Safer Chemicals within Reach.

Using the Substitution Principle to drive Green Chemistry.

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GREENPEACE

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.

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1 EXECUTIVE SUMMARY

Many synthetic chemicals are extremely useful and bring great benefits to our lives and our health. But many are also extremely dangerous. We should not be indiscriminately exposed to chemical pollutants on an ongoing basis, but 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 exposure, even to the most hazardous chemicals. Regulators determine acceptable levels of risk from these exposures.

It is further assumed that the quantity of substances that we are exposed to can be controlled through dilution and dispersion of chemicals throughout the environment. However, this assumption falls apart for chemicals which do not degrade, or degrade only slowly in the environment and which can bioaccumulate. 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 – 'chemicals of very high concern' – will continue. The 'disperse and dilute' model does not work for persistent bioaccumulative chemicals because Nature quite simply collects and concentrates these materials over time.

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

European chemicals regulations are currently being completely overhauled and new legislation will be passing through Parliament in 2004. 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. Continuing human exposure to certain 'tolerable levels' of chemicals that may cause cancer, or genetic damage, endocrine disrupting chemicals and substances that build up in our bodies, is set to be tolerated.

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

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, liability issues, competitive advantage and company ethics. However, there are also barriers and the development and adoption of safer substitutes is happening only slowly, in a piecemeal fashion and in some sectors not at all.

For this reason, the Substitution Principle cannot be implemented simply as a general policy statement, 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 chemical of very high concern as defined in Point 44 a) to f) of the REACH consultation document.

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

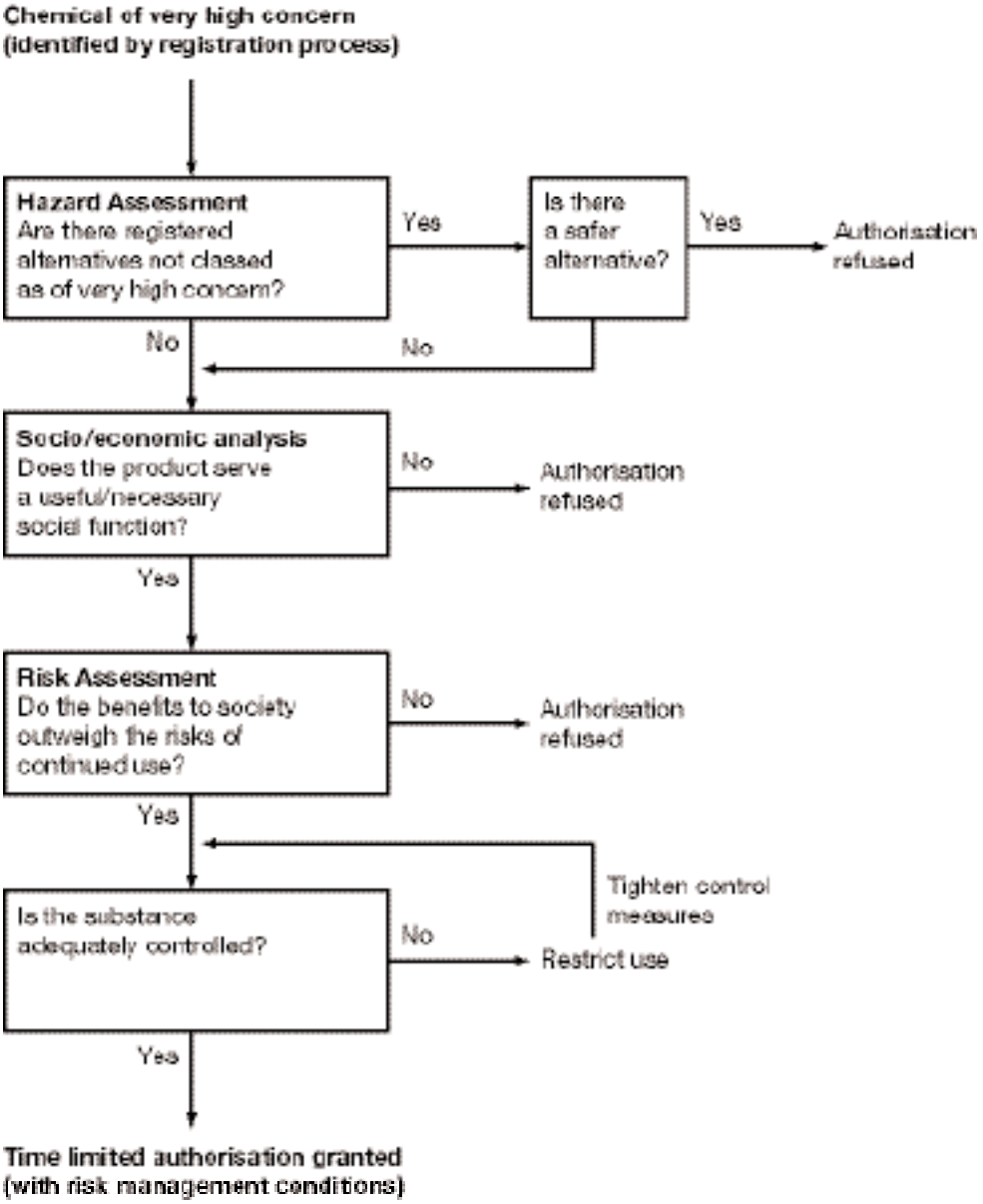
An alternative may be safer in that it does not meet the criteria for very high concern, but it may have other hazards such as corrosivity or flammability. These hazards are easier to control, but if there is a serious health and safety issue with a proposed substitute, that alternative would not be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

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

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

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

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. 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) 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 be a failure of it does not ensure 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 high concern is a central feature of the legislation.

Under the current proposal, chemicals with the most hazardous properties – those which have been named ‘chemicals of very high concern’ may be authorised for continued use if the risk to human health and/or the environment is ‘adequately controlled’. This principle of ‘adequate control’ is not one that should be applied to persistent, bioaccumulative substances. Those 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 night shirts provide unexplored routes of exposure despite the fact that 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[3] despite IPC permits that supposedly control environmental discharges.

The availability of alternatives should not be seen as one consideration in the authorisation process, it should be the decisive factor in deciding the future of a chemical of 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 implementing safer materials in their products. Without such a regulatory driver, however, the adoption of safer substances will proceed in a piecemeal fashion and entrench others in extensive risk assessment to justify ongoing use of chemicals of very high concern. Indeed the requirement to assess substitutes simply changes 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, and textiles. Studies show the flame retardants, PBDEs, to have similar effects to PCBs by affecting neurological development in the foetus. (Allsopp et al, 1999) Again, the youngest in our society are generally the most susceptible to such contamination.

2.2 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 they 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 bioaccumulative potential are surrogate measures of both hazard and exposure that can be applied quickly to all chemicals.[4] (RCEP 2003)
- 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 high concern. For example, where necessary the substitute may not be another chemical, but the redesign of a product. Computer companies are adopting metal framed 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 has been achieved with safer alternatives.

2.3 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 chemical 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.[5]

It is not possible to adequately control the risks of persistent, bioaccumulative chemicals. These intrinsic properties mean that there is a high risk of exposure at sometime during the lifecycle 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 escalating levels of brominated flame retardants, nonylphenols and other persistent chemicals in breast milk, umbilical cord blood and other human tissue.

Substitution, rather than risk management is therefore essential. Chemicals identified as of high concern, e.g. carcinogens, reproductive toxins, those that persist and bioaccumulate in the environment and affect the hormone system,[6] 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.'7
European Parliament and Council, 2002.

By defining chemicals of very high concern, REACH has already clarified substances that need to be phased out. Any chemical requiring an authorisation 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 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.[8]

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 then 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.[9]

2.4 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 priority chemicals 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.

There will undoubtedly be cases which 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 corrosivity, flammability or volatility. 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 available alternative.

Substitution can be performed on several levels.

The replacement of a hazardous chemicals by safer substitutes is usually accomplished by one of three procedures.

- Chemical (or material) substitution is the direct replacement of one substance for a hazardous substance, in a simple 'drop in' process. Many retailers, for example, have replaced PVC plastic with non halogen polymers or natural materials.
- Process substitution achieves the same results with less hazardous materials, such as the replacement of chlorinated solvents with aqueous cleaning techniques.
- Function substitution achieves the desired outcome with a change in function or system. The use of metal casings in computers as a heat sink and barrier to flammable components is a functional substitute for plastics impregnated with brominated chemical flame retardants since they both achieve the same goal (fire prevention) but with different functions. Similarly a change to organic agricultural techniques such as companion planting achieves the same pest free crop conditions as from initial use of toxic pesticides. [10]

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 is a much more objective process. Intrinsic properties can be established and quantified 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 have been developed 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 placed 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 downloaded 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 OASIS Pollution Prevention Optional Analysis System, developed by the Toxic Use Reduction Institute in the USA. Here, technologies are assessed on a variety of hazard criteria, including acute and chronic human, physical, aquatic, persistence/bioaccumulation, atmospheric, disposal, chemical, 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 which 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 and some downstream users of chemicals claim to only use benign chemicals in their processes and products. For instance the McDonough Braungart team of consultants have worked with the Design Tex company to produce a carpet which is made with non hazardous chemicals from their ‘Positive’ chemical list.[15] Other examples from the European Roundtable on Cleaner Production have been gathered and examples of successes in Green Chemistry, as listed in Annex I, demonstrate the feasibility of designing benign products.

3. WHY MAKE SUBSTITUTION A LEGAL OBLIGATION?

Few people would argue that substitution is undesirable but without a legal driver it happens only in a piecemeal fashion. 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 systematically reduce 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 substances and endocrine disrupting chemicals.

However, voluntary substitution will not end general exposure to chemicals of high concern. Several studies have shown that voluntary actions have severe limitations. Recently, the OECD published a report[16] 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 and the industry sector was adamant that restrictions must apply equally across Europe.

"We urge the Council to support the current legal basis of the Commission's Waste Electrical and Electronic Equipment and RoHS [Restriction of Hazardous Substances] directives. The European Parliament has confirmed that Article 95 should remain as the legal basis for the RoHS directive, so as to provide a high level of protection for citizens without creating uncertainty for business and undermining the Single Market. Environmental protection and consumer safety are equally precious for all EU citizens. An improvement affecting all 350 million citizens is more desirable than only a few countries going ahead with divergent national legislation."
Joint letter by Electrolux, HP, ICL, Nokia, Ericsson, Agilent, IBM, Gillette, Sun Microsystems, and Intel. to the European Commission, 2001.[17]

The OECD further note that the economic efficiency of voluntary approaches are 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 industry demonstrate that substitution is indeed feasible, voluntary action will not solve the global problem of increasing 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 size enterprises need clear criteria to chart their way forward in a competitive economy.

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 recently passed 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 in other regions also. 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 developed lead-free soldering technologies well ahead of the WEEE directive timescale, and ahead of European and American counterparts

Effects of the substitution requirement on pesticide registrations in Sweden
Since 1986, the Swedish Chemical Inspectorate has required the registration of pesticides. Beginning in 1990 a re-registration every 5 years for pesticides included a comparative assessment of substitutes. The year before the re-registration started, 619 pesticides were registered. The introduction of the substitution requirement caused a temporary decrease in numbers and only 343 appeared on the market the year after. Some pesticides were rejected for re-registration, others were substituted with better alternatives and for others, the producers did not apply for re-registration because they realised that their products did not fulfil the requirements and would be substituted. The temporary decrease in pesticide use lasted a few years, but today more than 700 pesticides are registered, demonstrating a wider range of products which are safer for human health and the environment.

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 for use 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 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.

Legislation is needed to ensure that data is available for substitution purposes.

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 concern is likely to lead to the entrenchment of hazardous chemical use within a more costly end of pipe management control. Any system that does not forc e 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.

Perchloroethylene in dry cleaners

Perchloroethylene is a probable human carcinogen and neurological toxin which poses risks to both workers and consumers, as well as a ubiquitous groundwater contaminant. A variety of safer substitutes have existed for over a decade which the Canadian and US governments have independently monitored. Both studies confirmed the economic and environmental benefits and technical feasibility of these alternatives. However, the majority of dry cleaners continue to use perchloroethylene because there is little awareness and no legislative imperative to choose safer substitutes.[25]

Researchers on substitution for the German government have documented a variety of reasons why substitution fails to be carried out.[26] 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.

3.3 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]

4. WHAT IF THERE IS NO SUBSTITUTE AVAILABLE?

4.1 Mandatory planning for substitution

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 a 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 14 million dollars over this period through the adoption of more efficient and safer processes. The program is ongoing and has been expanded to community outreach and assessment of substitutes for some hazardous material flows and products within the state.[28]

When a company applies for an authorisation it should be required to provide 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 should be transparent as to the methods and data used in seeking and assessing alternatives.

If the applicant 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 adequate control) a Substitution Development Plan should be required, so that chemical, process or function substitution can take place at upon expiry of the authorisation period.

The Substitution Assessments for each individual use of an authorised chemical should include a range of alternatives based on chemical, process or function substitution. Cost factors may initially be higher than continued use of a chemical of 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 in turn will find an expanded market for Green Chemistry products.

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.

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 which 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’[29] 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.

Finally 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 exhibits a large number of cases, where substitution has been carried out successfully, following a systematic approach to finding alternatives. The information was compiled from paper and on-line 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 data demonstrate that substitution is feasible and is already happening in the more progressive sectors of industry.

For example:

Hewlett-Packard monitor housings now typically contain phosphorous-based flame retardants, and its computer casings have no brominated flame retardants.

Bayer, a major supplier to the electronics sector, supplies an ABS/polycarbonate blend which contains flame retardants based on triphenyl phosphate or phosphate derivatives instead of bromine compounds. (Bayer, 1997)

Some manufacturers use internal metal 'shields' to protect computer housings from internal sparks and heat, and can therefore use non flame retarded plastics. The most recent example of this is Apple. The next generation of Apple products will move away from polycarbonate housing and towards metal housing, using an aluminium alloy

Until recently, halogen-free products were only available in Europe, but Sony has now adopted global design standards 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 vinyl chloride 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 wiring board.

Marks and Spencer initially targeted the successful phase out of pesticides in their product lines and then turned their attention to PVC. By eliminating PVC, they effectively eliminated most phthalates. Their transition from PVC in handbags, belts and shoes led to significant cost increases, but they have achieved a full phase out as well as an 89% phase out of PVC in packaging. Alternative plastics such as PET were used in some instances.

Boots decided to phase out alkylphenols in 1999 and by 2000 they had achieved 90% phase out.

Other than a phase out of all brominated flame retardants, H&M (Hennes and Mauritz) have achieved a strict phase out of alkyl phenol ethoxylates, organotins, azo dyes and all carcinogenic dyes, PVC, bisphenol-A, phthalates, antimony and a wide ranges of heavy metals as well as chlorinated aromatic hydrocarbons.

5.1 Downstream users promote a substitution requirement based in law.

Companies with experience from 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 EC commission on the REACH consultation in July 2003. Notably, companies with lengthy experience from national substitution requirements, 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 '*...continu-*

ously 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."* [30]

Tetra Pak, the world's largest producer of food packaging, take a similar stand: *'These two principles [precaution and substitution] are important principles in the Swedish national chemical policy and have 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.'* [31]

In fact, the collective construction industry in Sweden are strong advocates for an EU-wide substitution regulation. The Construction Federation which 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.' They emphasise that: '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 law 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'* [32]

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.*[33]

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

CASE STUDY: Electrolux

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 which have been banned as well as the percentage and types of materials and how they have improved material choices. For example, plastics do not contain cadmium, lead, mercury or their compounds or chlorinated or brominated flame retardants; metals 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.

6. CONCLUSIONS

The proposed REACH legislation attempts to address the lack of information on existing chemicals and the need to prioritise chemicals of high concern for regulation and control. 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: the risk posed by the uses of the substance; the socio-economic benefits as demonstrated by the applicant or other interested parties; and any available information on alternative substances or technologies.

Legislation in this form will mean that even the most hazardous substances will 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 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 to 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 programs on substitution. At the same time, expertise exists within the European Union to help small and medium sized companies implement safer products and processes.

A requirement to provide a Substitution Assessment with all applications for an authorisation will prevent unnecessary requests for authorisation and focus attention of 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, if 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 chemicals of very high concern would vastly increase the information flow and development of safer substitutes. It would also move Europe to 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.

ANNEX I

Industry case studies of successful substitution

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

The information was compiled from paper and on-line research and from direct phone conversations 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.

Substituting brominated flame retardants in products

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

As evidence grew by the late 1980s of the dangers of BFRs, particularly PBB 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.

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 functional substitution (replacement of plastic with metal housings). Much of the stimulus for better design and less hazardous materials has come from the Waste Electrical and Electronic Equipment (WEEE) and Restriction of the Use of Hazardous Substances (RoHS) directives and their emphasis on recycling and chemical bans. 80% of a typical product's environmental impact is determined by its design.[34]

As concern around bromine compounds grew, industry moved away from those under the greatest legislative pressure (PBDEs and PBBs). However, as the market for PBDEs and PBBs has declined, sales of bromine compounds such as TBBP-A and HBCD have gown in equal measure. Meanwhile, understanding of the toxicity and persistence of TBBP-A and HBCD has increased the pressure to address BFRs as a class, and in parallel the development and supply of non-halogenated chemicals has increased.

As information grew on the risks and feasibility of some of the phosphorous based alternatives, some companies developed non-phosphate alternatives. Product design is increasingly looking at non-chemical alternatives to flame prevention, such as the use of metal casings instead of plastics.

Hewlett-Packard monitor housings now typically contain phosphorus-based flame retardants, and its computer casings have no flame retardants at all.

Bayer, a major supplier to the electronics sector, supplies an ABS/polycarbonate blend which contains flame retardants based on triphenyl phosphate or phosphate derivatives.[35]

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

The most recent example of this is Apple. The next generation of Apple products will move away from polycarbonate housing and towards metal housing, using an aluminium alloy. Life cycle assessments show that although mining of metals increases energy use, the use of metals provides for better end-of-life management (than plastics), provides a better heat sink (than plastics) and enables the product life to be extended. The use of aluminium alloy shows little weight change, compared with polycarbonates. In addition, the use of lacquers in metal finishes does not cause problems during smelting, but the use of lacquers on plastics renders the plastic non-recyclable. The shift from plastics to metal alloys was in part driven by the flame retardant restrictions of WEEE and RoHS.

Motorola is a multi-national company that produces hundreds of different electronic systems for a large range of industry sectors, including the IT and automotive sectors. As Motorola became aware of the inherent human health risks posed by the use of BFRs, the company worked with suppliers to find safer substitutes for their printed circuit boards. Despite the bromine industry claim that BFRs are necessary to achieve fire safety standards, Motorola is able to meet the standards while using safer materials. Most of their new products use a safer halogen-free flame retardant alternative that is a nitrogen/phosphorus combination.

Motorola's research on the alternative flame retardants concluded:

- Eliminating BFRs from printed wire circuit boards (PWB) reduces risks associated with dioxin formation in fires.
- Eliminating BFRs enhances ISO 14000 performance.
- Some PWB resin systems with alternative flame retardants possess better electrical properties.
- Some PWB resin systems with alternative flame retardants possess better mechanical properties.
- Some halogen free PWBs have demonstrated compatibility with lead-free assembly.
- Cost curve is very acceptable and is projected to meet current costs for best in class FR-4 flame retardant standards.
- The availabilities of substitutes are acceptable and projected to get better.

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 wiring boards use resin which is an inherently flammable material. Sony's engineers adopted a resin structure containing nitrogen to increase heat resistance and modified the content and dispersibility 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 boards 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.

Until recently, halogen-free products were only available in Europe, but Sony has now adopted global design standards to ensure that all their projects meet the same standards. Sony aims to have all product lines free of BFRs by the end of 2005 if substitutes are found to be safer. They also aim to phase out all uses of vinyl chloride by 2005 as well as lead solder, and the heavy metals listed in the RoHS Directive. Details of their phase out of hazardous materials is given for specific product lines in their end-of-year report. For example a Walkman model has PVC free cables, no BFRs or lead solder in the printed wiring board.[36]

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 which responds rapidly to international environmental regulations. Information on alternatives is seen as confidential.[37]

National/Panasonic (Matsushita) joined forces with other major manufacturers to develop electric wires and plastics that do not contain halogen compounds. In September of 1999, they began marketing the world's first wide-screen television for which halogen compounds 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.[38]

Matsushita was at the forefront in substituting lead in their semiconductors. In 1991 the company committed itself to remove lead by fiscal year 2002 and it has succeeded in doing so. The company's website gives details on alternatives used: mostly silver, tin and bismuth compounds.[39]

IBM's Design for Environment guidelines focus on 15 environmental attributes. These guide product designers of Personal Computing Division products. The company mandates that resins and paints used on PC products must not contain polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs) lead, cadmium, or mercury metal. IBM gives its Original Equipment Manufacturer (OEM) suppliers, such as Samsung, a list of 11 banned PBDEs and PBBs but does not stipulate which flame retardants, if any, must be used and accepts what its suppliers manufacture.[40]

TBBA, a BFR which is reactive and thought to be bound to the polymer, is used in the epoxy resin laminate in printed circuit boards in most manufacturers' products. In 1997, a phosphorus-based alternative 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.[41]

The electronic 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' and is neither phosphorous nor halogen based. 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.[42]

The material is manufactured under licence by Sumitomo Dow which supplies it to NEC at the same price as that of ordinary polycarbonate resin. Sumitomo Dow also supplies NEC with a polycarbonate resin which dispenses with the need for brominated or phosphorus-based flame retardants.

Several Japanese firms – including NEC, Hitachi, Toshiba and Sony – have developed phosphorus-based flame retardants as alternatives to TBBA in circuit boards. Fujitsu-Siemens has eliminated TBBP-A from the maincard on their Scenic computers by substituting with phosphorous acid that is reacted within the laminate.

In 2000 NEC developed an epoxy resin with what it describes as a fire-retardant structure that avoids the need for either TBBP-A 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.[43]

BFRs and the retail industry

IKEA prohibits a range of hazardous materials in their product lines. They prohibit azo dyes in textiles and a product wide ban of 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 such as interliners made of non-woven inherently flame retardant materials. When the company has to meet more stringent fire standards for the UK and California 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 phosphorous and nitrogen compounds either applied by impregnation of the cover fabric or applied to a cotton interliner. The work was done in conjunction with Ciba Geigy.

Deca-BDE is used widely in polyurethane foam in the USA 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 graphites and their suitability within foam. 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.[44]

Marks & Spencer continue to develop substitutes for deca-BDE in some product lines. Their focus has been on PVC substitution, and that has now been completed.

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

H&M (Hennes & Mauritz) have chemical restrictions for textile, leather, plastic and metal products based on international regulations and some additional chemicals of concern. They test for compliance from all their suppliers in their own labs. H&M uses no flame retardants in any product line using instead natural materials that are inherently flame resistant. In a few cases the company cancelled clothing line items that proved a potential flammable hazard and could not be materially replaced.[45]

Leaders in the building trade phased out BFRs and focussed on functional alternatives

Skanska, ranked by the Financial Times as the world's most respected company in the property and construction sector, was also one of nine construction businesses listed on the Forbes A-list. Skanska Denmark and Sweden have been leaders in the task of developing a national industry-wide chemical database. The Skanska database now

contains 2,416 products. On the basis of these, Skanska Denmark has then selected 716 products that may be used in its own operations. The industry-wide database of chemical products is evolving all the time, and the number of chemical products listed is rapidly increasing.

Skanska Denmark has further refined the standard version of the industry-wide database so that each individual chemical product is classified on the basis of a number of criteria, taking into account both environmental and working environment as well as quality and economic factors. Products are classified in three categories: permitted products; products that should be phased out; and non-permitted products. In total more than 7,500 chemical products have so far been evaluated.

Skanska is replacing BFRs with product redesign and material substitution. They initiated a project – '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. The results of 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 no legal requirements supported the use of flame retardants.[46]

Assessing non-brominated flame retardant 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 phosphorous, ammonium polyphosphate and aluminium trihydroxide as the least environmentally problematic alternatives.[47] 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.[48]

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.'*

The summary of their investigation (Table 1) lists flame retardants under the headings:

- Phase out is recommended
- Reduction is expedient, substitution desirable
- Problematic properties; reduction expedient
- No recommendation possible due to gaps in knowledge
- Use is unproblematic

The Danish Environmental Protection Agency also investigated the profiles of 12 alternative flame retardants for environmental and health effects. From a survey of published literature, it was observed 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 that an assessment was needed to determine the amount and the manner in which they are released before a conclusion could be drawn.[49]

REACH will obviously help to fill this much needed gap in information. It can be surmised that the phosphorous 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 planning, substitution is not 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.

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.[50]

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.
- Scrutinising fire safety regulations: Are existing fire safety regulations genuinely justified, when the risk of fire is weighed against the risks associated with flame retardant chemicals (e.g. keyboards)?
- Substituting hazardous flame retardants with products 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 fire safety is paramount and particularly defends the increased rate of some of its chemicals in the USA by pointing out that less stringent fire standards in Europe are associated with more fire deaths.[51] An examination of fire death rates for countries in Europe and elsewhere reveal that in fact deaths by fire are no higher in Europe and that the USA has higher number of fire deaths per 100,000 persons than many European countries.[52] 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 lead to the creation of Green Flame, a program 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 USA 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.[53]

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.[54] They apply their expertise in fire prevention in buildings to that of product redesign. 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 formation 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.[55]

Substituting lead in electronic products

The WEEE Directive was a major catalyst for research and adoption of lead free solutions in electronic equipment. The range of alternatives to lead in soldering range from tin (Sn), silver (Ag), copper (Cu), bismuth (Bi) and zinc (Zn). These heavy metals do not have the persistence and bioaccumulation potential of lead (Pb).[56]

NEC targeted the use of Sn-Ag-Cu in their pagers by December 1998; the use of Sn-Zn-Bi in their notebooks PCs by October 1999; the use of Sn-Ag0Cu in their main computers and equipment by 2002.

Fujitsu targeted the use of 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, Sn-Bi-Ag by the end of 2002.

Sony targeted the use of Sn-Ag-Bi-Cu for use 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

Hitachi targeted the use of Sn-2Ag-2Bi-0.5Cu in video cameras, vacuum cleaners, and washing machines by spring 1999; and all new products will use Sn-Ag-Cu, Sn0Bi+Ag-Cu(+Bi/In) by March 2002.

Matsushita targeted the use of Sn-Ag0Bi in mini disks by September 1998; and all new products to use Sn-Ag-Cu, Sn-Ag-Bi by March 2003.

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 which provides lighting for the automotive industry and uses 99% less lead.[58]

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 tributyltin (TBT) is used as a treatment against dust mites and mould in some carpets and PVC floorings.
- **Alkylphenols** and their derivatives are primarily used as non ionic surfactants in industrial detergents, though also used 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.

Boots decided to phase out alkylphenols in 1999 and by 2000 they had achieved 90% phase out. A difficulty was first identifying where alkylphenol ethoxylates (APEs) were used in their 40,000–50,000 product range as some of their supply chains were complex. Also, finding substitutes for some products proved problematic on quality grounds, for example, all artificial musks in cosmetic lines were phased out but some substitutes did not hold the fragrance for as long. In general, they have substituted alcohol ethoxylates as replacements for APEs. According to Boots, unlike APEs, alcohol ethoxylates appear to be readily and completely broken down in the environment.[58]

Marks and Spencer initially targeted the successful phase out of pesticides in their product lines and then turned their attention to PVC. By eliminating PVC, they effectively eliminated most phthalates. Their transition from PVC in handbags, belts and shoes led to significant cost increases, but they have achieved a full phase out as well as an 89% phase out of PVC in packaging. Alternative plastics such as PET were used in some instances.

Marks and Spencer 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.

Safeway phased out musk xylenes and nitro musks by reformulating their product line. They also achieved a phase out of phthalates in fragrances in all but one line, and are working to eliminate this as well. They seek information from the International Fragrance Research Association, which has developed guidelines on what is permitted.

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.

Other than a phase out of all BFRs, **H&M** have achieved a strict phase out of APEs, organotins, azo dyes and all carcinogenic dyes, PVC, bisphenol A, phthalates, antimony and a wide range of heavy metals, and 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.

The Body Shop has a set of guidelines that are used when formulating new products. If a chemical is of concern (and this concern has some justification), then it is either prohibited from use in new formulations or it is restricted to certain product types (leave-on versus rinse-off, for example).

The Body Shop does not use PVC in its packaging or its accessory products and in this way avoids the use of higher phthalates – diethylhexyl phthalate and diisononyl phthalate. There is a range of alternative plastics available.

Many cosmetics manufacturers have used the lower phthalates (diethyl phthalate, dimethyl and dibutyl phthalates) for many years as solvents and diluents in perfumes. The Body Shop has also used phthalates for this application. The Body Shop states that while there is no clear evidence that they are responsible for any hormone disruption, as a precautionary measure they have decided to avoid the use of all phthalates in new perfumes, and aim to phase out phthalates that remain in existing perfumes. There are alternative solvents available such as dipropylene glycol, carbitol and ethyldiglycol.

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 reformulating out chemicals of concern may result in an increase in material cost. However, as more companies switch to alternatives, economies of scale are realised and the price will fall.[59]

Colgate, Palmolive and **Procter and Gamble** have removed APEs from all or part of their personal care ranges.[60]

Nike, Lego, Mattel, and **Sony** are some of the companies that have phased out PVC plastic. **Ford, Peugeot, Daimler Benz, Opel, Volkswagen, BMW, Mercedes Benz, Mitsubishi, Nissan,** and **Toyota** are all adopting PVC restrictions

PVC plastic is the largest end use of phthalates and a significant end use for organotins and BFRs with antimony. A phase out of PVC therefore directly reduces the 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.[61]

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[62] and its 12 criteria has spurred innovation into safer chemicals. A few examples illustrate the progress that is taking place and suggest a wider potential for innovation if a greater market demand for safer chemicals was to occur.

Pfizer has implemented a substitution for a range of hazardous solvents (methylene chloride, tetrahydrofuran, toluene, 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.

Bayer has developed a new chelating agent, which is benign from a toxicological and ecotoxicological standpoint, in a 'waste free and environmentally friendly manufacturing process'. The chemical, sodium iminodisuccinate, belongs to the aminocarboxylate class of chelating agents. Nearly all this chemical in use today is produced from amines, formaldehyde, sodium hydroxide and hydrogen cyanide. The industrial use of thousands of tons of hydrogen cyanide is an extreme toxicity hazard. In contrast, Bayer's substitute is produced from maleic anhydride, sodium hydroxide and water. The only solvent used in the production process is water and the only by-product formed – ammonia dissolved in water – is recycled back into the product cycle.

PPG Industries has developed a substitute for lead in a coating process used widely in the auto industry. The replacement is yttrium which, although 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 which 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 of lead will be avoided.

Solutia (formerly Monsanto) one of the world's largest producers of chlorinated aromatics, has funded research over the years to explore alternative synthetic reactions for manufacturing processes that do not require the use of chlorine. They have found a non-halogen route for the manufacture of a key intermediate in the rubber chemicals family of antidegradants. The new process generates 74% less organic waste, 99% less inorganic waste and 97% less wastewater.

The use of carbon dioxide (CO2) as a replacement for halogenated solvents has long been recognised as an ideal solvent that is non-toxic, non-flammable, safe to work with and reusable. A new CO2 surfactant system, discovered by a Professor DeSimone at the University of North Carolina, will expand the use of CO2 as an alternative to chlorinated solvents currently used in manufacturing and garment care industries. The use of CO2 as a blowing agent in polystyrene has now been developed by Dow Chemical Company as a replacement for ozone depleting CFC-12.

Table 1.
Flame retardants investigated by the German Environmental Protection Agency, UBA (2001)[63]

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

ANNEX II – SUBSTITUTION IN INTERNATIONAL AGREEMENTS

Political initiatives on substitution

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 (EU) agreed to eliminate releases of hazardous substances into the marine environment by the year 2020. As a first step towards implementing this goal, OSPAR agreed on a 'List of Chemicals for Priority Action', a list of 15 chemicals which would be dealt with by *'the drawing up of programs 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;'*

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 EU 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 No.: 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 byphenyls (PBB) and polybrominated dyphenyl ethers (PBDE) (2002/95/EC)
- Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF), hexachlorbenzene (HCB) and polychlorinated biphenyl (PCB) (Stockholm Convention on Persistent Organic Pollutants)
- Polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), polychlorinated biphenyls

(PCBs), polyaromatic hydrocarbons (PAHs), pentachlorophenol m(PCP, mercury and organic mercury compounds, cadmium, lead and organic lead compounds, BFRs, and nonylphenol/ethoxylates (NP, NPEs) amongst others (OSPAR Strategy with regard to Hazardous Substances)

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 1of 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'*
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)** *'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 precau tionary principle, arguing that *'although current scien tific knowledge is not such that a level can be estab lished 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 of the 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[65] 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, authori sation 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. In 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, paragraph 2, subparagraphs (a) and (b)(iii)** contain the relevant references.	**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 in 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 envi ronmental 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 have been 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 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[66] 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 applica tion of Toolex Alpha AB to continue using this sub stance.[67]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 partic ular. 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.[68] 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 electricaland 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[69] 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.[70] 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 byphenyls (PBB) or • Polybrominated dyphenyl 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 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 paragraph (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.

Convention	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.

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The OSPAR list of Substances for Priority Action

- Polychlorinated dibenzodioxins (PCDDs)
- Polychlorinated dibenzofurans (PCDFs)
- 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

[65] 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'

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

[67] 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 which 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

[68] 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)

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

[70] In total there are 10 product categories of electrical and electronic equipment allocated (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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