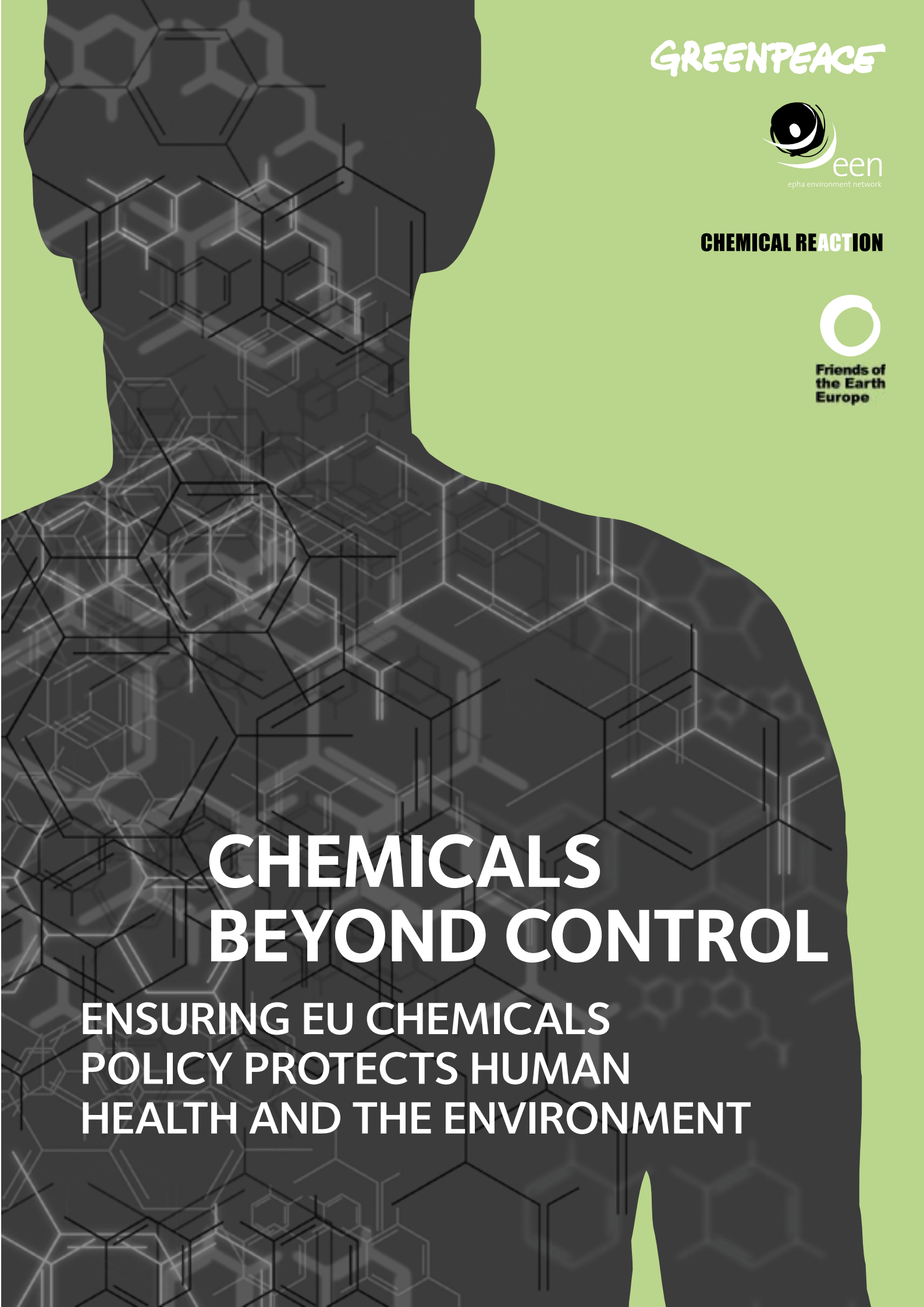

GREENPEACE

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CHEMICAL REACTION

Friends of the Earth Europe

CHEMICALS BEYOND CONTROL

ENSURING EU CHEMICALS POLICY PROTECTS HUMAN HEALTH AND THE ENVIRONMENT

EXECUTIVE SUMMARY

As a result of the failure of current chemicals regulations we are all constantly exposed to a wide range of synthetic chemicals, some of which are known to be capable of causing adverse effects on the health of wildlife and on ourselves.

Under current chemicals regulations there are extremely large data gaps. We know very little about the properties, environmental fate or human health impacts of many man-made chemicals found in our environment. The proposed EU Registration, Evaluation and Authorisation of Chemicals (REACH) legislation is intended to address that problem.

A further primary objective of REACH is to address a group of what are considered today's most problematic pollutants – chemicals that, once released, remain in the environment, and build up in wildlife and humans and/or are capable of causing cancer, genetic or reproductive damage. REACH calls these chemicals 'substances of very high concern' and requires producers, importers or users to obtain an authorisation for their continued use.

However, there is a major loophole in the current REACH proposal. The intrinsic properties of most of these chemicals of 'very high concern' mean that once they are manufactured and used, it is virtually impossible to prevent them from entering the environment at some stage. Nevertheless, under current proposals, continued manufacture and use of these chemicals will be authorised if the manufacturer or user can demonstrate 'adequate control' through a risk assessment. In effect this will mean little significant change to the current system of chemical regulation that has failed to protect the environment and human health from impacts of hazardous chemicals.

Even low concentrations and widely dispersed amounts of persistent, bioaccumulative substances can be re-concentrated by nature and accumulate in our bodies. In other words, "adequate control" of these substances is all but impossible. After all, it is because of these very properties that they have been classified as "substances of very high concern" in the first place. This is why the aim of authorisation must be to ensure these 'substances of very high concern' are replaced as soon as possible by suitable alternative substances or technologies - i.e. safer substitutes. To aim for 'adequate control' would be to subscribe to ongoing exposure to extremely hazardous chemicals, when such exposure could be avoided altogether.

In order to ensure that the authorisation process leads to a timed, managed, phase-out of substances of very high concern, the single most important change that should be made to REACH is the incorporation of the 'substitution principle' as a practical requirement, whereby a chemical of very high concern will not be authorised if a safer, viable substitute is available. When authorisation of a chemical of very high concern is granted, it should be for a limited period only, to encourage the search for substitutes.

If the authorisation procedure is based upon the premise that 'substances of very high concern' are not acceptable and must be replaced as soon as possible, REACH will drive innovation, promote Green Chemistry and Clean Production and ensure the sustainable future of the European chemical industry.

Fig. 1
Chemical Exposure Routes

Inhalation exposure: brominated flame retardants, phthalates, chlorinated paraffins, organic tin compounds and heavy metals

Oral exposure: plasticisers, organochlorines, heavy metals, alkylphenols

Exposure through skin: chemical ingredients of cosmetics, body creams, deodorants, shampoos, perfumes

Transfer of fat-soluble chemicals to offspring by breastfeeding

Accumulation of fat-soluble chemicals, brominated flame retardants, artificial musk compounds, alkylphenols, phthalates

Transfer from mother to foetus either directly or via amniotic fluid, or both

CONTENTS

1. THE CURRENT PROBLEM: EXPOSURE TO HAZARDOUS CHEMICALS AND ADVERSE EFFECTS ON HEALTH

Every day each of us is exposed to a wide range of synthetic chemicals. Some of these are known to be capable of causing adverse effects on the health of both wildlife and humans. Furthermore, for many chemicals there is simply no information available to know whether or not they have undesirable impacts on wildlife or on human health.

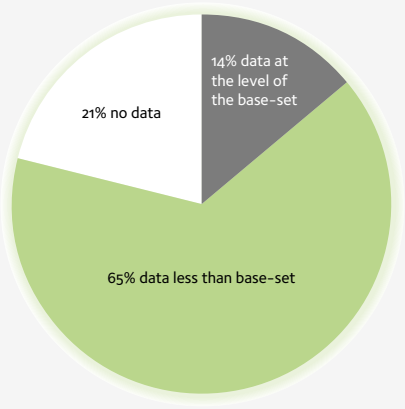


Fig 2.
Data gaps on the basic properties of chemicals. A base set of data is the minimum amount of data required to make a reasonable, informed judgement as to whether or not a chemical is likely to be dangerous.

Source: European Chemicals Bureau

The proposed new EU Chemicals Strategy 'Registration, Evaluation and Authorisation of Chemicals' (REACH) aims to register all chemicals sold in the EU together with data on their hazards. This legislation will oblige industry to provide safety data for the chemicals it sells so that there is effectively 'no data – no market'. Potentially this will vastly improve public information on hazards of chemicals and prevent use of those for which there are no data. As a consequence it will also spur research by industry into non-hazardous chemicals and chemical processes. As part of the registration procedure, REACH will identify, in particular, those chemicals that are extremely hazardous and give them a special classification as 'substances of very high concern'.

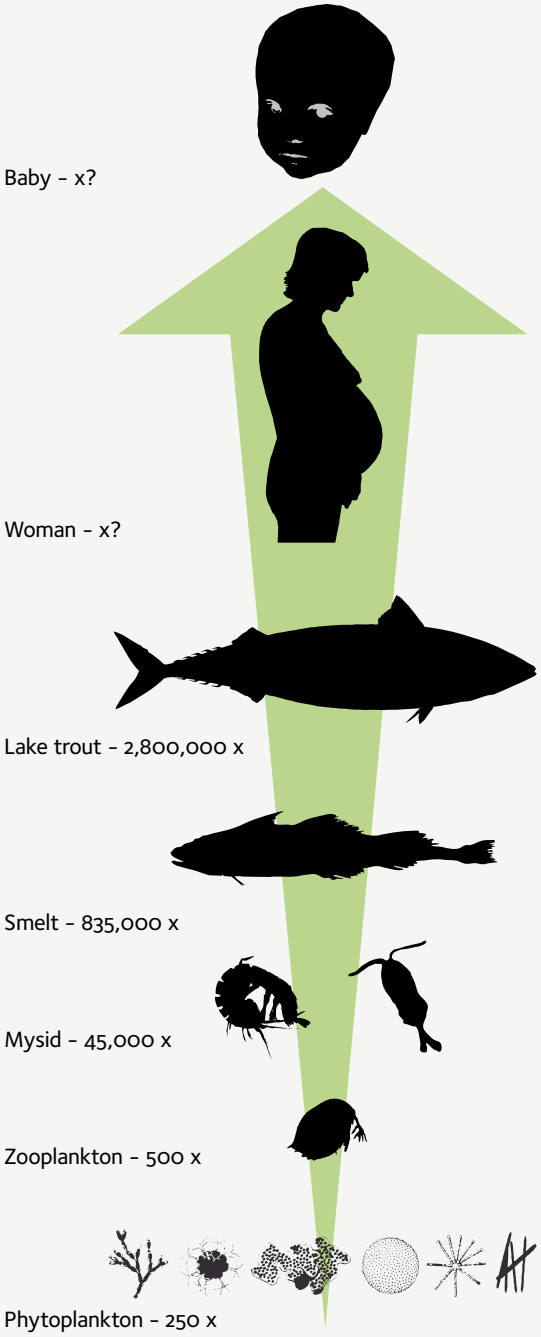
'Substances of Very High Concern'

The chemicals 'of very high concern' will include those that are persistent, bioaccumulative and toxic (PBT) and those that are very persistent and very bioaccumulative (vPvB). Also included are chemicals that have the ability to cause cancer (class 1 & 2 carcinogens), or give rise to genetic mutations (class 1 & 2 mutagens), and chemicals that affect the hormonal system (endocrine disruptors).

Among today's most dangerous chemical pollutants are those that are persistent and are also often bioaccumulative and toxic. By definition they are only broken down by nature very slowly; that is, they persist for extended periods of time, in some cases decades. Vast amounts of these chemicals have been released into the environment from industrial processes. Due to long-distance transport on air currents they have become widespread pollutants and now represent a global contamination problem. For instance, they now even contaminate the Arctic, deep oceans and mountain areas[1].

Many 'substances of very high concern' that pollute the environment become incorporated into food webs. They build up (bioaccumulate) and persist in the fatty tissues of animals and humans because they are soluble in fats and are not easily broken down by the body. Even low environmental levels of such substances can lead to high levels in the bodies of animals and humans. For many, the levels in fat increase as one animal eats another, so that the highest levels are found in predator animals at the top of food webs such as seals, birds of prey and humans.

Fig 3
Bioaccumulation of PCBs in a freshwater ecosystem
As PCBs work their way up the food chain, their concentration in animal tissue can be magnified up to many million times. Microscopic organisms pick up PCBs from sediments and water and are consumed in large numbers by filter-feeding tiny animals called zooplankton. Larger species like mysids then consume zooplankton, fish eat the mysids, and so on up the food web to mothers and their babies. No data is available for the biomagnification factors of trout to women or women to babies.



Source: adapted from Colborn T. *et al*

Exposure to 'Substances of Very High Concern'

Human exposure to 'substances of very high concern' is primarily via foodstuffs, although other routes of exposure can be significant. Direct discharge into the environment from industrial processes remains a dominant source. Discharges of these substances to the aquatic environment ultimately result in fish becoming contaminated. Similarly atmospheric deposition on plants and soil leads to domestic livestock becoming polluted resulting in milk and meat contamination. Other exposure on vegetable foodstuffs comes from pesticide residues left on crops.[2]

Exposure to chemicals 'of very high concern' may also come through use of consumer products. For instance, Greenpeace commissioned independent research that found nonylphenols in children's pyjamas, toys, household paints and cleaners. Brominated flame retardants are used in computers, televisions, carpets and upholstered furniture. Chlorinated paraffins are found in bathroom sealants and plastics, while phthalates are used in PVC plastics and perfumes. Artificial musk compounds are used in detergents and air fresheners.

Greenpeace tested Disney childrenswear from 19 countries and found high levels of hazardous substances in some of the garments.

'The widespread presence of small amounts of many chemicals ... is causing increasing concern, because alone, or in combination with other agents, they may contribute to cancer, allergies, impacts on reproduction and the immune response system, and neurotoxic effects.' European Environment Agency[3]

Adverse Effects on Wildlife and Humans from 'Substances of Very High Concern'

Certain persistent and bioaccumulative chemicals have been responsible for catastrophic effects in wildlife that has resulted in dramatic population losses. For example, seals in the Baltic Sea, peregrine falcons in Great Britain and European otters are just some of the species whose populations have crashed as a result of the adverse effects of these chemicals.[1, 4] They are suspected of causing a broad range of adverse health impacts in humans and there is evidence that current levels of these chemicals in women of the general population of some countries is sufficient to cause subtle undesirable effects in their babies due to the transfer of these chemicals across the placenta and via breast milk.[4]

Certain persistent and bioaccumulative substances have already been banned or restricted because of the serious impacts they have had on the environment or human health. Examples include dichlorodiphenytrichloroethane (DDT) and several other organochlorine pesticides and polychlorinated biphenyls (PCBs). Research in some European countries has shown a downward trend in levels of these chemicals in human tissues over the past two to three decades since their being banned.[4] However, the decline of PCBs is slow which is indicative of the persistent nature of these chemicals coupled with their continued leakage into the environment from waste sites.

Unfortunately, there are still a number of chemicals of 'very high concern' in widespread use whose intrinsic properties and impacts on wildlife or humans give cause for concern. For example,

- Tributyl tin (TBT), pehaps best known for its adverse effects on marine molluscs,[5] is also, along with other organotin compounds, an immunotoxin.[6] But despite this, organotin compounds are still found in certain textiles and plastics.

- Over 25% of EU rivers have levels of nonylphenols 'regularly in excess of the no effect concentration'.[7]

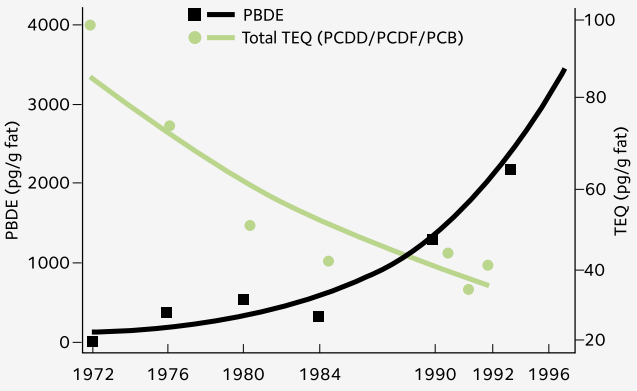
- Short chain chlorinated paraffins are now detected in 'higher predatory animals and human breast milk, which may produce irreversible effects in humans (eg cancer)'.[7]

- Studies have shown the ability of bisphenol A to alter male reproductive organs and affect behaviour in animals at doses only a little above the amount that human infants have been shown to ingest.[8]

- Scientists at the Karolinska Institute in Stockholm have found that levels of flame-retarding polybrominated diphenyl ether (PBDE) compounds, in human breast milk were doubling every five years.[9]

'Current approaches to assessing and managing the risks of man-made chemicals are cumbersome, unsound and rely heavily on animal testing.'
Royal Commission on Environmental Pollution[10]

Graph 1
Regulations are effective in reducing human body burdens of hazardous substances
Rising levels of PBDEs in human breast milk in Sweden as compared to falling human body burden (expressed as TEQ -toxic equivalent- values) of dioxins, furans and PCBs, groups of chemicals whose phase-out started in 1977 (Hooper and McDonald 2000). Since 1998 control measures have begun to reverse the rising trend in PBDE levels also, at least in Sweden. (Lind et al. 2003).



2. THE CURRENT PROBLEM OF REGULATORY STRATEGIES TO PROTECT THE ENVIRONMENT AND HUMAN HEALTH

Current legislation has failed to effectively protect humans and the environment from exposure to chemicals that can or may impact adversely on health. While several persistent, bioaccumulative substances have been banned from use because of their toxicity, many hazardous chemicals remain in use and wildlife and humans could suffer as a consequence.

Current regulations use the process of 'risk assessment' to determine the amounts of chemical releases that are permitted in the manufacture, use or disposal of synthetic chemicals. In other words, risk assessment is used to estimate 'acceptable' amounts of synthetic chemical emissions that can be released into the environment. It assumes that there is a level of environmental and human exposure to hazardous chemicals for which the risk is 'acceptably small'.

Risk assessment is considered by regulators to be an objective and scientific way of establishing chemical safety. However, standard risk assessment is limited and often a subjective process for a number of reasons: [11, 12]

- We know so little about pathways of exposure to many chemicals in the environment that this crucial part of a risk assessment is often highly subjective.

- Risk assessments generally deal with individual chemicals, rather than mixtures of chemicals to which we are commonly exposed. The toxicity of such mixtures of chemicals is largely unknown.

- Establishing what is an 'acceptable risk' is a subjective decision and not an empirical scientific one. This is especially true in the case of carcinogenic, mutagenic and hormone-disrupting chemicals for which it may be considered that there is no 'safe dose' of exposure. As noted by professor vom Saal (University of Missouri): *'There are no safe doses of endocrine disruptors, just as there are no safe doses of carcinogens'*.[13]

The use of risk assessment for the regulation of chemical releases is therefore problematic and ineffective for environmental and health protection. A new way forward, which would be protective of the environment and human health from hazardous chemicals, (eg. chemicals 'of very high concern'), would be to take action to prevent these chemicals at source. Steps should be taken to ensure the reduction and eventual elimination of hazardous chemicals from products, pipeline discharges, emissions to the atmosphere and losses from manufacturing processes and disposal operations.[14, 1] The new REACH proposal for chemical regulation should be used to help fulfil these safety goals and in so doing properly protect wildlife and human health from the health hazards posed by chemicals.

3. POTENTIAL OF THE **REACH** PROPOSAL

The new European chemicals legislation is intended to give the public greater protection from intentionally produced chemicals. The REACH legislation is intended to tackle the current lack of basic information on chemicals and to take precautionary action on the most dangerous chemicals, which it defines as 'substances of very high concern'. In short, chemicals in use will be registered, data sheets on their hazards prepared and the chemicals 'of very high concern' identified and potentially phased out of use.

Prioritisation and minimisation of costs

The registration phase of REACH was initially intended to require a base set of data for all chemicals on the market. A base set is the minimum amount of data required to make a reasonable, informed judgement as to whether or not a chemical is likely to be dangerous. Because it will take time, effort and money to gather this data, both the number of chemicals included in the process and the data requirements for those chemicals have been scaled down. Only around 30,000 of the 100,000 chemicals thought to be on the market in Europe will need to be registered.

Targeting the Most Hazardous Chemicals – 'Substances of Very High Concern'

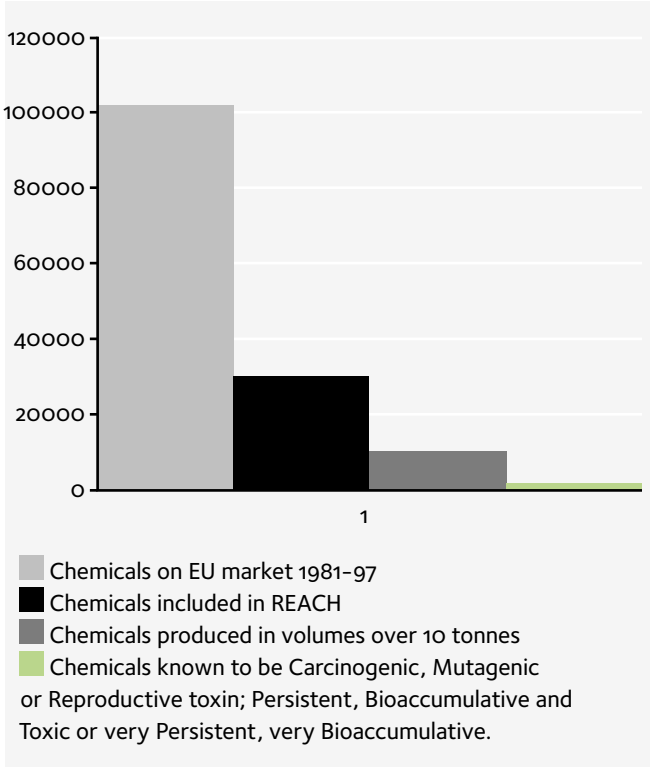
REACH will identify extremely hazardous chemicals as 'substances of very high concern'. These chemicals will require a special licence for continued use. This licence will be called an authorisation.

The authorisation process represents an opportunity to ensure that very hazardous chemicals are phased out of use altogether. An authorisation should only be granted if:

A there are currently no safer alternative chemicals, materials, products or processes to meet that same need, and
B the chemical in question is being used to serve an essential need.

If the substitution process in the REACH legislation is effectively carried out, it will lead to the progressive replacement of the chemicals 'of very high concern' with substances or technologies that reduce potential hazards to the environment and human health. Financial impacts from changes to production processes can be minimised by granting reasonable timelines in which the substitution of a chemical or chemical process should take place. We believe that where an alternative is not available, temporary authorisations may be granted to allow for alternatives to be developed, but any such authorisations must be strictly time-limited.

Graph 2
Chemicals to be included in the EU REACH proposal



Source: Environment Daily

'The new system will promote innovation as there will be the same rules for old and new chemicals.'
Frank Bill, Confederation of Danish Industries, October 2003[15]

A Driver for Innovation

One goal of REACH is to enhance the competitiveness of the European chemicals industry by encouraging innovation. If REACH is applied effectively, such that the chemicals 'of very high concern' are substituted for less or non-hazardous chemicals and processes, it will drive the development of safer non-hazardous chemicals and non-hazardous processes. This will, in turn, shift the chemical industry towards long-term sustainability. It should also boost the emerging 'green chemistry' industry by ensuring that environmental and human health considerations are built into research and development objectives along with technical efficacy and costs.

'In the chemicals industry there are numerous examples of regulatory changes ultimately saving companies money, opening up new markets and offering competitive advantages over less innovative producers.'
A Corner, The Financial Times,
10 September 2003[16]

4. WHY **REACH** NEEDS AMENDING TO ACHIEVE ITS AIMS

Unless amended, REACH will permit continued unnecessary use of the most hazardous chemicals

The proposed REACH legislation currently contains a loophole that will permit the continued use of a chemical 'of very high concern' even if a safer alternative is available. This will seriously undermine the aim of REACH to give improved protection to the environment and human health by the effective phase out these chemicals.

To obtain authorisation, and thereby avoid substitution, the user will simply have to demonstrate (A) that risks to the environment are 'adequately controlled' or (B) that the benefits of use outweigh the risks.

The phrase 'adequate control' assumes that we know the 'safe' level of exposure to a given chemical. Of course, exposure to chemicals that persist in the environment for long periods and bioaccumulate in the body cannot be accurately predicted or 'adequately' controlled. In effect, therefore, this loophole in the REACH legislation represents the same flawed risk assessment procedure that has to date failed to control hazardous chemicals. While it is true that under REACH, industry will have greater responsibility to justify its case, the effectiveness of this process in ensuring protection from the most hazardous chemicals will depend greatly on the strength of the conditions and the degree of precaution applied in evaluating applications for authorisations. Unless the current climate of reliance on standard risk assessment procedures is replaced with more precautionary approaches, it seems unlikely that, in practice, many authorisations will be refused.

Where an alternative safer substitute is available, the chemical industry should not be allowed to impose a health risk on its workforce, the general population or the environment. When not available, REACH should drive innovation to find alternatives.

'Given the inherent uncertainties about the way chemicals interact with the environment, it makes sense to assume that the continuing use of large numbers of synthetic chemicals will lead to serious effects, which we cannot predict on the basis of our current or foreseeable understanding of these processes.'
Royal Commission on Environmental Pollution [17]

Releases of Substances of Very High Concern from Facilities Subject to IPPC permits will be Ignored

As it stands, the current REACH proposal will exempt from its control any emissions of substances 'of very high concern' from chemical production facilities that already have an IPPC (Integrated Pollution Prevention and Control) permit. IPPC permits are granted on the basis of allowable discharge limits and acceptable costs. This regulation was not designed to prevent harm from persistent, bioaccumulative and/or hormone-disrupting chemicals.

To exclude emissions permitted under IPPC guidelines where chemicals 'of very high concern' are involved, will undermine the ability of REACH to protect the environment and human health effectively. It is argued that the IPPC exemption within REACH is necessary to avoid conflict between new and existing measures.

5. WHAT ARE THE COSTS AND BENEFITS OF **REACH**?

The European Commission estimates that the annual costs of REACH to chemicals producers will be around €2.3 billion over 11 years.[18] This represents 0.05% of the sector's turnover. These costs are expected to result in an overall cost to industry at large of €2.8–5.2 billion over the same period.

The benefits to health and the environment from a strong REACH legislation are difficult to quantify. A UK Government consultation paper on REACH states: 'The benefits of REACH are expected to accrue mainly in terms of reduced risks to human health, reduced risks of damages to the natural environment and benefits to the chemical industry in terms of improved reputation and competitive advantage.'[19]

As an example, the likely occupational health benefits from the new regulatory system should be estimated at between € 18 billion and € 54 billion over a 30-year period, which corresponds to an ultimate yearly reduction of some 2,200 to 4,300 cancer cases over the same period.'
Environment Commissioner Margot Wallström [20]

'There is a strong economic, let alone environmental, case for more, not less of this kind of regulation [REACH]. Indeed creative regulation favouring sustainable development is emerging as a critical policy area for government, an instrument that has immense potential both to advance citizens' wellbeing and provide a consistent framework for industrial strategy.'
Adair Turner, former director general of the Confederation for British Industry[21]

6. THE SOLUTION

'Without the strong support of the substitution principle, it will be difficult for an individual company that is a downstream user to be proactive in substituting substances.'
Skanska AB, Internet response to EU consultation, summer 2003[22]

Substitution is the solution

Currently, many hazardous substances are used without need, even though safer alternatives already exist, simply because there is no legislative or economic incentive for substitution to take place systematically.

The most important step towards a safe chemicals regime – one that truly aims at protecting both human health and the environment – is to give a central place to the substitution principle. This can be defined quite simply as the substitution of any chemical requiring an authorisation by less hazardous substances where such alternatives are available. A less hazardous substance is one that will not itself require an authorisation.

The decision to grant or refuse an authorisation for a 'substance of very high concern' should therefore be based primarily on the availability of an alternative. If a suitable, economically feasible alternative is available, that in itself should be sufficient reason to refuse an authorisation. If an alternative is not currently available, the application of a time-limit to any authorisation granted can be used to stimulate innovation to identify or develop such an alternative.

Advantages of the substitution principle

The principle of substitution provides a stimulus and direction for innovation. Public authorities need not prescribe particular substitutes, but simply define the criteria to guide the identification and development of alternatives. Thus, 'substances of very high concern' as defined by REACH should be substituted by chemicals that are not of high concern, or alternative non-chemical techniques.

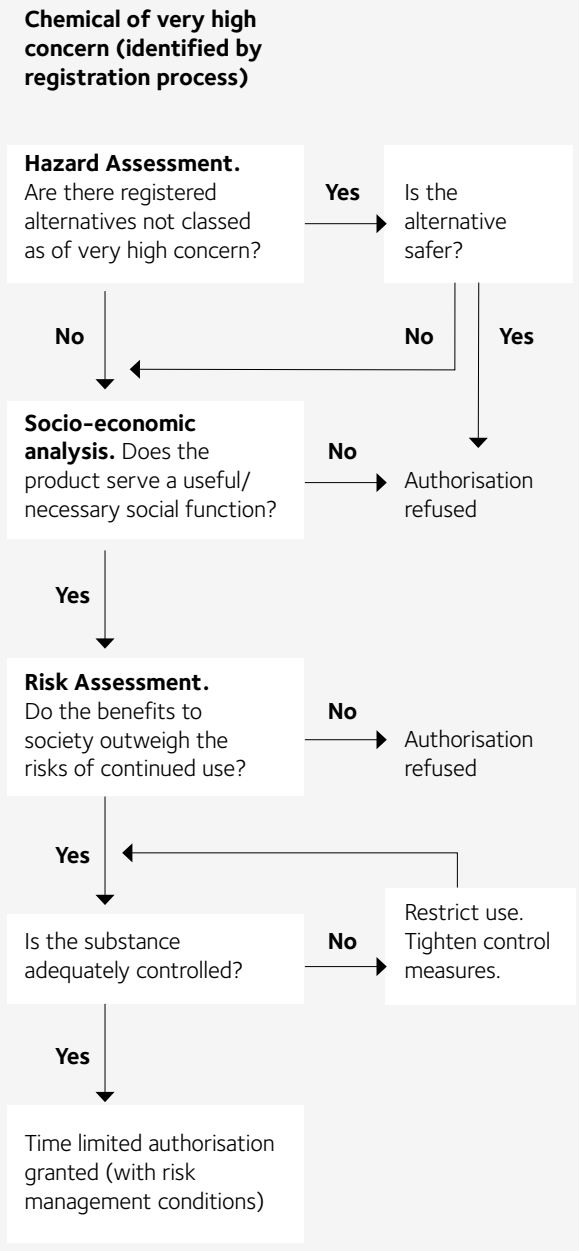
Under the substitution principle, it is not necessary to wait for cancers, reproductive disorders or other evidence that damage has been done before banning a substance; the potential for harm is reduced or avoided in advance by using substitute chemicals with less hazardous intrinsic properties. The substitution principle eliminates the need for the lengthy risk assessments that have paralysed the regulation of chemicals to date. By assessing chemicals and potential substitutes on the basis of their intrinsic hazard, the need for difficult and controversial risk assessments is much reduced. For example, persistence and bioaccumulative potential are surrogate measures that can be applied to all chemicals as indicators of some key aspects of hazard and exposure.[23]

A requirement to substitute safer alternatives for chemicals of very high concern where possible 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.
- Systematic 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 from its current low ebb.
- Persistent, bioaccumulative chemicals and hormone disruptors such as nonylphenols would be systematically phased out and replaced with safer alternatives. Environmental levels and human body burdens of these substances would begin to fall. Recurring problems and associated costs of hazardous chemicals in food, toys, breast milk and so on would over time be dramatically reduced.
- Replacement of hazardous chemicals with other hazardous chemicals would be greatly reduced. The chemicals industry and downstream users would have greater certainty over which chemicals were acceptable and which were not. The wasting of time and money by changing to unacceptable alternatives would be avoided.

7. CONCLUSION

Fig 4
Proposed decision-making process for use-specific authorisation under REACH



There is widespread and justified concern that synthetic chemicals may be contributing to increasing incidences of a number of non-infectious health problems, including adverse impacts on the immune system, the reproductive system, the nervous system as well as cancers. There is evidence that some of these problems are caused by chemical damage that occurs to the developing child in the womb and during infancy.

Waiting for more evidence of chemical effects on health and the environment will always mean risking irreversible damage for both humans and wildlife. In contrast, taking action to substitute the most dangerous chemicals with safer alternatives will not only protect the health of many people and lead to significant savings in health care and associated costs; it will also spur the European chemical industry to make innovations towards safer chemistry and so increase its competitiveness worldwide.

In order for REACH to achieve this double goal of protecting human health and boosting Green Chemistry and Clean Production in Europe, the authorisation procedure must be amended. Instead of merely encouraging better management of substances of very high concern, the purpose of authorisation should be to phase out such substances and replace them with intrinsically safer alternatives. REACH must ensure that no substance of very high concern is authorised if a viable alternative is available.

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