that started production after 1981 require this data – that is less than 10% of chemicals on the market.)

REACH will then identify extremely hazardous chemicals and give them a special classification as ‘substances of very high concern’. These chemicals will be few in number (perhaps around 1500) but will require a special licence for production, even ones that have already been on the market for many years. This license will be called an authorisation. **One of the goals of REACH is to ensure chemicals of very high concern are phased out and replaced with suitable, safer alternatives.**

A chemical is classified as of very high concern if it can cause cancer, damage genetic material or is a reproductive toxin. Any chemical that cannot be broken down by nature and builds up in the bodies of human beings or wildlife is also classified as of high concern, even if there is no evidence that it is toxic. This is because many substances that do this eventually turn out to be hazardous even though they are at first thought safe. Examples from the past are PCB's, DDT, asbestos and TBT. Substances

that are known to interfere with the body's hormone system are the final category that will require an authorisation.

A significant number of chemicals that are likely to be classified as ‘substances of very high concern’ are in a variety of consumer products. Greenpeace commissioned independent research that found nonylphenol in children's pyjamas, toys, household paints and cleaners. Brominated flame retardants are in computers, televisions, carpets and upholstered furniture. Chlorinated paraffins are in bathroom sealants and plastics, phthalates are in perfume, shampoos and plastics and artificial musk compounds in detergents and air fresheners.

Further research, commissioned by Greenpeace, found these and other chemicals in ordinary house dust and in children's bodies. Because of the vast number of chemicals for which data is currently not available (100 000 known chemicals) REACH will prioritise. About 30 000 chemicals will be included in the system. Those produced in the highest volumes and those already known to have dangerous properties will be dealt with first.

REACH will also reduce the complexity of current chemicals legislation. New and old chemicals will be brought under the same regime and over forty pieces of separate legislation will be replaced.

Another goal of REACH is to enhance the competitiveness of the European chemicals industry. It aims to do this by encouraging innovation (the old regulations stifled innovation) and by setting clear rules which will make the EU chemical industry a world leader in sustainable chemical production.

To work, the REACH draft needs changes

As it is currently drafted, the proposal will not work. The current proposal contains an enormous loophole that means even if a safer alternative is available, at a comparable price, production of a chemical of very high concern can continue. The producer will have to demonstrate 'adequate control'. This issue goes right to the heart of chemicals policy (and wider). Experience shows that substances that are persistent and bioaccumulative cannot be controlled. Because Nature cannot easily break them down and they are attracted to fatty tissue, they inevitably find their way into the environment and human bodies, sooner or later. 'Adequate control' is based on an acceptable level of risk. Greenpeace argues that when a safer substitute is available at a reasonable cost, there is no need to take that risk. This is the

Substitution Principle and it is a great driver for innovation and green chemistry.

It is now up to the European Parliament and Council to close the loophole. Unless they do this, REACH will not offer the improved protection for human health and the environment that has been promised.

In summary, REACH is designed to;

- a) make chemical companies obtain and provide health and environmental safety data on their products for the first time**
- b) identify and substitute chemicals with certain extremely dangerous properties**
- c) enhance the competitiveness of the European chemical industry**

but it will not do any of these unless Parliament insists on improvements.

A BIT MORE DETAIL

We need REACH

Many synthetic chemicals are extremely useful and bring great benefits to our lives and our health. But many are also extremely dangerous. We should certainly not be indiscriminately exposed to chemical pollutants on an ongoing basis. However, we are. Research into levels of industrial chemicals in the human body shows that we are continuously exposed to a large number of chemical pollutants.ⁱ

We are all continuously exposed to so many different chemicals largely because the law allows this to happen. European law is currently based on an assumption that there are 'acceptable' levels of exposure, even to the most hazardous chemicals, and regulators determine acceptable levels of risk from these exposures.

It is further assumed that the quantity of substances that we are exposed to can be controlled through dilution and dispersion of chemicals throughout the environment. However this assumption falls apart for chemicals which do not degrade, or degrade only slowly in the environment and which can bioaccumulate. Chemicals which do not degrade tend to be reconcentrated by nature, and via the food chain accumulate in higher mammals, such as humans.

Additionally, a surprising number of hazardous chemicals are used in everyday consumer products. Exposure to hazardous chemicals from consumer products and other dispersed sources is often assumed to be negligible, but recent research suggests this may not be true.ⁱⁱ As a result of these

assumptions we are all continuously and quite legally, exposed to multiple and ongoing small doses of many different synthetic chemical substances.

As long as chemical regulation is based on this risk-based philosophy, human and environmental exposure to dangerous chemicals – ‘chemicals of very high concern’ – will continue. The ‘disperse and dilute’ model does not work for persistent bioaccumulative chemicals because nature quite simply collects and concentrates these materials over time.

What is needed is a shift from ‘permissive’ regulations based on attempted control of exposure and risk, to one based on prevention. The goal of chemicals’ policy should be the elimination of exposure to intentionally manufactured substances whose intrinsic properties give cause for high concern.

REACH, the EU’s proposed new chemical policy, does not – as yet – include measures that will move us away from a permissive regime. Although the framework (REACH) and mechanism (Authorisation) are there, as it stands, the draft legislation continues with ‘adequate control’ as the regulatory paradigm. Continuing unnecessary exposure to certain ‘tolerable levels’ of chemicals that may cause cancer or genetic damage, to endocrine disrupting chemicals and to substances that build up in our bodies, will still be tolerated.

We know there is a problem, the solution is the Substitution Principle

The most important step towards a preventive regime, one that truly has protection of human health and the environment at its core, is to give a central place in chemicals legislation to the Substitution Principle. This can be defined quite simply as *‘the substitution of hazardous substances by less hazardous substances or*

p referably non-hazardous substances where such alternatives are available’. It means that if a product that uses a hazardous chemical can be manufactured using a safer alternative, at a reasonable cost, the hazardous substance will no longer be permitted for that use. Common sense? Yes, but currently things do not work that way, and many hazardous substances are used without need, simply because there is no legislative or economic reason for substitution to take place systematically.

The Substitution Principle can only work if written into the REACH authorisation procedure

Some companies are already using substitution as a means of eliminating hazardous chemicals from their businesses (see the Greenpeace report ‘Safer Chemicals within REACH’). A variety of reasons exist for why some companies are searching for safer substitutes. These include regulatory drivers such as the recent Directive on the Restriction of Hazardous Substances, increased public awareness, demands from down stream users or clients, liability issues, competitive advantage and company ethics. However, there are also barriers and the development and adoption of safer substitutes is happening only slowly, in a piecemeal fashion and in some sectors not at all. For this reason, the Substitution Principle cannot be implemented simply as a general policy statement or goal as it is in the current draft of REACH. This will be an insufficient driver for change. Instead it needs a clear mandatory imperative to drive it. Within REACH this means that the Substitution Principle needs to be written into the authorisation procedure so that *‘the availability of a safer alternative is sufficient grounds for an authorisation to be refused’*.

A safer alternative is one that does not meet the requirements for a chemical of very high concern as defined in Article 54 (a) to (f) of the current REACH proposal.

‘Availability’ means the substitute must be available on the market and is defined to include an economic element (i.e. at a reasonable cost). It must also be technically effective and fit for the use to which the application applies.

An alternative may be safer in that it does not meet the criteria for very high concern, but it may have other hazards such as corrosivity or flammability. These hazards are easier to control, but if there is a serious health and safety issue with a proposed substitute, that alternative would not be deemed an available alternative. A proposal for a workable authorisation procedure based on the substitution principle is shown schematically in figure 1.

When an application for an authorisation is made, the applicant should provide details of alternative substances, materials, processes or products currently in use. A comparative hazard assessment of alternatives should be provided. Other parties (e.g. manufacturers of potential substitutes) should be invited to respond to this Substitution Assessment.

If the manufacturer, importer or user of a chemical of high concern can demonstrate that no viable alternative is available, that there is need for the chemical (with a transparent socio/economic assessment) and that the substance can be adequately controlled, a time-limited authorisation, may then be granted. A time-limit will both ease costs of a phaseout and encourage development of alternatives.

The basis of this system is the presumption that a chemical of very high concern will be phased out unless the applicant can demonstrate that there is no safer alternative, there is a compelling reason for production to continue and that the risks can be controlled. Only in those circumstances would a time-limited authorisation be granted.

Substitution has many benefits

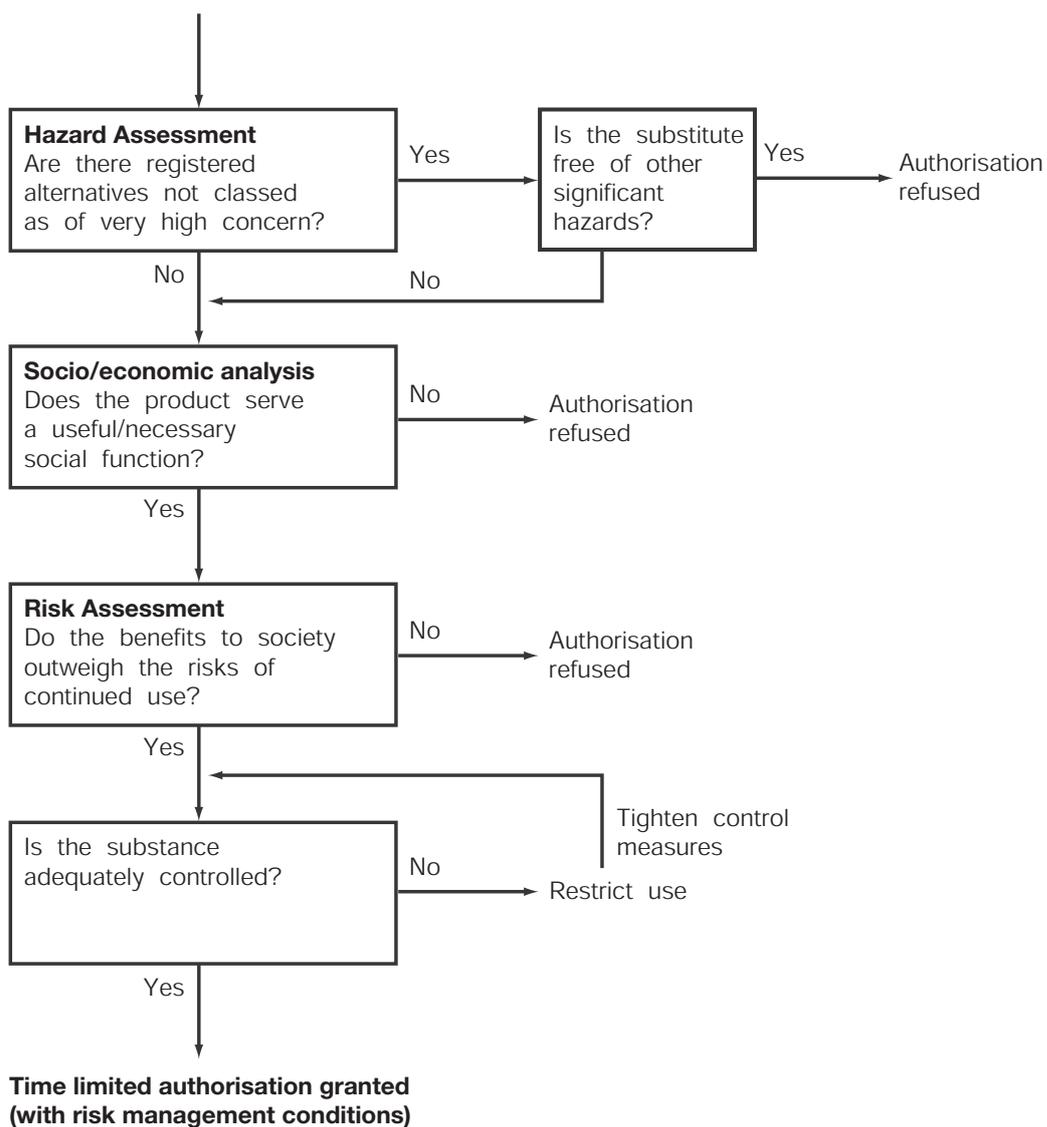
Basing decisions to grant an authorisation on the availability of viable substitutes instead of ‘adequate control’ would have the following benefits;

- It would provide a systematic driver for innovation, and focus research and development onto intrinsically safe chemicals. This would be a significant boost to the nascent ‘green chemistry’ industry in the EU.
- Mandatory substitution of the most hazardous chemicals would end the confusion, inefficiency and unfairness of voluntary self-regulation.
- Systematic substitution of chemicals of very high concern would create a healthy market for safer chemicals.
- Substitution of hazardous chemicals and the development of green chemistry would have wide support. Public confidence in the chemical industry would start to recover.
- Persistent, bioaccumulative chemicals and endocrine disrupters, such as nonylphenol would be systematically phased out and replaced with safer alternatives. Environmental levels and human body burdens of these substances would begin to fall. Recurring scandals and associated costs of hazardous chemicals in food, toys, breast milk etc. would over time be dramatically reduced.
- Replacement of hazardous chemicals with other hazardous chemicals would be greatly reduced. The chemicals industry and down stream users would have greater certainty over what chemicals are acceptable and which are not. Wasted time and money changing to false alternatives would be avoided.

i Greenpeace 2003 ‘Chemical contamination of the child’

ii Greenpeace 2003 ‘Consuming Chemicals: Hazardous chemicals in house dust as an indicator of chemical exposure in the home’

Figure 1.

**Proposed decision making process
for use specific authorisation under REACH****Chemical of very high concern
(identified by registration process)**

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