GREENPEACE

EnvironmentalTrust

SAFER CHEMICALS WITHIN REACH

Using the Substitution Principle to drive Green Chemistry

February 2005

Children playing in Cancer Alley,
Louisiana, USA

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Safer Chemicals within REACH
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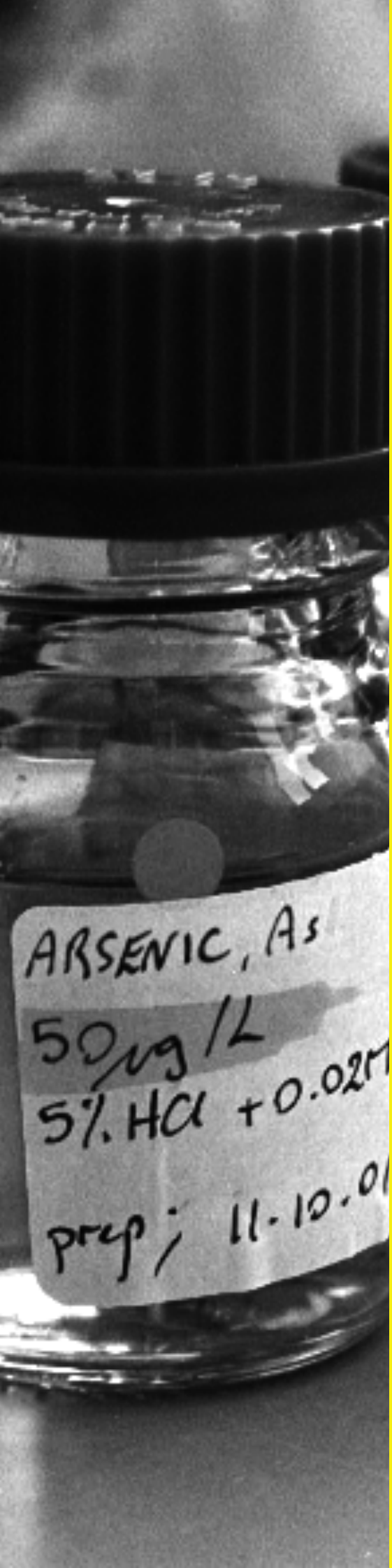


EU chemicals policy must ensure a high level of protection of human health and the environment as enshrined in the Treaty both for the present generation and future generations while also ensuring the efficient functioning of the internal market and the competitiveness of the chemical industry. Fundamental to achieving these objectives is the Precautionary Principle. Whenever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment. Another important objective is to encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available. It is also essential to ensure the efficient functioning of the internal market and the competitiveness of the chemical industry.

White Paper. Strategy for a future chemicals policy, 2001

Greenpeace laboratory at Exeter University, UK

1. EXECUTIVE SUMMARY

Synthetic chemicals have become very much part of our lives. They may be seen to serve useful purposes and to bring substantial benefits to our lives and our health. At the same time, however, many are already known to possess dangerous properties while many more have never had their safety properly assessed. We should certainly not be indiscriminately exposed to chemical pollutants on an ongoing basis. Nevertheless, 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.[1]

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

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. Additionally, a surprising number of hazardous chemicals are used in consumer products and there is another, implicit, assumption that exposure to hazardous chemicals from consumer products and other dispersed sources, is negligible. Recent research suggests it is not.[2] As a result of these assumptions we are all continuously, and quite legally, exposed to multiple and ongoing small doses of many different substances.

As long as chemical regulation is based on this risk-based philosophy, human and environmental exposure to dangerous chemicals – 'substances 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.

European chemicals regulations are currently being completely overhauled and new legislation will be passing through Parliament in 2005. But 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. Human exposure to what are considered 'acceptable levels' of exposure to chemicals that may cause cancer, or genetic damage, endocrine disrupting chemicals and substances that build up in our bodies, seems set to continue.

We know there is a problem, what is the solution?

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, or preferably non-hazardous, alternatives 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.

Is the Substitution Principle workable?

Some companies are already using substitution as a means of eliminating hazardous chemicals from their businesses. (see Annex I) A variety of reasons exist for why some companies are searching for safer substitutes and these include regulatory drivers (such as the recent Directive on the Restriction of Hazardous Substances), increased public awareness, demands from downstream users or clients, worker protection, 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 to its full and necessary effect simply as a general policy statement within the regulatory framework, since 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 substance of very high concern as defined in the authorisation procedure of the REACH

proposed regulation. Obviously, every effort must be made to select the least hazardous alternative within this universe of 'safer' chemicals.

'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.

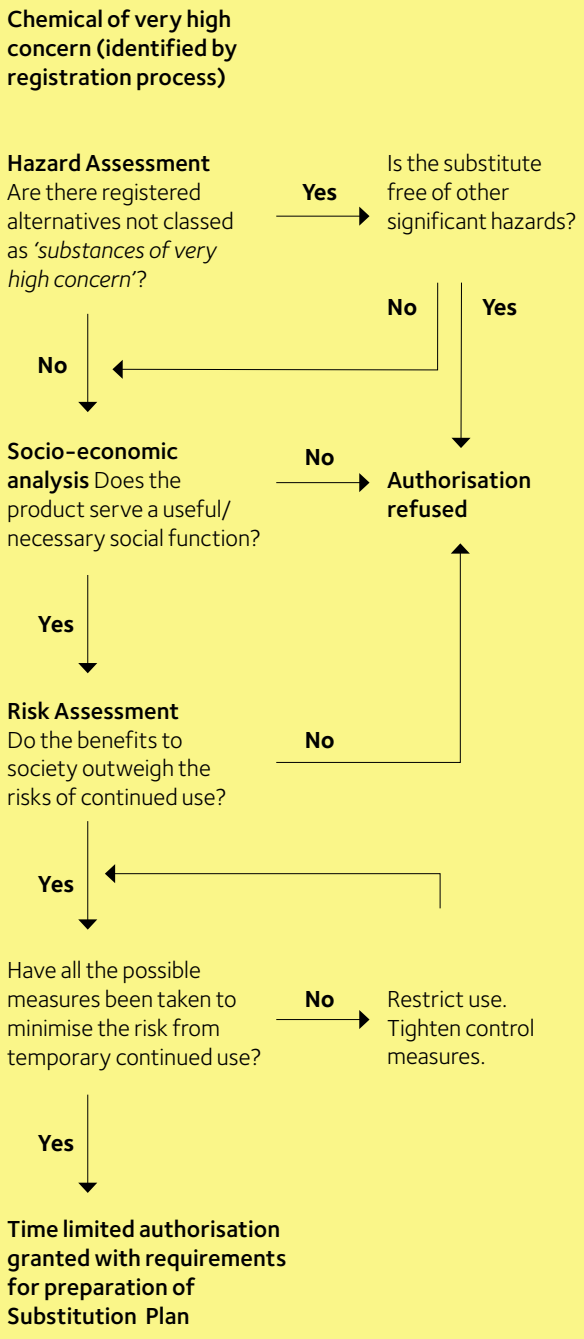
An alternative may be safer in that it does not meet the criteria for very high concern, but it may have other hazards such as corrosivity or flammability. These hazards are easier to control, but if there is a serious health and safety issue with a proposed substitute, that alternative would not be 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 (substitution plan). A comparative assessment of alternatives should be provided in order to justify the need seen by the applicant for authorisation to be granted. 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 very 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 all steps are taken to minimise exposure, and therefore risks, from continued use of the substance, then a time-limited authorisation may be granted. A time-limited authorisation will both ease costs of a phase out 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. Otherwise authorisations should be refused.

Figure 1. Proposed decision making process for use specific authorisation under REACH



2. INTRODUCTION

Europe is at a crucial time in its development of chemical policy and the European Commission has proposed what can be considered the most comprehensive system of chemicals regulation in the world. The intent of REACH (Registration, Evaluation and Authorisation of CHemicals)[3] is a comprehensive overhaul of a chemical system that has failed to protect people and the environment from ongoing exposure to many different chemicals with unknown properties. The Commission must be congratulated for deciding to end the lack of information on chemicals in wide use today and for targeting the most hazardous chemicals for stringent measures. However, the new legislation will fail to deliver its protection goals for human health and the environment if it does not ensure that the most hazardous chemicals are systematically phased-out and replaced with safer alternatives. The Commission has created a unique opportunity to protect human health and the environment, while at the same time stimulating development of safer chemicals and increasing innovation within the industry. But it is unlikely that any of these goals can be achieved unless the mandatory substitution of chemicals of very high concern is a central feature of the legislation.

Under the current proposal, chemicals with the most hazardous properties – those that have been named 'substances of very high concern' – may be authorised for continued use if the risk to human health and/or the environment is deemed to be 'adequately controlled'. However, this principle of 'adequate control' is, quite simply, not one that should be applied to persistent, bioaccumulative substances. Their intrinsic properties mean that exposure is virtually impossible to control. Small releases from production processes, from applications that disperse them widely, or from disposal operations lead to significant accumulation of the chemicals in the food chain and consequently in human beings. Chlorinated paraffins in PVC flooring are not adequately controlled for instance. Brominated flame retardants in computer circuitry, or nonylphenol in children's pyjamas provide unexplored routes of exposure despite the fact that these substances have been recognised as persistent, bioaccumulative toxins for many years and are subject to control regimes. These chemicals are consistently found in house dust, breast milk, umbilical cord blood and other places that demonstrate ongoing human exposure despite pollution permits that supposedly control environmental discharges.

The availability of alternatives should not merely be seen as one consideration in the authorisation process. It should be **the decisive factor** in deciding the future of a substance of very high concern. Producers and users of chemicals of very high concern should be required to assess alternatives to these chemicals, and where none exist to develop them. This requirement will redirect the focus of chemical producers and downstream users towards safer chemicals and processes and stimulate the development of Green Chemistry. It will be a major driver towards clean production and effectively level the playing field for companies who are already using safer materials in their products. Without such a regulatory driver, however, the adoption of safer substances will proceed in a piecemeal fashion and entrench other substances in extensive risk assessment procedures to justify ongoing use of substances of very high concern. On the other hand, a requirement to assess substitutes has the potential to change the focus from trying to manage and justify intrinsically hazardous chemicals to one that advances the use of safer processes and products in our society.

BACKGROUND: TOXIC CONTAMINATION

We are all contaminated by a wide range of chemicals. Each generation is progressively exposed to persistent chemicals in the womb and intake of persistent organic pollutants by nursing infants is high. Effects caused during development may cause permanent irreversible damage and some effects may not even become apparent until later in life. This is no longer acceptable, particularly when safer product design and chemical substitution is feasible.

Chemicals such as brominated flame retardants have become widespread contaminants and are now detectable even in marine mammals from remote areas as well as more generally in human blood and breast milk. Release to the environment occurs not only during the manufacture of these chemicals but also during the routine use and final disposal of a wide range of household and consumer products such as computer components, sofas, carpets, toys and textiles. Studies show the flame retardants, PBDEs, to have similar effects to PCBs by affecting neurological development in the foetus.[4] Again, the youngest in our society are generally the most susceptible to such contamination.

2.1 What is the Substitution Principle?

The Principle of Substitution states that hazardous chemicals should be systematically substituted by less hazardous alternatives or preferably alternatives for which no hazards can be identified.

As a basis for protection of human health and the environment from chemicals of concern, the Substitution Principle has several advantages:

- It provides a stimulus and direction for innovation. Governments need not prescribe particular alternatives, but rather define criteria to guide the identification of alternatives. **This will end the common practice of replacing a hazardous chemical under legislative pressure with a similar hazardous chemical that is less in the spotlight.**

- It implements the Precautionary Principle. Arguments against the Precautionary Principle commonly centre on what degree of evidence of harm is necessary before action is taken to restrict the use of a substance. When applying the Substitution Principle, it is not necessary to wait for cancers, reproductive disorders or genetic defects and elusive evidence of cause and effect. **If alternatives with less hazardous intrinsic properties are available, use of the hazardous substance is not permitted. The potential for harm is then reduced or avoided altogether.**

- It will avoid the current 'paralysis-by-analysis' syndrome where we have upwards of 30 000 chemicals on the market that have not been adequately tested. Substitution reduces the need for cumbersome, time-consuming, subjective and data-poor assessments of risk**. If an alternative is available which is intrinsically less hazardous, intensive assessment of the original hazardous chemical is unnecessary.**

- **In many cases, hazard based substitution eliminates the need for notoriously difficult exposure assessment.** Persistence and bioaccumulation potential are surrogate measures of both hazard and exposure that can be applied quickly to all chemicals[5] In order to identify those of greatest concern.

- **The Substitution Principle provides the stimulus for Clean Production and sustainable product and system design.** A focus on substitution also opens up other possibilities for solving the dilemma of how to replace chemicals of very high concern. For example, where necessary the substitute may not be another chemical, but the redesign of a product. Computer companies are adopting metal housings to avoid the use of toxic flame retardants in plastic. Fire services point to preventative sprinklers, product redesign and alternative materials to achieve fire prevention in buildings. The same function is achieved but by using safer alternatives.

2.2. Why not control the risks instead of insisting on substitution?

"The considerable inherent uncertainty in our understanding of the way that chemicals interact with the environment means that there will continue to be a risk of serious effects, as a result of the use of chemicals products, that we cannot predict on the basis of our current or foreseeable understanding of these processes. This requires a precautionary approach to chemicals management, and this is best implemented through substitution ... We recommend that the UK Government adopt substitution as a central objective of chemicals policy."
UK Royal Commission on Environmental Pollution, 2003[6]

It is not possible to achieve 'adequate control' of the risks of persistent, bioaccumulative chemicals. The fact that traditional risk assessment cannot reasonably be applied to such chemicals, and that a revised PBT (persistent, bioaccumulative, toxic) assessment is necessary, is explicitly recognised in the EU's Technical Guidance Document for risk assessment. Their intrinsic properties mean that there is a high risk of exposure at sometime during the life cycle of the chemical or the article that contains it. Even small releases, if they are continuous, can result in significant exposures. This is why we see significant and, in some cases, escalating levels of brominated flame retardants, nonylphenols and other persistent chemicals in breast milk, umbilical cord blood and human tissue.

Substitution, rather than risk management is therefore essential. Chemicals identified as of very high concern, e.g. carcinogens, reproductive toxins, those that persist and bioaccumulate in the environment and affect the hormone system,[7] should be targeted for substitution based on their intrinsic hazards.

"....It has been suggested by producers of brominated flame retardants that the health risks related to the extrusion of plastics containing PBB and PBDE could be avoided by strengthened worker protection measures in the recycling installations. As an example it was recommended that workers carry protection masks.... Clearly, the substitution of the concerned substances would provide the best protection of the concerned workers."[8]
European Parliament and Council, 2002.

By defining criteria for substances of very high concern, REACH has already clarified which properties of substances make them a priority for phase-out. Any chemical that, by its nature, would require an authorisation to permit continued

use should immediately be targeted for substitution. This is a natural progression from what some Member States have already suggested:

In August 1999, a government decision in the German Bundestag called for a staged but drastic reduction in discharges of endocrine disrupters drawing on a similar decision by the European Parliament on 26th January 1999. The German Environmental Protection Agency (UBA) stated:

> *"Substances whose endocrine potential has been shown in in vivo tests, but where the available data is (as yet) insufficient for legal restriction or prohibition, should be named publicly in blacklists, and made subject to a substitution requirement under the Hazardous Substances Ordinance. Such a list could provide sufficient incentive to substitute, even where there is only a suspicion of danger."*[9]

The Swedish government has also reiterated the need to substitute substances of very high concern. These substances are estimated to be relatively few and would not overload the authorisation system. Sweden states that authorisation of such chemicals may be granted only if industry can demonstrate that no feasible alternatives are available; the socio-economic arguments clearly outweigh the potential risks and emissions are foreseen to be negligible during manufacture, use and disposal.[10]

2.3 What is a 'safer alternative'?

The goal of substitution is to progressively move to safer materials and system design, so it is important to have a clear decision process and set of criteria to define what is 'safer'. As information has increased over the last few decades, there is a general tendency to move from halogenated chemicals to non-halogens specifically because many organohalogens are toxic, persistent and bioaccumulate in living systems or give rise to by-products with these properties throughout their different product life cycles. As more information emerges on endocrine disruption and neurotoxicity, suspect chemicals are highlighted. This has resulted in lists of restricted chemicals drawn up by both regulatory and industrial bodies. For example, the OSPAR list of Chemicals for Priority Action first drawn up in 1998 has focused much attention on the search for safer substitutes for all uses of these chemicals.

However REACH moves the list approach forward by setting a clear standard across Europe on what must be substituted. Any chemical meeting the criteria of 'very high concern' because of its inherent hazards should be subject to the substitution procedure. Conversely, any chemical not intrinsically of 'very high concern' is a candidate for a safer alternative (though cannot, of course, be automatically considered to be non-hazardous).

There will undoubtedly be cases that are not as simple as this. For example, 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 corrosiveness or flammability. However, these hazards are generally easier to control and fall under appropriate health and safety regulations. If there is a serious health and safety issue with a proposed substitute, that alternative would not be deemed an acceptable alternative.

2.3.1 Substitution can be performed on several levels

Substitution may be performed in a variety of ways depending on the application of the hazardous chemical. Approaches vary from 'drop in' substitution with a less hazardous chemical that exhibits the same technical functionality to complete product or process redesign. This allows the same desired result to be obtained by different methods and encourages innovation at all levels from chemical engineering and Green Chemistry to product and systems design. Annex I (6) shows how some chemical producers have reduced the need for toxic intermediates by employing different synthetic routes. Similarly hazardous solvents, in both cleaning and synthesis, may be replaced with more benign alternatives.

The case of toxic phthalates in PVC carpet backings can be used to demonstrate the different levels of innovation available in the search for a safer product:

- **Chemical Substitution** Phthalates are used to provide flexibility to the polymer backing. The use of alternative plasticizers represents the most direct method of substitution. In some cases this choice may have little impact on production techniques, and so be the most economically favourable option in immediate terms.

- **Material Substitution** Replacement of the entire backing with a different material, e.g. a different plastic polymer that does not require phthalate plasticizers removes the need for these chemicals. Other hazards associated with PVC are also then avoided, with potential economic benefits in the medium to long-term. An innovative use of this approach is demonstrated in Annex I (6).

- **Functional/System Substitution** Substitution may also occur at a higher level. The function of the carpet (in this case) is to provide a floor covering. Other alternatives that also fulfil this need are e.g. linoleum, sisal flooring.

2.3.2 Assessment of alternatives

Risk assessment is the conventional tool for decision making on the acceptability of chemical use. It is based on predicted exposure levels, predicted no-effect levels of individual chemicals and politically defined degrees of acceptable risk. Each of these processes involves a series of value judgements and estimations. Risk assessment is therefore highly subjective.

On the other hand, the assessment of intrinsic hazard can be a much more objective process. Intrinsic properties can generally be established and quantified more empirically and provide a better basis for decision-making.

The assessment of substitutes will rely on various factors and a number of methodologies have been developed to compare the alternatives available. A variety of software and tools are available to enable a comprehensive review of chemical properties.

One model, developed for the German Ministry of Environment, uses an evaluation matrix based on indicators to compare a range of criteria, such as specific chemical properties, intrinsic mobility, amount used and indirect releases into the environment. Weightings are given for each chemical assessed and then results are place on a risk index ranging from very high to very low. The evaluation matrix then ranks the most preferable. The indicators for the evaluation and a software tool for carrying out an evaluation can be down loaded from the Internet.[11] Additionally, the German government has studied in some detail the drivers and barriers to sustainable substitution of hazardous chemicals.[12]

Another model, used in the USA, is the OASYS Pollution Prevention Optional Analysis System, developed by the Toxic Use Reduction Institute. Technologies are assessed on a variety of hazard criteria, including acute and chronic human toxicity, physical properties, aquatic impacts, persistence/bioaccumulation, atmospheric releases, disposal, chemical properties, energy/resource use, product hazard and exposure potential. Alternatives are rated to display a series of scores and the final weighted score displays the best option for the manufacturer.[13]

The Swedish Chemical Inspectorate (KEMI) has used substitution analysis to assess biocides with the goal of promoting sustainable agriculture. KEMI uses a seven-step process that evaluates not only the intrinsic hazards of a chemical but its efficiency, its cost and its intended use. Alternatives are monitored and assessed for effectiveness. Since the Substitution Principle has been operational, 20% of the pesticides on the Swedish market have been substituted with less hazardous products. Users have a reasonable time frame to adopt the substitute and this enables smaller pesticide formulators and farmers to adapt to the change with few complications. When a safer product is put on the market, KEMI allows the existing and more hazardous product to be used until its approval expires.[14]

Many progressive companies have used the Substitution Principle to move towards the goal of clean production. Some downstream users of chemicals claim to only use benign chemicals in their processes and products. For instance, the McDonough Braungart team of consultants has worked with the Design Tex company to produce a carpet that is made with non-hazardous chemicals from their 'Positive' chemical list.[15]

In February 2005, M&S launched a new range of household cleaning products called "Naturally Inspired", from which they claim to have removed all synthetic chemical ingredients. According to the press release: "*We've taken out petro-chemical based cleaning ingredients .... We've made sure that every single ingredient we've used actually adds a benefit and isn't there for show, and that each product performs just as well as conventional cleaners*".[16]

Examples of successes in Green Chemistry, as listed in Annex I (6), demonstrate the feasibility of designing benign products.

3. WHY MAKE SUBSTITUTION A LEGAL OBLIGATION?

Many people would argue that substitution is desirable, but without a legal driver it happens only in a piecemeal fashion. Without legislation, the objective - to eliminate all but absolutely necessary uses of chemicals of very high concern - is not achieved.

3.1 The Substitution Principle must be an obligation for all – not only for the most progressive companies

Substitution is already a goal for some progressive companies. It helps them to reduce systematically their use of hazardous chemicals and develop new products. Some companies have agreed on substances that need to be avoided. As documented in the case studies in Annex I of this report, they are instructing their suppliers to phase out a range of carcinogenic, mutagenic and reproductive toxins, as well as some persistent, bioaccumulative, and endocrine disrupting chemicals.

However, voluntary substitution will not end general exposure to chemicals of very high concern. Several studies have shown that voluntary actions in isolation have severe limitations. The OECD published a report[17] pointing out some of the major problems with voluntary as opposed to obligatory schemes. In particular, they point out that 'free riding' is a significant problem among many collective voluntary approaches. This fact was highlighted during industry's lobby for the Directive on the Restriction of Hazardous Substances (RoHS) when the industry sector was adamant that restrictions must apply equally across Europe.

The OECD further note that the economic efficiency of voluntary approaches is generally low because they fail to equalise the costs between all producers and environmental targets are set on individual sectors rather than at a national level.

While the proactive efforts of some of industry demonstrate that substitution is indeed feasible, voluntary action will not solve the global problem of chemical contamination. Such action needs to be universal and across all industry sectors and size of firms. Industry needs clear criteria in which to operate and innovate. In particular, small and medium sized enterprises (SMEs) need clear criteria to chart their way forward in a competitive economy.

A common position statement issued on 25th October 2004, by the Confederation of British Industry (CBI), the UK's Chemicals Industry Association (CIA) and Greenpeace recognises the ability of a strong REACH regulation to drive innovation: "*We share the view that a requirement within the authorisation procedure to substitute substances of very high concern if an acceptable alternative that does not fall into the very high concern category is available has the potential to drive innovation to the benefit of business, human health and the environment.*"
(For full statement see Annex II)

3.2 Substitution regulation spurs innovation

"Just as sustainability presents us with the most troubling and complex technical challenges we face, it also highlights the most important technological opportunities crying out to be cracked by today's chemists. Finding the solutions will result in major economic progress." Terry Collins, Director of the Institute for Green Oxidation Chemistry, 2003[18]

The role of regulations in promoting innovation has been a matter of discussion for a long time. The Royal Commission on Environmental Pollution in the UK appointed the Science and Technology Research Unit at the University of Sussex to report on the impact of regulations on innovation in the chemical industry. The report concluded that the introduction of new regulation sometimes causes a temporary decrease in innovation activity, but in the long term has no negative influence on innovation. It notes that in many countries the most successful firms and industries are those that face the highest levels of regulation.[19]

The 1982 Swedish ban on the use of cadmium as a pigment, surface treatment and stabiliser, backs up this conclusion. The ban was implemented in the face of strong protest from companies claiming the costs would be too high. Later, an assessment of the effects of the ban was undertaken. It was discovered that the ban had caused some short-term financial difficulties for some companies, but in the longer term, no effect was seen on the companies' market shares or profits.[20]

In fact, regulatory drivers are often seen as instrumental in spurring innovation. An assessment by a major aerospace manufacturer of what drives innovation towards safer processes for hazardous waste streams revealed that: 'The regulatory drivers for waste reduction are familiar to most by now, and may be summarised into three categories of legislation: 1) inventory reporting, 2) emission reporting, and 3) employee exposure levels. Anticipation of future restrictions was a decisive factor in this project.[21]

The mandate within the Directive on the Restriction of Hazardous Substances (RoHS) to phase out a range of hazardous materials in new electrical and electronic products by 2006, has been the most significant driver to product redesign not just in Europe, but also in other regions. For example, an

assessment of the high tech industry in Asia has revealed that impending European legislation was the driver for hazardous chemical phase-out and adoption of alternative designs and chemicals.[22] While manufacturers in Europe were opposing the impending WEEE and RoHS directives, Japanese companies strategically positioned themselves as promoters of greener products, and took the lead in finding substitutes for lead solder in electronics. As a result, Japan adopted lead-free soldering technologies well ahead of the WEEE directive timescale, and ahead of European and American counterparts.

Regulatory drivers are needed to stimulate the research and market for safer substitutes. If the cost of a safer substitute is too high due to lack of market demand and interest among companies within a sector, the innovation will remain marginal at best. In particular, it may not spread to the SMEs who would face an even more difficult financial challenge to adopt the safer substitute. A clear regulatory focus on substitution would stimulate the research, development and adoption of safer processes and products. For example, it is well documented that impending legislation under the Montreal Protocol to ban ozone-depleting CFCs stimulated the widespread research and adoption of non ozone depleting alternatives.[23]

Similarly, the various EU directives that mandate substance bans have initiated wide scale research and development of alternative materials. Lead is a case in point. Lead has been widely used in the electronic industry in solders. Lead-free solders have existed for many years but it was the mandate in the Restriction of use of certain Hazardous Substances Directive (RoHS) to have products free of lead by July 2006 that spurred industry research, planning and adoption of the substitutes.[24] Annex I lists examples of Green Chemistry case studies where research was stimulated in response to legislation targeting hazardous materials.

3.3 Legislation is needed to ensure that data is available for substitution

A common complaint from downstream users of chemicals is that data gaps prevent adequate characterisation of the risks from chemicals. Increased information under REACH will change this situation as long as data are transparent, readily available and accessible to the public. But collecting information on chemicals in the absence of a clear goal to replace chemicals of very high concern is likely to lead to the entrenchment of hazardous chemical use within a more costly end-of-pipe management model. Any system that does not force an examination of safer substitutes and make this a priority over the risk management of hazardous substances, will ultimately fail to protect people from needless exposure to chronically dangerous chemicals.

Researchers for the German government have documented a variety of reasons why substitution fails to be carried out.[25] For example, they detail how cement manufacturers in Scandinavia solved the problem of skin contact with cement containing hexavalent chromium back in the 1980s, but the information was not diffused to other European manufacturers.

An extensive overview of the incentives and barriers to substitution prepared for the European Union concluded that well-designed regulatory signals are needed because market forces alone often fail to provide a competitive advantage for the safer product. This is a particular problem where the markets are 'too far away' from consumer awareness to be influenced by the potential demands of consumers.[26]

3.4 Legal precedents for the Substitution Principle

The acceptance of the Substitution Principle as a workable legal act was demonstrated in a European Court of Justice (ECJ) court case in 2000. Trichloroethylene (TRI), a cancer-causing chemical, was banned in Sweden and companies had to find alternatives. Exemptions were only given when a suitable alternative was not available, when use did not lead to unacceptable exposure and on the condition that the company continued to seek alternatives. For the majority of exemptions, the firms had managed to substitute TRI in most of their production, but had not found a suitable alternative for a specific use in the production process. One firm appealed against the ban, but the European Court of Justice ruled against them. The ECJ ruling demonstrates acceptance of the Substitution Principle in EU courts.[27]

3.5 Case Study: Alternatives to Dry cleaning with Perchloroethylene

The solvent perchloroethylene (PERC) is used by approximately 90% of all EU dry cleaners today.[28]

PERC has serious environmental and health impacts, it is toxic to the liver and the central nervous system, can accumulate in the body and is probably carcinogenic to humans.[29] The compound induces leukaemia in rats and increases risk for oesophageal cancer, non-Hodgkin's lymphoma and cervical cancer. It has been shown to cause liver tumours in mice and kidney tumours in male rats.[30] PERC is very persistent in ground water and soil, as well as toxic to the aquatic environment. Perversely, everything perchloroethylene comes into contact with at the dry cleaners must be handled as 'hazardous waste' except the dry cleaned clothes we wear. As a result, dry cleaning operations using PERC are regulated under the recent EU VOC Directive,[31] which requires that VOCs that are carcinogenic, mutagenic or toxic to reproduction should be replaced as far as possible, by 2007. In addition many EU countries have set national regulations.

Wet cleaning
In the early 1990s a significant new alternative to dry cleaning with PERC was developed. The process, termed 'wet cleaning', involves gentle washing with water and specialist detergents, followed by careful drying and finishing. Electrolux first launched a wet cleaning system 'Aquaclean' in 1992,[32] as a complement to dry cleaning. In the UK, the 'Aquatex' system was developed by the company JLA,[33] and was launched in 1994 as a complete alternative to PERC.

Wet cleaning is a direct alternative to dry cleaning for 40 – 60% of items.[34] However, the take-up of wet cleaning has been relatively small, despite its advantages over cleaning with PERC, including lower cost of machinery and nicer smelling clothes. In the UK, the take up of wet cleaning was not sufficient to sustain investment in the drying and finishing technology, and Aquatex is now no longer sold in its complete form. Elsewhere in Europe, especially in the Nordic countries, the Netherlands and Belgium, wet cleaning has had slightly more success, with some shops offering it as a complete alternative but PERC still dominates.[35]

Carbon Dioxide (CO_2) and other alternatives
CO_2 technology provides a complete alternative to PERC and can process some additional fibres such as leather and fur, which are problematic with perc-cleaning. Capital investment is relatively high,[36] but the process is very efficient, with a greater throughput than cleaning with PERC, lower costs per kg,[37] and lower maintenance costs. This means that over the course of machine lifetime CO_2 is cheaper than PERC. CO_2 cleaning technology has been available commercially since 2003; in the US and Canada there are over 90 installations, but in Europe it is still relatively new, with 5 installations in the Netherlands and 3 in Sweden.[38]

Other alternatives exist though these are associated with risks such as flammability and potential toxicity.

Barriers to take-up of alternative cleaning technologies
It is likely that greater uptake of alternative technologies to dry-cleaning with PERC has been hindered by a combination of factors including:
Improving efficiency of PERC dry cleaning machinery Equipment manufacturers are able to offer advanced machinery complying with the stricter emission control standards, to the extent that the consumption of PERC has reduced by more than 50% since 1980, and in some countries 90%[39] - misguided efforts that could have been better directed towards removing this toxic substance totally.
Economies of Scale Due to the lack of 'push or pull' pressures (regulatory or governmental aid) take up has been low, this results in no reduction in capital costs that would inevitably occur if take up increased.
Resistance to change There is reluctance to change to an unknown technology, has different technological properties and depends on skilled operators.
Lack of a wet cleaning label for garments To date, there has been no care label for wet cleaning. In 2002, the International Committee of Textile Care (CINET) proposed such a new label (a bold **W** in a circle), which will be voted on in 2005.

The fact that regulations required users of PERC to meet emission limits, rather than substitute PERC by investing in alternative technology, meant that few dry cleaners were bold enough to convert to new methods. A variety of safer substitutes have existed for over a decade that the Canadian and US governments have independently monitored. Both studies confirmed the economic and environmental benefits and technical feasibility of these alternatives.

A recent EU-funded study examined the operation of two full-scale liquid carbon dioxide (LCO_2) pilot units in Denmark and the Netherlands, based on 38 different textile materials and nine different garment types. The study identified several advantages of LCO_2 textile cleaning compared to perc dry cleaning:

- Less dimensional change of sensitive fabrics;
- Less colour loss of the fabrics;
- Less direct bleeding of colour from one fabric to another;
- Less loss of glitter, glued on a basic fabric;
- Less loss of oily/fatty finishes;
- Less damage to coatings or laminates that swell with perc;
- Less loss of textile fibres during the cleaning cycle leading to a longer lifetime of the garments.[40]

However, the majority of dry cleaners continue to use perchloroethylene because there is little awareness and no legislative imperative to choose safer substitutes.[41] With both wet cleaning and CO_2 now available in Europe and commercially competitive, there can be no justification for the continued use of PERC to 'clean' clothes.

4. WHAT IF THERE IS NO SUBSTITUTE AVAILABLE?

Substitution is already a goal for some progressive companies and case studies have been extensively documented. (See Annex I) Reasons why some companies are searching for safer substitutes include:

- regulatory drivers (such as the European Directives on the Restriction of Hazardous Substances in electronic equipment and End-of-Life Vehicles);
- increased public awareness;
- demands from downstream users or clients;
- worker protection;
- liability issues, and
- competitive advantage and company ethics.

In addition to legislation mandating substitution, other activities and instruments will be required to ensure proper implementation of the law. These include:

- mandatory planning for substitution;
- technical and financial support to identify safer chemicals, and
- use of taxes
- regulatory drivers such as time-limited authorisations, in order to encourage timely action.

4.1 Mandatory planning for substitution

Any company using a chemical that requires authorisation should be required to provide a Substitution Plan, namely an assessment of available substitutes. This should include a full description of the alternatives available, a comparative assessment of their intrinsic hazards and an assessment of technical feasibility. This substitution assessment would form the basis of a justification of why an intrinsically less hazardous alternative cannot be used to replace the substance of high concern. The Substitution Assessment Plan should be transparent as to the methods and data used in seeking and assessing alternatives and should be open for independent scrutiny.

If the company demonstrates that no suitable alternative is available, and can satisfy the other requirements for an authorisation to be granted (a social need, a positive cost benefit analysis and minimisation of exposure and risks) a Substitution Plan should be required, so that chemical, process or function substitution can take place upon expiry of the authorisation period. In other words, any authorisation granted must be time-limited and conditional on companies putting in place an effective Substitution Development Plan.

Costs of alternatives may initially be higher than continued use of a chemical of very high concern, but increased demand for the alternative will drive costs down, particularly as competition increases among producers to supply the new market demand. Chemical producers will in turn find an expanded market for Green Chemistry products.

Making companies prepare plans which focus on safer chemical use has proved particularly successful in the USA. The benefits of mandatory pollution prevention planning have been demonstrated in the state of Massachusetts. Here, over 550 companies had to assess toxic use reduction options with technical help supplied by university and government experts. Toxic use reduction strategies included material substitution and product reformulation. Within ten years, industry has reduced the use of toxic chemicals by 40%, by-product waste by 58% and toxic emissions by 80%. A cost benefit analysis reveals that the same companies saved a total of Saved a total of USD 14 million (Euro 10.47 million) over this period through the adoption of more efficient and safer processes. The programme is ongoing and has been expanded to community outreach and assessment of substitutes for some hazardous material flows and products within the state.[42]

4.2 Economic Instruments

To further stimulate the drive to safer substitutes, a fee could be levied on users of all authorised chemicals. This fee could be used to centralise and disseminate information on alternatives, and fund research. At the same time, any direct or indirect subsidies and tax exemptions to the chemical industry should be withdrawn.

In some EU countries, green taxes are already being used to help achieve environmental goals. In 1996, Denmark abolished some of the taxes on personal income, while at the same time introducing new green taxes on environmental 'bads', including pesticides and chlorinated solvents. This type of ecological tax reform could be used to tax producers of chemicals requiring authorisation, and use the revenues to subsidise the development of safer chemicals.

4.3. Technical Support to find safer alternatives

Expertise to help companies already exists in many countries. Companies who are adopting safer alternatives often contract outside help. Chemical producers have their own in-house research teams. Other institutes work

with SMEs such as the European Cleaner Production networks and some Member States have well-established programmes that focus on sustainable product design and safer chemical use.

Some Member States give prominence to substitution in government policy. For example, the Danish environmental strategy prioritises action on their dangerous substances list and encourages manufacturers and importers to find substitutes and to develop alternative products. The Danish EPA's 'Cleaner Products Support Programme' grants subsidies to a number of projects that promote substitution. It supports the development, testing and assessment of alternatives to brominated flame retardants, as well as the dissemination of knowledge to manufacturers about the feasibility of implementing alternatives.[43] Such information helps small and medium size enterprises who cannot afford the same level of research into hazards and technical feasibility as large corporate users.[44]

The Swedish government's 'Seven Steps to Substitution' are based on comparative assessment and the feasibility and availability of substitutes. The government gives help to industry through its PRIO interactive database that contains both substances that are regulated and those that are not covered by any legislation. PRIO provides data on the intrinsic health properties and environmental properties of substances. Through an interactive website, it allows companies to assess their chemical use, examine the opportunity for risk reduction through substitution and anticipate future legislation.[45] A variety of other software tools in other countries exist to help industry assess alternatives.[46]

The UK, Germany, Denmark and Sweden have disseminated information on safer substitutes for specific industrial sectors as well as guidance documents for industry. The UK Government agrees with the Royal Commission's assessment of the importance of substitution and has decided that they "*will take a more strategic approach to discussions with industry by examining substances of concern in groups of say 10 to 12 per Forum meeting.... An approach which will, in turn, help to prepare UK industry for the requirements expected of it under REACH.*"[47]

It is essential that ALL authorisations are time-limited. This is necessary to move towards the goal of phasing out all chemicals of very high concern.

5. SUBSTITUTION IN PRACTICE – THE INDUSTRY EXPERIENCE

Annex I to this report presents a large number of cases in which substitution has been carried out successfully, following a systematic approach to finding alternatives. The information was compiled from desk research and from conversations with industry representatives. Other case studies show how leading retailers are moving to phase out hazardous materials and how some chemical companies are researching and implementing Green Chemistry. The information available demonstrates that substitution is feasible and is already happening in the more progressive sectors of industry.

For example:

Apple does not use brominated flame retardants in the enclosure plastics of its products and is actively seeking alternatives to brominated flame retardants in circuit boards.

Some manufacturers use internal metal 'shields' to protect computer housings from internal sparks and heat, and can therefore use non-flame retarded plastics.

Electrolux is the world's largest producer of powered appliances for kitchen, cleaning and outdoors. They have created comprehensive Environmental Product Declarations (EPDs) for many of their product lines. Information within the product profiles details chemicals that have been banned as well as the percentage and types of materials and how they have improved material choices. For example, plastic components do not contain cadmium, lead, mercury or their compounds or chlorinated or brominated flame retardants; metal components are not coated with cadmium, chromium, or nickel; and metal paints do not contain pigments and additives based on heavy metals. Many Electrolux products are also PVC-free.

Until recently, halogen-free products were only available in Europe, but **Sony** has now adopted global design specifications to ensure that all their projects meet the same standards. Sony aims to have all product lines free of brominated flame retardants by the end of 2005 if substitutes are found to be safer. They also aim to phase out all uses of polyvinyl chloride (PVC) by 2005 as well as lead solder, and specified heavy metals. For example, a Walkman model has PVC-free cables and no brominated flame retardants or lead solder in the printed circuit board.

5.1 Greenpeace efforts to win corporate commitments to chemical substitution

Some of these company decisions to substitute hazardous substances were prompted by Greenpeace letters and meetings with companies. In 2003, Greenpeace started writing to companies asking them to commit to implement chemical substitution based on the precautionary principle, and as a concrete measure to commit to substituting a list of Chemicals for Priority Action, first identified by OSPAR in 1998, with some additions by Greenpeace.

OSPAR LIST +

OSPAR List of Chemicals for Priority Action (1998)
Polychlorinated dibenzodioxins (PCDDs)
Polychlorinated dibenzofurans (PCDFs)
Polychlorinated biphenyls (PCBs)
Polyaromatic hydrocarbons (PAHs)
Pentachlorophenol (PCP)
Short chained chlorinated paraffins (SCCP)
Hexachlorocyclohexane isomers (HCH)
Mercury and organic mercury compounds
Cadmium
Lead and organic lead compounds
Organic tin compounds
Nonylphenol/ethoxylates (NP/NPEs) and related substances
Musk xylene
Brominated flame retardants
Certain Phthalates – Dibutylphthalate and Diethylhexylphthalate

In addition, Greenpeace includes **ALL synthetic musks, phthalates** and **alkylphenols** on the banned substances list and has added **PVC** because some of these substances are mainly used as additives for PVC or created during its production, and because PVC hampers recycling of products.

Companies and their brand name products are ranked red, amber and green according to their commitment to substitute OSPAR+ chemicals. The rankings are updated on a database, known as the Chemical Home at: http://www.greenpeace.org.uk/Products/Toxics/

Since the launch of the international database in May 2004, several companies have committed to substituting OSPAR+ chemicals and their products have been graded amber. The first was **Samsung**. In June 2004, Samsung committed to phasing out the specified chemicals, and is currently working on a phase out programme which sets dates for a ban on PVC, organotins and brominated flame retardants.

Gregor Margetson, Head of European Environmental Affairs for Samsung Electronics Europe said: "*Samsung Electronics*

has always taken environmental issues seriously and our work with Greenpeace shows we welcome constructive input on such subjects. Their initial criticism motivated us to re-evaluate our goals and consider what is truly possible. We choose to take the difficult option because we have ambitions to become a more sustainable company, and we realise that this prize comes at a price".[48]

In November 2004, following discussions with Greenpeace, brand name products made by Unilever, Nokia, Puma, Adidas, and Chicco were graded on the database.[49]

Puma, a sport-lifestyle brand, committed to eliminating the OSPAR+ chemicals from both its sports shoes and perfumes with immediate effect, across their whole product range.

Dr Reiner Hengstmann, Global Head Environmental & Social Affairs at Puma, said: "*The intentional use of hazardous chemicals is forbidden and when traces of hazardous substances are found in the product (due to contamination), Puma looks into the source and eliminates the cause. From Puma's point of view, it is well worth the effort to be proactive with our standards whenever the health of our consumers and manufacturing partners is at stake.*"

Adidas, a sporting goods company, has committed to phasing out OSPAR+ substances from its sports shoes, so is ranked amber on the database. However, Adidas has yet to adopt a phase-out policy for its perfume and body care products so the company grading remains red (February 2005).

In October 2004, **Unilever** confirmed that its new personal care products, such as the Organics and Timotei shampoo lines, and household products in Europe do not contain OSPAR+ chemicals. These include: shampoo, body lotion, cleansers, cleaning products and detergents. Almost all phthalates will be banned from these products, except for one phthalate DEP, which will take a bit longer to phase out. Unilever has not yet eliminated phthalates and musks in their perfumes.

Nokia, the world's largest manufacturer of mobile phones, has committed to phasing out brominated flame retardants (BFRs) and PVC plastic. **Chicco**, a manufacturer of toys and baby products, will eliminate the use of PVC within three years; small amounts of this plastic are still used in components, accessories and packaging.

Toxic recycling of printed circuit boards in China

5.2 Downstream users promote mandatory substitution

Companies with experience in working systematically with substitution are in many cases actively promoting the inclusion of the principle in legislation. This is, for instance, seen in comments from companies to the European Commission during the REACH consultation in July 2003. Notably, companies with lengthy experience from national requirements embracing the substitution principle praise the legislative instrument, and promote its use in REACH.

Skanska, one of the world's largest construction companies with 75 000 employees and activities world-wide, are stating that operating for many years under substitution regulation in Sweden has lead them to *"...continuously seek less harmful alternatives. This is something that our clients expect from us as a producer of buildings or infrastructure. As we are not*

experts on the components in our products, we have to go back to our suppliers with the requests that our clients put on us. As manufacturers of building components they will have to go back to their suppliers etc. This is the way we want the market to work in order to reduce the environmental impact."

Skanska are disappointed with the lack of a strong substitution rule in REACH: *"The present proposal is much more static, focusing only on evaluation and registration. Without the strong support from a Substitution Principle it will be difficult for an individual company that is a downstream user to be proactive in substituting substances."* [50]

Tetra Pak, the world's largest producer of food packaging, takes a similar stand: *"These two principles [precaution and substitution] are important principles in the Swedish national chemical policy and has proven to be a good basis for chemical control. Tetra Pak is therefore supportive to building the REACH system on these two fundamental principles. Precaution and substitution need to be introduced early in the text as guiding principles for the whole policy."* [51]

In fact, the collective construction industry in Sweden strongly advocates an EU-wide substitution regulation. The Construction Federation that represents the interests of the construction industry in Sweden, state in their response to the REACH consultation that: "*Particularly hazardous substances must be blacklisted and, accordingly, banned. Only substances for which there is no safer alternative may be exempted and this only if there are strong social or economic reasons for doing so. If an exemption is granted, producers/users must take precautions in order to minimise the risks….Products containing particularly hazardous substances should not be authorised just because the producer/importer can show 'adequate control'. Substitutions should always be considered.''*

The Federation calls for the following text on the Substitution Principle to be incorporated in the legal text: *"Particularly hazardous substances must be blacklisted and banned. Exemptions may be granted only when it is clear, after a thorough investigation, that there is no safer alternative and if the social and economic advantages are greater than the risks involved with using the substance."* [52]

5.3 Recyclers support mandatory substitution

Industry sectors further down the product chain express their concern about a weak or non-existing Substitution Principle in REACH. The Recycling Industry Association in Sweden, for instance, considers both precaution and substitution practically absent in the legislative proposal. They insist that: *"In order for EU to maintain a high level of chemical control, it ought to be explicitly stated in introducing articles of the legislative text, that the Precautionary Principle and the Substitution Principle constitute the fundamental principles of the entire legislation. The principles also ought to be incorporated into the Duty of Care chapter, to make clear that all parties will follow the principles, and be responsible for having sufficient knowledge to uphold the duties set up by REACH."* [53]

5.4 Retailers support mandatory substitution

H&M, one of Europe's largest retail chains, is a strong proponent of safer substitutes. They state:

"H&M is applying the precautionary principle. In practice, this has meant working closely with our suppliers to phase out substances and materials that are, or could potentially be, harmful to our customers or the environment, from our products. In doing so, we have constantly, together with our suppliers, searched for less harmful solutions. We have encouraged our suppliers to be innovative and when we have found a better alternative somewhere among our suppliers we have helped to spread that knowledge to other suppliers and other markets.

In doing so, we have found that almost anything is possible as long as you set clear guidelines on what is not acceptable. We have not had to compromise on fashion or quality in a way that has harmed our business. Prices may have gone up temporarily but as soon as mass production has started, the prices have gone back to previous levels.

With the background of this experience, we find it important that EU legislation supports the idea of substitution when a better alternative is available. Such legislation would support us in our continued effort to eliminate hazardous substances from our products and to find better solutions that are less harmful to the environment."
Ingrid Schullström H&M

6. CONCLUSIONS

The proposed REACH legislation attempts to address the lack of information on existing chemicals and the need to prioritise substances of very high concern for regulation and substitution. However, under the current draft, even the most hazardous chemicals will be authorised for continued use if a manufacturer can demonstrate that the risk to human health and/or the environment is 'adequately controlled'. If adequate control cannot be demonstrated, an authorisation may still be granted if socio-economic benefits outweigh the risk to human health and/or the environment arising from the use of the substance. This decision shall be taken after consideration of: (1) the risk posed by the uses of the substance; (2) the socio-economics benefits as demonstrated by the applicant or other interested parties; and (3) any available information on alternative substances or technologies.

These loopholes in the REACH proposal will effectively mean that even the most hazardous substances could be granted authorisations for continued production, even when safer alternatives are available. 'Adequate control' does not prevent releases into the environment and the intrinsic properties of chemicals of very high concern mean these releases will lead to ongoing exposure and continued build up of these chemicals in the environment and in human beings.

If REACH allows the continued production of chemicals of very high concern under a provision for 'adequate control', even when intrinsically less hazardous substitutes are available, it will not provide the high level of protection for human health and the environment required under the EU Treaty.

The Substitution Principle should be the key principle of the authorisation process. Specifically, it must be mandated that **the availability of a safer alternative is in itself sufficient reason to refuse an authorisation.** This is the only way to ensure REACH is a driver of safer chemical production and innovation; not an entrenchment of hazardous chemical use that permits the continued, unnecessary exposure of people to hazardous chemicals for the sake of short term profits.

Some sectors of industry are already developing practical programmes on substitution. At the same time, expertise exists within the European Union to help small and medium companies implement safer products and processes. Some governments, such as in Sweden and Denmark, already provide technical and other support to companies to help them identify safer substitutes to harmful chemicals.[54]

A requirement to provide a Substitution Plan with all applications for an authorisation will prevent unnecessary requests for authorisation and focus attention on safer chemicals. If substitution is not currently feasible for a particular use, the use of an authorised chemical would be allowed under a strict risk management regime, providing social need could be demonstrated and a positive cost/benefit analysis provided. The authorisation would be time-limited to allow the development of safer substitutes, and manufacturers and/or users would be required to produce a substitution development plan to enable substitution to take place before the authorisation expires.

Such planning for substances of very high concern would vastly improve the information flow and development of safer substitutes. It would also move Europe to become a more competitive, innovative and sustainable producer of chemicals, goods and services. More importantly, it would begin to reverse the body burdens of hazardous chemicals that we all now carry.

Baby sucking a non-PVC teething ring

ANNEX I: CASE STUDIES OF SUCCESSFUL SUBSTITUTION

The following case studies focus on chemicals likely to be defined as 'substances of very high concern' i.e. that would require authorisation under the REACH system.

The information was compiled from paper and on-line research and from direct phone conversations and meetings with industry representatives. The more comprehensive overview of case studies of company substitutions for brominated flame retardants demonstrates both the complexity and feasibility of implementing safer alternatives. Other case studies show how leading retailers are moving to phase-out hazardous materials and how some chemical industries are researching and implementing Green Chemistry alternatives.

1. SUBSTITUTING BROMINATED FLAME RETARDANTS (BFRs)

BFRs are used in a wide range of consumer products: electronic components, textiles, foam in upholstery, carpets and building materials – all uses where the risk of fire necessitates caution. The increase in the use of plastics and flammable synthetic materials has contributed to the rise in the use of flame retardants.

As evidence grew by the late 1980s of the dangers of brominated flame retardants, particularly PBBs and PBDEs, Germany, Denmark, the Netherlands and Sweden began restricting and banning their use. In a declaration of intent in 1989, the chemicals industry and plastic manufacturers in Germany declared that they would neither produce nor use PBDEs.[55]

1.1 The electronics industry found alternatives to BFRs

The electronics industry moved quickly to find alternatives ranging from material substitution (replacement of halogenated flame retardants with non-halogens) to function substitution (replacement of plastic with metal housings). Much of the stimulus for better design and less hazardous materials has come from the WEEE and RoHS Directives and their emphasis on recycling and chemical bans respectively. 80% of a typical product's environmental impact is determined by its design.[56]

As concern around bromine compounds grew, industry moved away from those under the greatest legislative pressure (PBDEs and PBBs) towards other bromine compounds such as TBBP-A and HBCD. Meanwhile, understanding of the toxicity and persistence of TBBP-A and HBCD has increased the pressure to address brominated flame retardants as a class and, in parallel, the development and supply of non-halogenated chemicals has increased.

Apple does not use brominated flame retardants in the enclosure plastics for its products.[57]

In response to the German Dioxin Ordinance of 1994, **Sony** Europe started investigating safer substitutes for halogen-based flame retardants. Sony has developed halogen free circuit boards used in European television sets, VCRs and DVD players. Printed circuit boards use resin that is an inherently flammable material. Sony's engineers adopted a resin structure containing nitrogen to increase heat resistance and modified the content and dispensability of the phosphate compounds and fillers. Since the circuit boards must be completely halogen free, Sony also substituted phthalocyanine green, which contains chlorine, with phthalocyanine blue as the photoresist pigment that covers the board's surface. By substituting all chlorine- and bromine-based chemicals with safer alternatives, there is no longer a risk of dioxin formation throughout the product's life cycle.

In 2001, **Samsung** Electronics Co. Ltd. developed a 'Green semiconductor' that uses no halogen compound or toxic substances such as lead, chlorine and bromine. The company was the first to develop a package and module that contains neither lead nor halogens. The alternative increased quality, and has saved 960 million won (684,000 euros) since its inception. Samsung has marketed its efforts in substitution to enhance its corporate image as an environmentally friendly company that responds rapidly to international environmental regulations. However, precise information on alternatives is seen as confidential.[58]

National/Panasonic (Matsushita) joined forces with other major manufacturers to develop electric wires and plastics that do not contain halogen compounds. In September 1999, they began marketing the world's first wide-screen television free of halogen compounds that had been eliminated from low voltage internal wires, from the cabinet, from the back cover and from a number of printed circuit boards. At present, this technology is being successively applied to a wide range of other products, such as PCs and monitors. The company does not state on its website what alternatives they are using.[59]

TBBA, a brominated flame retardant, is used in the epoxy resin laminate in printed circuit boards in most manufacturers' products. In 1997, a phosphorus-based alternative to TBBA was developed by the German engineering giant, **Siemens,**

with support from the German Research and Technology Ministry. The laminate is manufactured under licence by Siemens-Nixdorf, a wholly-owned subsidiary of Siemens, and by the German chemical group **Hoechst.** Furthermore, the production waste, which can amount to 30% of the final product's weight, can be recovered more easily because of the absence of halogens. All of the housings and keyboards manufactured by Siemens-Nixdorf are BFR-free.[60]

The electronics giant, **NEC** produces mobile phones, office equipment and personal computers. Its environmental policy includes a target to stop using halogenated flame retardants by 2011. In 1999, the company went one step further and launched a polycarbonate containing a silicone flame retardant which it claims to be 'far superior to conventional flame-retarding plastics in environmental safety'. Sold under the brand name NuCycle, the new material is used to make NEC's liquid crystal display (LCD) monitors and battery packs for portable computers and it can be recycled up to five times for the same purpose.[61]

In 2000, **NEC** developed an epoxy resin with what it describes as a fire-retardant structure that avoids the need for either TBBA or phosphorus-based flame retardants in circuit boards. The new resin contains a metal hydroxide retardant. The company claims the new board is 'almost totally free of pollutants', and is easy to process and thermally recycle. By also integrating flame retardant properties within the board, use of the metal hydroxide is minimised, while offering good electrical properties, higher heat resistance and improved processing characteristics.[62]

1.2 Retailers target BFRs for substitution

IKEA prohibits a range of hazardous materials in their product lines, including azo dyes in textiles and a product-wide ban on BFRs and PVC. IKEA chooses textiles and materials that by nature are difficult to set on fire and can often completely avoid the need for chemical flame protection in their products with innovations such as inter-liners made of non-woven inherently flame retardant materials. When the company has to meet more stringent fire standards for the UK and Californian market, they employ chemical substitutes for some product lines. To meet UK fire standards which are the most stringent in Europe, IKEA replaced brominated compounds with organic phosphorus and nitrogen compounds either applied by impregnation of the cover fabric or to a cotton inter-liner.

Deca-BDE is used widely in polyurethane foam in the United States due to the lack of regulatory controls, and limited awareness of the dangers of BFRs within the upholstery industry. IKEA was able to meet the stringent Californian standards by switching three years ago to melamine combined with chlorinated paraffins. Melamine is not a bioaccumulative or persistent material. They are now researching alternatives to chlorinated paraffins, including the use of novel substances, such as expanded graphite. IKEA is conducting this research in isolation in the USA and points out that the cost of new substitution will be high unless other upholstery designers and retailers follow suit.[63]

Marks & Spencer continue to develop substitutes for deca-BDE in some product lines.

Suppliers to **Laura Ashley** have confirmed they do not use any BFRs in their product lines.

H&M (Hennes & Mauritz) uses no flame retardants in any product line, using instead natural materials that are inherently flame resistant. In a few cases, the company has cancelled clothing line items that proved a potential flammable hazard and could not be materially replaced.[64]

1.3 Leaders in the building trade are phasing out BFRs

Skanska is one of the world's largest construction companies and was ranked by the Financial Times as the world's most respected company in the property and construction sector. Skanska Sweden was a leader in developing a national, industry-wide chemical database. The Skanska database now contains over 5,000 chemical products and stipulates if a substance is banned from use, should be avoided or represents an environmentally favourable choice.[65] This positive approach, based on the substitution principle, prevents the company being stifled by the prohibition of a substance, since existing alternatives are instantly presented.

Skanska is replacing BFRs through product redesign and material substitution. They initiated a project entitled 'Brominated Flame Retardants in the Building Industry' to audit the use of BFRs in building materials, analyse substitutes, and draw up a plan of action. Their investigation found that fire standards for individual components should shift to the installation as a whole and be more function-oriented. They identified several examples where purchasers selected a flame retarded product marketed as 'fire proof', even where there was no legal obligation to use flame retardants.[66]

2. ASSESSING NON BFR CHEMICAL ALTERNATIVES – ARE THEY SAFER?

The Bromine Industry in particular, points out that non-brominated chemical flame retardants may be very hazardous and that the phase-out of BFRs may not be safe. The non-brominated alternatives listed in the above case studies are likely to be safer if they exhibit less persistence and bioaccumulation in living systems, but some do possess significant toxicity. In the last few years, some agencies have therefore investigated the relative merits of alternatives to BFRs.

The German Environmental Protection Agency (UBA) surveyed 13 flame retardants for toxicity to humans and the environment and their suitability for closed-loop substance management. The aim was to assess the feasibility of substitution with less hazardous flame retardants. They selected red phosphorus, ammonium polyphosphate and aluminium trihydroxide as the least environmentally problematic alternatives.[67] Red phosphorus can technically be used in a variety of polymers to meet even the toughest fire safety standards, although it may not work for all applications.[68]

UBA remarked that: *"It is encouraging that there is a general trend to refrain from the use of halogenated flame retardants in products and to replace them with less problematic flame retardants or to redesign flame retardant systems, e.g. by creating greater distances to potential heat sources."*

Their findings are summarised in Table 1.

The Danish Environmental Protection Agency also investigated the profiles of 12 non-brominated flame retardants for environmental and health effects. From a survey of published literature, they found that the amount of data available is often very limited, particularly for important criteria such as degradation. Furthermore, the screening study showed that the majority of the alternatives also had undesirable environmental and health characteristics, but an assessment was needed to determine the amount and the manner in which they are released before a conclusion could be drawn.[70]

REACH will obviously help fill this much-needed gap in information. It can be surmised that the phosphorus alternatives to BFRs listed in the case studies above are generally safer because of the non-organic, less bioaccumulative nature of the compounds. Some alternative compounds are in need of more research depending on the type of mix used. Specific information on the exact chemical composition was generally not available. However, it is vital to remember that, within the context of Substitution Assessment

Table 1. Flame retardants investigated by the German Environmental Protection Agency, Umweltbundesamt (2001)[69]

Summary evaluation of flame retardants	
I Phase-out is recommended	• Decabromodiphenyl ether • Tetrabromo bisphenol A, additive
II Reduction is expedient, substitution desirable	• Tetrabromo bisphenol A, reactive • Tris(chlorpropyl)phosphate
III Problematic properties; reduction expedient (Borax)	• Hexabromocyclodo-decane • Sodium borate decahydrate • Antimony trioxide • Antimony trioxide
IV No recommendation possible due to gaps in phosphate knowledge	• Bis(pentabromophenyl)ethane • Resorcinol-bis-diphenyl- • Pyrovatex CP new • Melamine cyanurate
V Use is unproblematic	• Red phosphorus • Ammonium polyphosphate • Alluminium triydroxide

Planning, substitution is not envisaged as a simple process. It also takes account implicitly of the need to develop effective alternatives where they are not already available and to adapt rapidly to technical progress.

2.1 Material and functional approaches to substituting BFRs

Using alternative chemicals is only one route to safer substitution. Material and functional alternatives also exist as well as preventative action to ascertain the real need for flame retardants.

An analysis of possible substitution choices for BFRs in the computer and auto industry was conducted in Germany and subsequent stakeholder sessions were held to further discuss the types and feasibility of alternatives.[71]

Substitution fell into the following basic types:

- **Using non-flammable materials**: Merely substituting flammable with non-flammable materials, e.g. plastic with ceramic circuit boards, can render the use of flame retardants unnecessary.

- **Preventing fire risk by improving design**: Increasing the distances between possible flashpoints and flammable materials may be sufficient.
- **Substituting hazardous flame retardants** with safer ones that have less impact on the environment and human health.

Some companies have gone down the non-chemical solution route: e.g. IKEA and Sony's use of non-flammable materials. The issue of fire safety regulations is topical. The bromine industry maintains that fire safety is paramount and particularly defends the increased use of some of its chemicals in the USA by pointing out that less stringent fire standards in Europe are associated with more fire deaths.[72] An examination of fire death rates for countries in Europe and elsewhere reveals in fact that deaths by fire are no higher in Europe and in fact the USA has higher number of fire deaths per 100,000 persons than many European countries.[73] Europe, on the whole, uses a fire standard based on a smouldering cigarette test, whereas California uses criteria based on direct flame tests.

The disparity of opinions about European and American approaches to fire safety and standards led to the creation of Green Flame, a programme of the International Consortium for Fire Safety, Health and the Environment. The Swedish Rescue Services Agency, the Swedish National Chemical Inspectorate, the Swedish Environmental Protection Agency and the US National Association of State Fire Marshals and corresponding US environmental agencies jointly run the system. The goal of Green Flame is to promote the design of products and systems that are fire resistant but environmentally safe.[74]

The Swedish National Association of State Fire Marshals, a member of Green Flame, has been at the forefront of advocating more function based alternatives to BFRs.[75] They apply their expertise in fire prevention in buildings to products. They emphasise the role of product design in avoiding flammability and advocate that such criteria should be part of eco-labels. Prevention is key, and fires need to be detected at an early stage. They advocate the use of fault detectors to shut off the electrical supply, as well as automatic extinguishing systems inside personal computers and televisions. In particular, they point out sprinkler systems are used for protection inside racing cars so their use in personal cars, buses and trains is also possible and would provide a significant increase in fire safety.

They also outline a selection of materials that can favour fire safety in certain applications:

- wood (to replace borders and edgings made of polymers)
- Metal
- glass, stone, and ceramics
- plaster (to replace fake stucco details)
- leather, wool, cotton, linen, hemp
- living trees or flowers (to replace synthetic variants)
- stone or glass wool as insulation
- paper (packing materials)

Flammable materials, air and a high temperature are needed to keep a fire burning. The State Fire Marshals advocate:

- lowering the energy that might be produced in the event of electrical failure
- lowering the power requirements for electrical appliances
- preventing heat production from friction in engines or movable parts in fans
- placing electrical heat sources at sufficient distances from flammable materials
- using internal fuses to cope with overloads or short circuits
- maintaining sufficient distances between warm parts and flammable materials
- cooling down parts which generate heat
- using an extinguishing system that reduces the temperature

Supply of air can be stopped by:

- enclosing the heat producing technical components of products in metal
- using materials that creates a layer of tar (or similar) on burning
- designing sandwich constructions with non-inflammable surfaces
- using an extinguishing system that separates the fuel from the air

The creation of a two-year research programme into fire prevention within the EU will accelerate the move to safer substitutes to BFRs in buildings. The project, backed by the Commission, began in 2003. The aim is to stage a series of workshops at which member states can share expertise and experience as a basis for agreeing best practice in fire prevention.[76]

3. SUBSTITUTING LEAD IN ELECTRONIC PRODUCTS

The RoHS Directive was a major catalyst for research and adoption

of lead-free solutions in electronic equipment. Alternatives to lead in soldering range from tin (Sn), silver (Ag) and copper (Cu) to bismuth (Bi) and zinc (Zn). These heavy metals do not have the same toxicity and bioaccumulation potential of lead (Pb).[77]

NEC achieved the substitution of lead solders by Sn-Ag-Cu in their pagers by December 1998; by Sn-Zn-Bi in their notebook PCs by October 1999; and by Sn-Ag-Cu in their main computers and equipment by 2002.

Fujitsu replaced lead solder with Sn-Ag-Cu for their high-end servers by October 1999; the use of Sn-Bi-Ag for their main board; and all new products to use Sn-Ag-Cu and Sn-Bi-Ag by the end of 2002.

Sony replaced lead solders with Sn-Ag-Bi-Cu solders in their digital video cameras by March 2000; and all products, electronic components and maintenance services to be lead-free by end of March 2006.

Panasonic achieved the full adoption of Pb-free solder using Sn-Cu in 2001.

Philips has developed new lighting for cars – the Philips HiPerVision Technology - that provides lighting for the automotive industry and uses 99% less lead.[78]

4. RETAILERS ARE SUBSTITUTING A RANGE OF HAZARDOUS MATERIALS

- **Phthalate esters** are used as softeners in flexible PVC products, including floors, wallpapers, furnishings, clothing and toys, as well as ingredients in cosmetics and perfumes.
- **Organotin** compounds are used as stabilisers in plastics, especially PVC, and the organotin TBT is used as a treatment against mould in some floor coverings.
- **Alkylphenols** and their derivatives (APEs) are primarily used as non-ionic surfactants in industrial detergents, though also in textile and leather finishing treatments, water based paints and as components of some personal care products.
- **Artificial musks** are used in fragrances and perfumes, air fresheners and laundry powders.

Marks and Spencer (M&S) has identified 14 groups of 'chemicals of concern', that include phthalates, artificial musks and brominated flame retardants, which the company has targeted for removing from its products.[79] So far, M&S has eliminated 96% of their use of PVC in packaging.[80] PVC has also been eliminated from childrenswear, thereby reducing their exposure to damaging phthalates and APEs, though it remains in handbags, belts and shoes.[81] In a clear case of chemical substitution, nitro-musks have been substituted by macrocyclic musks. However, very little information is available about macrocyclic musks, both on their scale of use and their potential hazards to human health or the environment.

M&S targeted the substitution of alkyl tins in the dyeing and finishing of clothing, along with azo dyes and APEs some years ago. Their product specialists are working with the Green Chemistry department at York University to explore safer alternatives. They have not yet found substitutes for bisphenol A in some of their tin can linings. They observed that the market needs to move *en masse* with this issue and that major multinationals such as Coca Cola, Heinz and Walmart could demand safer substitutes if they chose to do so.

Homecare Products got their suppliers to remove a polycyclic musk and diethyl phthalates from their products after talking to Greenpeace in August 200l. Their suppliers subsequently informed them that the two substances added no benefit to the cleaning properties of the product.

As well as achieving a total phase out of PVC, **H&M** have restricted the use of APEs, organotins, azo dyes, bisphenol A, BFRs, phthalates and a wide range of heavy metals, as well as chlorinated aromatic hydrocarbons. They stipulated a clear set of criteria to all their suppliers, used testing to ensure compliance and relied on their suppliers and chemical formulators to provide alternatives.

Puma, a sport-lifestyle brand, committed to eliminating the OSPAR+ chemicals from both its sports shoes and perfumes with immediate effect, across their whole product range. Results of perfume testing commissioned by Greenpeace revealed that Puma's Jamaica Man and Puma Woman had some of the lowest levels of nitromusks and polycyclic musks of all of the samples analysed.[82]

In October 2004, **Unilever** confirmed that its new personal care products, such as the Organics and Timotei shampoo lines, and household products in Europe, will not contain OSPAR+ chemicals, including nitro musks, polycyclic musks and all phthalates with the exception of DEP. Unilever has not yet eliminated phthalates and musks from their perfumes.

Many cosmetics manufacturers have used the lower phthalates (diethyl phthalate, dimethyl and dibutyl phthalates) for many years as solvents and diluents in

perfumes. On the whole, the cosmetic industry is able to innovate quickly because cosmetic products have a relatively short life cycle; this provides short to medium-term opportunities to formulate out the problem ingredients in the next version of the product. Raw materials come at different costs and to reformulate-out chemicals of concern may result in a temporary increase in material cost. However, as more companies switch to alternatives, economies of scale are realised and the price will fall.[83]

5. PVC PHASE OUT IS WIDESPREAD

PVC plastic is the largest end user of phthalates and a significant end user for organotins and brominated flame retardants with antimony. A phase out of PVC therefore directly reduces use of these hazardous constituents. Alternatives to PVC vary and must be assessed on their chemical profile. Greenpeace has charted the move to PVC alternatives over the last few years and has compiled an extensive database of PVC restrictions world-wide, which is available on line.[84]

Nike, Lego, Mattel, and Sony are some of the companies that have already phased-out PVC plastic. **Ford, Peugeot, Daimler Benz, Opel, Volkswagen, BMW, Mercedes Benz, Mitsubishi, Nissan, Toyota** are all adopting PVC restrictions. These initiatives are driven by the EU Directive on End-of-Life Vehicles which requires automakers to meet reuse/recovery target of 85% of scrap vehicles by weight by January 2006.

6. CHEMICAL SUPPLIERS ARE ADOPTING GREEN CHEMISTRY

The chemical industry is often the strongest link in the supply chain since they provide the chemical formulations to their buyers and are in control of research into alternatives. The recent emergence of Green Chemistry[85] and its 12 criteria has spurred innovation into safer chemicals. A few examples illustrate the progress taking place and suggest a wider potential for innovation should more market demand for safer chemicals occur.

Pfizer has implemented a substitution for a range of hazardous solvents (methylene chloride, tetrahydrofuran, toluene, and hexane) in its formulation of Zoloft – the most prescribed agent of its kind to treat depression. The new synthesis involves optimising the more benign solvent, ethanol, in its process and has achieved significant hazard waste reductions as part of its conversion.

PPG Industries has developed a substitute for lead in a coating process used widely in the auto industry. The replacement is yttrium that, though much less studied than lead, is considered orders of magnitude lower in hazard. In addition it was discovered that as yttrium is used in the process it is converted to yttrium oxide that is appears to be non-toxic by ingestion, in stark contrast to lead. As PPG customers implement yttrium over the next several years, it is projected that the use of approximately one million pounds (some 454 tonnes) of lead will be avoided.

The utility of carbon dioxide as a replacement for halogenated solvents has long been recognised. CO_2 is an ideal solvent that is non-toxic, non-flammable, safe to work with and reusable. A new CO_2 surfactant system discovered by a Professor DeSimone at the University of North Carolina is likely to expand the use of CO_2 as an alternative to chlorinated solvents currently used in manufacturing and garment care industries. The use of CO_2 as a blowing agent in polystyrene has now been developed by **Dow Chemical Company**, as a replacement for ozone depleting CFC-12.

Shaw Industries Inc, the world's largest carpet manufacturer,[86] sought an environmentally friendly backing material for its carpets. Historically, carpet tile backings have been manufactured using bitumen, polyvinyl chloride (PVC), or polyurethane (PU). These have several inherently negative attributes due to their feedstocks or their inability to be recycled. PVC has, to-date, held the largest market share of carpet tile backing systems. PVC raises health and environmental concerns around vinyl chloride monomer, chlorine based products, plasticized PVC-containing phthalate esters, and toxic by-products of combustion of PVC, such as dioxin and hydrochloric acid. Due to the thermoset cross-linking of polyurethanes, they are extremely difficult to recycle and are typically down-cycled or landfilled at the end of their useful life.

Shaw selected a combination of polyolefin resins as the base polymer of choice for its substitute, EcoWorx™. Due to the low toxicity of its feedstocks, superior adhesion properties, dimensional stability, and its ability to be recycled, EcoWorx™ meets all of the design criteria necessary to satisfy the needs of the marketplace from a performance, health, and environmental standpoint. Research also indicated that the post-consumer carpet tile had a positive economic value at the end of its useful life. The cost of collection, transportation, elutriation, and return to manufacturing processes is less than the cost of using virgin raw materials. This is a truly recyclable (or Cradle to Cradle) product and is a good example of how substitution through innovation can make economic as well as environmental sense.[87]

ANNEX II:
COMMON POSITION OF CBI, CIA AND GREENPEACE ON SUBSTITUTION


Common position with regard to the authorisation of substances of very high concern within REACH

The Confederation of British Industry, the Chemical Industries Association and Greenpeace share the common position that substances requiring an authorisation within REACH according to Title VII, Article 54 of the Commission's proposal (*i.e.* substances of very high concern) should be replaced with less hazardous alternatives wherever and whenever practicable.

We agree that, for the authorisation procedure to be justified, effective and fair:-

- Substances of very high concern must be identified as such through the application of a robust, science-based and transparent process, co-ordinated at a European level and subject to European agreement.
- The authorisation procedure must be flexible enough to provide for authorisations to be granted where justified by the absence of available alternatives and by the balance of socio-economic benefits over risks to human health and the environment.
- "Availability" of an alternative in this context implies the existence of an alternative - capable of providing an acceptable level of performance - acceptable to the regulator, user, (and consumer if relevant) at a cost that is not prohibitive and whose supply is adequately assured.
- The requirements for resources to be invested in the search for available alternatives should be proportional to the benefits expected from substituting the substance.
- Authorisations granted for uses of substances of very high concern should be time-limited appropriately such that the benefits of emerging alternatives can be realised as soon as possible.

We share the view that a requirement within the authorisation procedure to substitute substances of very high concern if an acceptable alternative that does not fall into the very high concern category is available has the potential to drive innovation to the benefit of business, human health and the environment. However, to be effective, substitution will require commitment from the total supply chain, not just from producers.

We therefore urge the Minister to press for substitution to be incorporated into REACH in such a way that the authorisation procedure is effective, but flexible, in progressively phasing-out substances of very high concern.

ANNEX III: SUBSTITUTION IN INTERNATIONAL AGREEMENTS

In 1998 at a meeting held in Sintra, OSPAR delegates from each of the 15 States of the North East Atlantic Region and the European Union agreed to eliminate releases of hazardous substances into the marine environment by the year2020. As a first step towards implementing this goal, OSPAR agreed on a 'List of Chemicals for Priority Action', a list of 15 chemicals that would be dealt with by: *The drawing up of programmes and measures by 2003 for the control of discharges, emissions and losses of substances on [the Priority] list, and their substitution with less hazardous or non-hazardous substances where feasible;*[88] The OSPAR Commission invited industry to help achieve this objective through the incorporation of clean production and clean products and the development of less hazardous or preferably non-hazardous substances.

This focus on substitution and the reference to industry developments has been mirrored elsewhere. This annex provides an overview of existing European Union law, mostly directives, which incorporate the principle of substitution. In the text, substitution is generally referred to as replacing a substance of concern with a safer alternative.

All the highlighted directives and the European Court Ruling, as well as the two examples of internationally binding agreements that mandate substitution, have been analysed closely with respect to the scope of each text and the rationale for the requirement of substitution. For this purpose it seemed most practical to present the findings in a table format. The following directives have been analysed:

- **Council Directive 89/391/EEC** of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work
- **Council Directive 90/394/EEC** of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work
- **Directive 98/8/EC of the European Parliament and of the Council** of 16 February 1998 concerning the placing of biocidal products on the market
- **Directive 2000/53/EC of the European Parliament and the EU Council** of 18 September 2000 on end-of-life vehicles
- **Directive 2002/95/EC of the European Parliament and of the Council** of 27 January 2003 on the restriction of certain hazardous substances in electrical and electronic equipment
- **ECJ Ruling of 11 July 2000 in Case C-473/98**

In addition, two examples of stringent substitution legislation on the international level, which the EU is, party to have been analysed:

- **Stockholm Convention on Persistent Organic Pollutants**
- **OSPAR strategy with regard to hazardous substances (Reference Nr.: 1998-16)**

All together these legal texts target the substitution of the following toxic substances:

- Carcinogens such as auramine (manufacture thereof), polycyclic hydrocarbons and isopropyl alcohol **(90/394/EEC, Annex 1)**
- Biocides **(98/8/EC)**
- Lead, mercury, cadmium or hexavalent chromium (**2000/53/EC)**
- Lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) (**2002/95/EC)**
- Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF), hexachlorbenzene (HCB) and polychlorinated biphenyl (PCB). All of these are POPs. **(Stockholm Convention on Persistent Organic Pollutants)**
- Polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), polychlorinated biphenyls (PCBs), polyaromatic hydrocarbons (PAHs), Pentachlorophenol (PCP), mercury and organic mercury compounds, cadmium, lead and organic lead compounds, brominated flame retardants.

In all of the texts below, the respective EU institutions that have initiated mandatory substitution, demonstrate a clear understanding of the long-term necessity to apply sustainable measures to control the effects of the aforementioned substances on human health and the environment. This is furthermore evident when considering the objectives laid down in the directives. The overriding tenor is the protection of human health (workers health in 89/391/EEC, 90/394/EEC, 98/8/EC) and the protection of the environment through increasing the environmental performance of a particular product (2000/53/EC), and finally through the prevention of hazardous waste (98/8/EC, 2002/95/EC & 2002/96/EC).

As the substitution of dangerous/hazardous substances is one of the means to achieve the general goal of protecting human health, omitting the principle of substitution from the proposed chemicals legislation or the inclusion of a weak version of this Principle, will be interpreted as a lack of serious commitment by the Commission to this goal.

EU LEGISLATION

Directive	Exact Wording	Scope & Context
Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work **Section II, Article 6 paragraph 2(f)** contains the substitution provision	**Article 6** **2(f) '***The employer shall implement the measures referred to in the first subparagraph of paragraph one on the basis of the following general principles of prevention: replacing dangerous by the non dangerous or the less dangerous***'.** **(Note: the above referred first subparagraph to paragraph 1 of the Directive reads just like the Directive itself: '***The object of this Directive is to introduce measure to encourage improvements in the safety and health of workers at work***')**	**Scope** Directive 89/391/EEC takes a general approach towards introducing safety and health standards for workers in various fields, including chemical industry. **(Article 1.2 '***To that end it contains general principles concerning the prevention of occupational risks, the protection of safety and health, the elimination of risk and accident factors***...').** Article 16.3 of the Directive rules that this directive also applies, if the individual directives which are established in the context of this particular one, contain more stringent and more specific provisions. The commission thereby provides further opportunities for the development of more binding legislation. **Context** **The substitution clause appears in Section II of the Directive under '***Employer's obligations***' and under the Article 6 heading '***General obligations on employers***'** **Further reference in text** **Article 6(c) also speaks of '***combating the risk at source***'**

Directive	Exact Wording	Scope & Context
Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work **Section II, Article 4, paragraph 1** contains the substitution provision	**Article 4 (1)** **1.** '*The employer shall reduce the use of a carcinogen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to worker's health or safety, as the case may be.*	**Scope** This directive is an individual directive as required by 89/391/EEC, Article 16(1) targeting, amongst others, the protection of workers from carcinogens in the workplace in order **'***to guarantee the health and safety of workers***'.** The directive also contains reference to the precautionary principle, arguing that *'although current scientific knowledge is not such that a level can be established below which risks to health cease to exits, a reduction in exposure to carcinogens will nonetheless reduce those risks.***'** **Context** The substitution regulation appears in Section II of the Directive which is called '*Employers Obligations*' which encloses the respective Article 4 with the sub-heading '*Reduction and Replacement*'. **Further reference in text** **Article 5(d) ('***Prevention and Reduction of Exposure***'):** [...] *evacuation of carcinogens at source*

Directive	Exact Wording	Scope & Context
Directive 98/8/EC of the European Parliament and Council of 16 February 1998 concerning the placing of biocidal products on the market **Article 10, paragraph 5, subparagraph (i)** refers to substitution	**Article 10 (5)(i)** '*An entry of an active substance in Annex 1 and, where relevant, I A or I B may be refused or removed (...) if there is another substance on Annex I for the same product type which, in the light of scientific or technical knowledge, presents significantly less risk to health or to the environment*'	**Scope** This directive is concerned with the authorisation and the placing on the market of biocidal products. It attempts to establish a list of active substances[89] that may be used in biocidal products within the EC. In order to assess which substances should be included in the list, a system of registration, authorisation and periodic evaluation is legislated with this Directive. Once approved, active substances will be incorporated into Annex I of the directive. The system of registration is created for active substances, which pose a low risk for humans, animals and the environment and will be incorporated in Annex IA. In Annex I B so called basic substances such as are listed. For products of higher concern, usually not an active substance, an authorisation system is established, that includes the formulation of dossiers on these products which need to be submitted to the respective national authority. **Annex I B** **Context** Substitution in 98/8/EC is maintained indirectly though the application of comparative risk assessment, which is mandated in Article 10 of the directive. In order to include active substances in Annex I, IA or IB, several requirements have to be fulfilled. For example, active substances cannot be incorporated in the list if they are carcinogenic, mutagenic, toxic for reproduction, sensitising or bioaccumulative. In addition, the replacement of an active substance can only occur within the same product type (as classified by the directive in Annex V). Twenty-three product types are listed in Annex V. These are divided into four main groups: • Disinfectants and general biocidal products (i.e. human hygiene products, drinking water disinfectants) • Preservatives (i.e. in-can preservatives, wood preservatives) • Pest control (i.e. insecticides, rodenticides used to control mice & rats) • Other biocidal products (i.e. antifouling products) Authorisations that have been given have to be mutually recognised by all EU Member States.

Directive	Exact Wording	Scope & Context
Directive 2000/53/EC of the European Parliament and the EU Council of 18 September 2000 on end-of-life vehicles Article 4. 2(b)(iii)	**Article 4(2)(a)** *'Member States shall ensure that materials and components of vehicles put on the market after 1 July 2003 do not contain lead, mercury, cadmium or hexavalent chromium other than in cases listed in Annex II under the conditions specified therein'.* **Article 4(2)(b)(iii)** *'delete materials and components of vehicles from Annex II if the use of these substances is avoidable'*	**Scope** 2000/53/EEC aims to prevent waste from vehicles through prioritising reuse, recycling and other forms of recovery of vehicles, end-of-life vehicles and their components and materials. This should lead to a general reduction of waste, and in the long-term, the gradual phase-out of hazardous substances that can be avoided/substituted. In addition, the directive is meant to improve '*the environmental performance of the economic operators involved in the life cycle of vehicles*', and especially the performance of those operators, which are directly concerned, with the treatment of end-of-life vehicles (Art.1, Objective). The directive, moreover, means to stimulate renewed product design of vehicles taking into account the new demands posed by the reuse and recycling provisions in this legislation. Furthermore, reference is made to an environmental impact assessment of PVC, which is conducted by the Commission. The outcome of such an evaluation will be included in new Commission proposals regarding the use of PVC in vehicles. **Context:** Although the application of the Substitution Principle is not specifically ruled in this directive, substitution follows from the principle of avoidance as required through paragraph 4(2) (a) and paragraph 4.2(b) (iii). In all cars produced and placed on the market by 1 July 2003, lead, mercury, cadmium or hexavalent chromium must be replaced by other substances, with the exemption of those substances listed in **Annex II** Annex II lists all those materials and components that are exempt from 4(2) (a). For example: lead as an element (i.e. steel up to 0.35% lead by weight, aluminium, copper), lead compounds in components (i.e. batteries, petrol tank coatings, vibration dampers, stabilisers in protective paint), hexavalent chromium (used as coating on various key vehicle components) and mercury (as can be found in bulbs and instrument panel displays). As ruled in 4(2) (b), the Commission shall regularly amend Annex II, i.e. review all substances that are currently exempt from 4(2) (a). If the use of any of the materials or compounds listed in Annex II can be avoided, those substances will be deleted from this Annex. The Commission amended Annex II on 27 June 2002 and the decisions of the amendment are in force since 1 January 2003. The amendment clarifies the need of such an Annex, which in some respect reverses the 'good' provisions of Article 4 (2) (a). According to the Commission certain materials and compounds continue being exempt from phase-out because they are still unavoidable. The body has, however, decided to delete lead that is used for coating inside petrol tanks from this Annex, since the use of this element is already avoidable. One thing that has been added to the amendment is clear expiry dates for the exemption of about half of those materials and components listed in Annex II. A lot of those expiration DA dates apply to the exempt status for lead compounds in vehicles.

Directive	Exact Wording	Scope & Context
ECJ Ruling of 11 July 2000 in Case C-473/98 **Paragraph 47** of the Ruling contains the reference to the Substitution Principle.	**Paragraph 47** '*Those requirements*[90] *are compatible with the 'Substitution Principle' which emerges inter alia, from Council Directive 89/391/EEC (12 June 1989) on the introduction of measures to encourage improvements in the safety and health of workers at work [...] and Council Directive 90/394/EEC (28 June 1990) on the protection of workers from risks related to exposure to carcinogens at work [...] and which consists in the elimination or reduction of risks by means of replacing one dangerous substance with another, less dangerous substance.*' **Final ruling in C-473/98:** '*National legislation which lay down a general prohibition on the use of Trichloroethylene for industrial purposes and establishes a system of individual exemptions, granted subject to conditions, is justified under Article 36 of the EC Treaty (now, after amendment, Article 30 EC, on the grounds of protection of health of humans*'.	**Context** ECJ court case C-473/98 rules in favour of the Swedish Chemicals Inspectorate (Kemikalieinspektionen) (and thus Swedish chemical products legislation) over Toolex Alpha AB a Swedish company, which uses Trichloroethylene in industrial processes (the production of machine parts). This highly toxic substance is used to remove grease residues forged during the manufacturing of these machine parts. The Swedish Chemicals Inspectorate had initially rejected the 1997 application of Toolex to continue using this substance.[91] This decision was, however, overruled by the County Administrative Court in Stockholm. It argued that Swedish legislation with regard to this matter was inconsistent with EC law and Article 36 in particular. In return the Chemicals Inspectorate appealed the decision before the Swedish Administrative Court of Appeal in Stockholm, who referred the question of the interpretation of EC treaty Article 36 (and article 30) of the EC treaty to the ECJ.[92] The ECJ's final ruling is that there is no inconsistency between Swedish national legislation, which prohibits the use of Trichloroethylene for industrial purposes, and the provisions of Article 36 (now after amendment Article 30) '*on the grounds of the protection of health of humans*'. Paragraph 47 of the ruling discusses the exemption of the import of chemical products such as Trichloroethylene. According to Swedish law, such an exemption is only granted if '*no safer replacement of the product available*' under the condition that the applicant (i.e. a company) continues to search for safer alternatives that are not harmful to the environment and public health. In support of Swedish legislation, the court refers at this point to the Substitution Principle as established in Council Directives 89/391/EEC and 90/394/EEC (both have been discussed above), which ask for the substitution of hazardous substances for general prevention purposes (89/391/EEC), and to guarantee the health and safety of workers in the workplace (90/394/EEC). With this decision, the ECJ establishes the Substitution Principle as a principle of EU law. Clearly, the court's decision is of high significance with regard to the strengthening of environmental legislation within the EU. The court, however, also advances a less recognised, yet strategic, environmental argument for incorporating the Substitution Principle in the existing EU Directives; namely the protection of human health. The objective of protecting human health, as the court confirms through its ruling, can only be achieved when protecting the environment is given priority.

Directive	Exact Wording	Scope & Context
Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of certain hazardous substances in electrical and electronic equipment **Preamble 6 contains reference to the Substitution Principle**	**Preamble 6** *'Taking into account technical and economic feasibility, the most effective way of ensuring the significant reduction of risks to health and the environment relating to those substances in electrical and electronic equipment by safe or safer materials.'* **Article 4** *'Member states shall ensure that, from 1 July 2006, new electrical and electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated byphenyls (PBB) or polybrominated dyphenyl ethers (PBDE).'*	**Scope** This directive accompanies directive 2002/96/EC, also known as WEEE, which addresses the handling[93] of wastes from electrical and electronic wastes. These wastes cover a wide range of electrical and electronic products from household appliances such as refrigerators, freezers and microwaves to personal computers, cell phones to electrical toys, medical devices and electrical tools.[94] As specified in Article 4 (1) of directive 2002/95/EC the following substances which are contained in all of the defined product groups have to be substituted from 1July 2006 on: • Lead • Mercury • Cadmium • Hexavalent chromium • Polybrominated biphenyls (PBB) or • Polybrominated diphenyl ethers (PBDE). This list of substances has to be reviewed and extended by the parliament and the council as soon as further scientific evidence on other hazardous substances is available which recommends their substitution with safer alternatives. Materials or components of electrical and electronic substances can only be exempt from the substitution provision if their replacement is not scientifically or technically practicable or if there are no safer alternatives. Annex 1 of the directive specifies in detail which applications of lead, mercury, cadmium and hexavalent chromium fall under the above-mentioned exemption. However, these exemptions also need to be reviewed every four years (Preamble 11 and Article 5 (b) and (c)) **Context** Through the mentioning in the preamble, the Parliament and the Council establish substitution as a guiding principle for the directive. Given that the substances that are covered by this directive are well researched and evaluated (Preamble 7), both entities aim at protecting human and animal health as well as the environmentally sound recovery and disposal of electrical and electronic waste with the application of the Substitution Principle (Article 1).

INTERNATIONAL LAW (related)

As the EU has signed the texts below, it has thereby committed itself to the principles established in those conventions (such as the Substitution Principle) and their implementation in an EU context as well.

Convention	Exact Wording	Scope & Context
Stockholm Convention on Persistent Organic Pollutants Adopted at the Conference of the Plenipotentiaries, 22-23 May 2001 **Article 5(c)** contains the substitution provision	**Article 5(c)** **'***Promote the development and, where it deems appropriate, require the use of substitute or modified materials, products and processes to prevent the formation and release of the chemicals listed in Annex C, taking into consideration the general guidance on prevention and release reduction measures in Annex C and guidelines to be adopted by decision of the Conference of the Parties***'.**	**Scope:** This convention aims to eliminate and phase out of the 12 most hazardous POPs (amongst which the below mentioned Annex C chemicals) with the goal of protecting human health and the environment from the impacts of POPs **Context:** **Article 5** (*Measures to reduce or eliminate releases from unintentional production*') of the convention generally aims at regulating the reduction of total releases derived from anthropogenic sources (combustion/burning of organic material and chlorine at the same time) of the so called Annex C chemicals, which are HCBs, PCBs and PCDD/PCDF as well as their continuous minimisation and (where feasible) ultimate elimination. The Substitution Principle is closely tied to the general goal of elimination, which is manifested in Article 5. A direct consequence of the employment of the Substitution Principle is the application of best Available Technologies (BAT) and Best Environmental Practice (BEP) when dealing with unintentional sources as classified in Annex C. BAT as such also requires '*the use of less hazardous substances***'.** Annex C, part V, A (b) again refers to the Substitution Principle demanding in para (d) the '*replacement of feed materials which are POPs or where there is a direct link between the materials and releases of POPs from the source*' and consequently health effects and harm for humans and the environment.

Directive	Exact Wording	Scope & Context
OSPAR, Strategy with regard to Hazardous Substances (Reference Nr.: 1998-16) Paragraph 2, Guiding Principles Paragraph 5.5 Implementation Measures	**Paragraph 2, Guiding Principles** **'** *In addition the principle of substitution, i.e. the substitution of hazardous substances by less hazardous substances or preferably non-hazardous substances where such alternatives are available, is a means to reach this objective*' **Paragraph 5.5, Implementation** '*Measures should be selected taking into account: b) the guiding principles[...]. If in this process hazardous substances are to be substituted by other available substances, it has to be assured that less hazardous, or preferably non-hazardous, substances are to be selected'*.	**Scope:** This is an Implementation Strategy towards reaching the target of cessation of discharges, emissions and losses of hazardous substances by 2020. **Context:** The OSPAR Contracting Parties have in the Convention for the Protection of the Marine Environment of the North–East Atlantic agreed to take all necessary steps to eliminate and prevent pollution AND to take the necessary measures to protect the maritime environment against the effects of human activities and to safeguard human health The ambition of the OSPAR Commission, moreover, as manifested in the Objective of the Strategy aims at *'continuously reducing discharges, emissions and losses of hazardous substances (as defined in Annex 1) with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances'*. The Substitution Principle is one of the guiding principles of the OSPAR Strategy. In this function, the Substitution Principle continues to play an important role with regard to the implementation of the Strategy (Paragraph 5.5) where the application of the principle as a means of implementation requires the substitution of hazardous substances. Preferably non-hazardous substances should be selected over less-hazardous when replacing a substance.

ENDNOTES

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Polychlorinated biphenyls (PCBs)
Polyaromatic hydrocarbons (PAHs)
Pentachlorophenol
Short chain chlorinated paraffins
Hexachlorocyclohexane isomers
Mercury and organic mercury compounds
Cadmium
Lead and organic lead compounds
Organic tin compounds
Nonylphenol ethoxylates and related substances
Musk xylene
Brominated flame retardants
Certain phthalates – dibutylphthalate and diethylhexylphthalate

[89] Active substance is defined in the directive as 'substance or micro-organism, including a virus or a fungus having general or specific action on or against harmful organisms'

[90] This refers to the requirements of Swedish legislation on the import of chemical products.

[91] The application was rejected because Swedish legislation on chemical products enables Swedish authorities such as the Chemicals Inspectorate to prohibit the import and the export of chemical products that pose a threat to health and the environment. There are, however, individual exemptions allowed within this legislation, i.e. if there is no safer alternative available

[92] Article 36 is now Article 30 in the Treaty establishing the European Community as amended by the Treaty of Amsterdam. This article allows for a prohibitions and restrictions of imports and exports within EC members amongst others on the grounds of protecting human health. (The above cited article 30, now 28, prohibits the restrictions of imports between EC member states)

[93] The handling of wastes in this case refers to the prevention, reuse, recycling, recovery, disposal and the treatment of electrical and electronic wastes.

[94] In total there are 10 product categories of electrical and electronic equipment identified (Annex 1A):
1. Large household appliances
2. Small household appliances
3. IT and telecommunications equipment
4. Consumer equipment
5. Lightening equipment
6. Electrical and electronic tools (with the exception of large-scale stationary industrial tools
7. Toys, leisure and sports equipment
8. Medical devices (with the exception of all implanted and infected products)
9. Monitoring and control instruments
10. Automatic dispensers

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