

# Environment, Health and Safety Committee

## Position Statement On

### PRACTICAL ASPECTS OF CHEMICAL SUBSTITUTION



#### 1) INTRODUCTION

One of the controversial issues in the debate on the proposed EU Chemicals Policy, known as REACH, is the degree to which industry should be encouraged or required to adopt the 'Substitution Principle'. The substitution principle has wide application, both within and outside REACH. In the current proposal, applicants must consider substitution as part of a request for certain 'authorisations' to continue the use of a hazardous substance. However, substitution may also be necessary when manufacturers cease to produce a chemical or to support its use in a particular type of preparation or when downstream users or the public seek the elimination of a particular substance from certain types of preparation and/or article. The buying power of informed users/consumers and suppliers is an effective mechanism for driving substitution

Many of the organisations that have commented on the REACH proposal want to see this principle strengthened so that, at least for those substances that require 'authorisation' the availability of an alternative not requiring authorisation should be sufficient grounds for the request for authorisation to be refused. This approach is simplistic as substances are rarely only used for one purpose and, sometimes, the risks (e.g. acute toxicity of a 'difficult to control' replacement) may be such that it is less risky to use the substance subject to authorisation (which may be classified as 'toxic for reproduction', but of low potency and used in circumstances where exposure can be readily minimised to acceptable levels).

#### 2) THE 'SUBSTITUTION PRINCIPLE'

The 'Substitution Principle' is a deceptively simple concept whose implementation turns out to be much more complex than people realise. Like other 'principles' such as the 'Polluter Pays' and the 'Precautionary Principle', there have been numerous attempts at producing a universally acceptable definition. However, for the purposes of this note the following definition is used (Lohse et.al. 2004).

**“Substitution means the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures.”**

This definition is unsatisfactory in that it talks of hazardous substance, rather than risk arising from the particular use of that hazardous substance. Minimisation of risk or reduction of risk to a broadly acceptable level is the ideal solution. This may take the form of elimination of use of the hazardous chemical through process changes, process controls minimising exposure to that hazardous chemical (including minimising waste and optimising waste disposal) and substitution. Thus substitution of one chemical by another is one element of a risk management strategy. Often, there is a lack of clarity amongst stakeholders about the desired outcome and a lack of clarity as to who should make key decisions, whether substitution is appropriate and, if it is appropriate, how it can be implemented.

The purpose of this paper is to consider the 'how' rather than the 'why' of substitution, and to propose some practical approaches that could lead to sustainable and improved human and environmental health.

***This draft statement was produced by a Working Party of the Environment, Health and Safety Committee [EHSC] of the Royal Society of Chemistry.***

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The EHSC welcomes comments on this Report. Please send them to the Committee Secretary:  
Health, Safety and Environment Committee  
Royal Society of Chemistry  
Burlington House  
Piccadilly  
London W1J 0BA

Tel: +44 (0) 207 440 3337  
Fax: +44 (0) 207 437 1227  
Email: ehsc@rsc.org

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In an ideal world it might be preferable not to use hazardous processes and chemical substances when 'less harmful' processes and substances exist. However, there is a toxicological dictum provided by Paracelsus (1493-1541): 'All substances are poisonous; there is none which is not a poison. The right dose differentiates a poison from a remedy' (for our purposes, substitute 'innocuous substance' for 'remedy'). In reality, risk has to be the main consideration as, to some extent; all process and chemicals are hazardous. Chemicals are 'authorised' for specified uses in those cases where the perceived benefit, either, as with human medicines, to the individual, or as with biocides, plant protection products, food additives, etc. to society as a whole) is disproportionate in comparison with the risk.

### **3) RISK ASSESSMENT AND RISK EVALUATION**

The Organisation for Economic Co-operation and Development (Description of selected key generic terms used in chemicals hazard/risk assessment, 2003) define **risk assessment** as:

A process intended to calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system.

And **risk evaluation** as:

Establishment of a qualitative or quantitative relationship between risks and benefits of exposure to an agent, involving the complex process of determining the significance of the identified hazards and estimated risks to the system concerned with or affected by the exposure, as well as the significance of the benefits brought about by the agent.

This is based on the Royal Society study group on risk assessment's 1983 definition:

Risk evaluation is the complex process of determining the *significance or value* of the identified hazards and estimated risks *to those concerned with or affected by the decision*.

The OECD placed risk evaluation as the first stage in risk management. The Authorisation process is essentially a risk management process, and, on that basis, a risk evaluation is the first stage of this process. The italicised sections of the Royal Society definition clearly identify that there is a need for stakeholder participation in decisions.

These definitions were essentially intended for substance by substance risk evaluation and apply to Authorisations. If the risk evaluation produces a circumstance whereby adequate control (control to 'safe' levels of exposure) can be achieved for the use examined, there is no requirement to investigate substitution [Article 57(2)]. If not, then, under Article 57(3) substitution must be examined, and in the case of substitution under the Authorisation procedure the risk assessment and risk evaluation are comparative risk assessments and risk evaluations in order to optimise the choices of chemical and use under the Authorisation process.

### **4) STAKEHOLDER PARTICIPATION**

Substitution decisions require considerable stakeholder involvement. Substitution decisions involve tradeoffs between risks and benefits for the various uses to which a chemical substance is put. These decisions need to consider factors that go beyond the scientific evidence. Such tradeoffs are very difficult because they involve both objective and subjective judgements that have societal implications.

Questions arise as to how potential negative impacts and potential gains should be weighted against each other and how impacts on one section of the community should be balanced against the benefits for another? Hence decisions have to take account of different stakeholder perspectives (manufacturers, downstream users/formulators, the public, environmental organisations, etc.).

At present, no universally acceptable mechanism for dealing with these complex issues exists. 'Rules' setting out the criteria for substitution and defining the thresholds of acceptability are needed to ensure consistency and transparency. It is likely that such rules will develop as experience of substitution is gained and it should be possible to draw up a set of protocols with time.

The approach to risk first described by the Royal Society study group in 1983 and most recently re-stated by the Health and Safety Executive in 'Reducing risks, protecting people' (Sudbury, Suffolk: HSE Books, 2001) is applicable to substitution. This process involves description of a 'broadly acceptable' level of risk ('safe') and a level of risk deemed 'unacceptable in all circumstances' ('banned'). In between lies the 'tolerability' region. When a risk is unacceptable or tolerable risk management is required. The Authorisation process is the intended risk management process for REACH and is theoretically associated with the question of comparative risk, and management through substitution. The objective is that the final management outcome is at least 'tolerable' and at best, 'broadly acceptable'. The Health and Safety at Work Act 1974 [HSWA] and the Control of Substances Hazardous to Health Regulations (which now implements EU Directives) provide a suitable legislative model for the control of substitution.

By providing examples of how substitution operates in practice, a 'Manual of Decisions' (as is currently available for decisions concerning new substances) may be the way forward. The 'Tolerability of risk' approach set out first by the Royal Society study group includes the principle of 'reasonable practicability', now enshrined in UK law, which would provide a suitable test by which to assess whether substitution is justified and whether the proposed substitution is appropriate. The test of reasonable practicability would allow appropriate balances to be made between technical feasibility (the technological criterion of 'Reducing risks, protecting people') and costs and benefits (the utility criterion), including the costs of modifying existing plant and equipment. At all times, the onus to initiate substitution would rest with the manufacturer/downstream user but would be goal oriented rather than prescriptive. When a substance is taken into the Authorisation process of REACH, the regulatory authority's role would be to ensure that the manufacturer/downstream user had acted diligently and to base the regulatory management on the information supplied by the manufacturer/downstream user. This approach also allows for the development of guidance and approved codes of practice on difficult issues such as how to balance environmental risks against workplace health and safety risks.

A key question will be 'who decides, initiates or revisits substitution?' This might be the "Authorisation body" which could decide that some or all of the uses of a substance are no longer 'acceptable', thereby forcing all the suppliers and users to seek substitutes. However there are other circumstances where substitution might be initiated by a manufacturer. The decision on when and what to substitute in a particular application could reside further down the supply chain. The buying power of informed users/consumers and suppliers could be an effective mechanism for driving substitution. A chemical supplier might seek a substitute e.g. in order to drop a PBT chemical when the market for it is likely to disappear or where the procedure is too onerous to make it worthwhile seeking authorisation; the down-stream user of a chemical may seek a substitute e.g. in response to pressure from a risk-averse customer.

Although it won't be reasonable for all stakeholders to be involved at every stage, information should be available on how substitution decisions are reached. In this regard much could be learned from the UK Chemical Stakeholder Forum experience on how to consider and give just weighting to all factors.

## **5) SUBSTITUTION AND RISK REDUCTION**

Substitution is not a simple process since it is necessary to ensure that the overall risk is reduced, ideally to a 'broadly acceptable' level of risk – a 'safe' level of exposure - and that a decrease in one risk is not overshadowed by the increase in another. In many cases, substituting one chemical by another can make an important contribution to producing a lower overall risk, ideally to 'broadly acceptable' levels. However, it is important to note that risk is not eliminated in this process.

Substitution is a practical outcome of comparative risk assessment and evaluation. Comparative risk evaluation aims to optimise the choice of substances for a particular use, taking into account potential risks to health, wildlife and the environment and the benefits to society as a whole. Comparative risk (and benefit?) evaluation is currently applied in one form or another e.g. to the approval of pesticides and biocides in a small number of overseas countries, notably Sweden, and is incorporated into the Health and Safety at Work Act 1974 in the UK. However, the Swedish system differs from that in the UK in that the Swedish model is hazard based. Comparative risk and benefit evaluation is undertaken by NICE for medicines used by the UK NHS. Generally there has to be an acceptance that, at the regulatory level, there is a need for more than one solution so that, at the user level, there is a possibility of tailoring one of the available options specifically to the user's requirements.

Comparative risk evaluation poses major scientific challenges not least of which are the choices of what to compare and the decisions about what level of risk is the maximum tolerable and what level of risk is broadly acceptable. Although it may not be possible, due to time and resource constraints, to conduct a complete comparative risk assessment of all the chemical substances used for a specific purpose, comparative risk evaluation should still aim to establish:

1. The need for a particular chemical substance;
2. The availability of alternative substances that can produce the required effect;
3. The risks to humans and the environment of alternative chemical substances grouped on the basis of required use/effect;
4. The efficacy (benefits) of alternatives, that can deliver the required effect;
5. The socio-economic impact of proposed substitutions with the group of alternatives that can deliver the required effect.

Essentially, 'life cycle analysis' is required for the particular use in question. Chemicals for substitution should be considered on a case-by-case basis as each will have its own unique properties and exposure patterns. The circumstances of use of a chemical should provide information on possible problems with regard to that use. It is important to recognise that all substances possess a range of hazards, such as toxicity, flammability, corrosivity etc. and that each hazard will vary from one substance to another in terms of its magnitude and probability of causing harm to humans, animals and the environment. If however comparison of chemical substances were to be based on hazard alone, it would not be possible to allow for the differences in exposure that will occur through differences in usage patterns.

For example, a particular chemical substance with a lower intrinsic hazard may need to be used in greater quantities or at higher concentrations than a chemical substance with a higher intrinsic hazard that would be more effective at lower concentrations.

The aim of comparative risk evaluation is to facilitate the development of rankings that place the 'risk profiles' of chemical substances, according to their intended uses, on an ordered scale of reducing overall risk. This is still an area in which methodologies are being developed. Comparison of chemical substances with similar use patterns is a useful tool in risk reduction. If the area of use and mode of application is similar for chemical substances then the exposure conditions can normally be assumed to be the same. Under such circumstances assessors and regulators can essentially base comparative evaluations on the hazard attributes of the chemical substances being compared.

Ranking risks requires information about the hazards of concern and judgements about their likely effects and impacts. Effective substitution of a 'problem' chemical by an alternative requires an 'adequate' set of data for the alternative. This may seem obvious, but is often overlooked with materials being substituted to remove one problem without recognising that different problems may arise as a consequence. For example ionic liquids are universally recognised as 'green' alternatives to organic solvents, however the data on ecotoxicological impact and environmental fate data for these materials is often inadequate to allow a realistic environmental risk assessment to be undertaken. There is experimental evidence that some ionic liquids are highly toxic to aquatic life and also very persistent in the environment. In the case of the REACH authorisation process, chemicals that have entered the process can be deemed to have an 'adequate' set of data on hazard and exposure, but this cannot be assumed for currently low-tonnage non authorisable chemicals.

Materials, products and chemical processes cannot be considered in isolation. In the real world chemicals exist in the context of a life cycle of activities in which people, animals and the environment may be exposed. Whether or not substitution is justified depends upon the relative acceptability of each of those risks as they are affected by such substitution. For example materials to which exposure in use offers little risk to human health may still pose considerable risks to the environment and vice-versa. Thus considering CFCs, the decision to ban their use was a good example of risk based substitution. If there had been foolproof ways of preventing their escape to the environment then it might have been better not to replace them: the alternative materials though posing less risk to the ozone layer, are often more dangerous (e.g. flammable) or toxic to man. However given the impracticality of preventing CFC escape to the atmosphere, the risk they posed to the ozone layer was judged less acceptable compared with the risks to human health from their replacements. Therefore CFCs were withdrawn from use.

It is clear from this example that risk based substitution may not always be simple. It involves weighing up and comparing different hazards and their magnitudes. It also requires value judgments about the acceptability of different risks to different targets, such as judging that the risk to the ozone layer from CFCs was more important than the risk to human health from the materials that replaced them. Simultaneously ranking health, safety and environmental risks requires the participants to make difficult trade-offs among a larger and more diverse set of relevant properties of chemical substances. Cognitive constraints make it difficult for us to choose among several options which can be described in terms of several attributes that vary in terms of the nature of their effect, magnitude and timing. In order to develop a pragmatic approach to making these complex decisions, ways need to be found to simplify the decision process. This needs to be done in a way that will allow complex trade-offs among non-commensurate attributes to be made. Another point to consider is that the simpler the system the more likely it is to be implemented and actually achieve its objectives.

## **6) COMPARATIVE RISK EVALUATION**

The key objective of comparative risk evaluation is to identify alternative chemical substances that could be substituted for existing chemical substances with similar uses where the proposed substitute presents a significantly reduced level of overall risk. Comparative risk assessment could be used to identify chemical substances for substitution in the following way:

### ***Step 1: Identify the substances to be compared***

This step involves the identification of a group of chemical substances (with a common use e.g. flame retardants) capable of delivering the desired effect, that are to be considered as possible substitutes. Qualitative judgments are then made about the likely to impact on human health and the environment of each chemical substance in turn. For example a particular substance may be responsible for a number of health effects. These effects are called 'end points' and may encompass a wide variety of conditions including cancer, reproductive abnormalities, developmental disorders, central nervous system symptoms, trauma, infections, and rashes.

The identification of the group of candidate chemical substances for substitution is usually followed by an exposure assessment. This involves a description of the sequence of events through which exposure to a risk agent could occur and a determination of the extent of adverse effects likely to result from given levels of exposure to risk agents. Though this step only consists of the qualitative determination of causation based on the weight of the available evidence, it should lead to a conclusion of whether or not an adverse health or environmental effect exists as a result of the presence of a particular chemical substance.

### ***Step 2: Specify the key impacts to be considered***

Once a list of chemical substances from which a substitute could be chosen has been compiled based on the exposure assessment the next stage of the process should seek to clarify and quantify (where possible) the 'risk profiles' of substitution candidate chemical substances by determining the expected impact caused by a range of likely exposures.

Normally a series of toxic and environmental end points are assessed when examining the risks posed by individual substances. These end points are set out in Technical Guidance Documents such as that for new and existing substances and biocides. It is anticipated that an updated version of this document will be produced for REACH. The process adopted is essentially that described in the International Programme on Chemical Safety - Environmental Health Criteria documents 170 and 210 (Geneva, World Health Organisation).

In the 'Authorisation' process a limited range of effects (the PBT and vPvB end points) are considered initially when identifying the 'key impacts' for a series of chemicals and uses. The 'key impacts' are, in effect, the PBT and vPvB end points that caused the index substance to enter Authorisation, and are the impacts for which comparative data are sought. Occasionally an additional 'key impact' may have to be considered – for example when dealing with substitutes that are acutely very toxic by their likely route of exposure, and hence are unacceptable as substitutes.

For many end points the 'Derived no effect level' (DNEL) was sought in the chemicals safety assessment. This DNEL includes uncertainty factors and therefore combines risk assessment (the technical process) with a standardised first approximation at a risk evaluation (the process involving societal judgements as well as technical considerations (see e.g. Illing, H P A, 'Are societal judgements being incorporated into the uncertainty factors used in toxicological risk assessment', *Regulatory Toxicology and Pharmacology* 29, 300-308, 1999; or Illing, H P A, 2006). Thus, for the purposes of the Authorisation process a pure risk assessment statement, the OECD 'margin of exposure' (Descriptions of selected key generic terms used in chemical hazard/risk assessment, 2003; the ratio between the No-Observed-Adverse-Effect-Level (NOAEL) (or equivalent) for the critical effect ('key impact') to the theoretical, predicted or estimated exposure dose or concentration) is required, not the DNEL. The judgement concerning whether the margin of exposure is adequate is a part of the risk evaluation. The term 'margin of exposure' is preferred in this document to 'margin of safety' as the OECD gives two different definitions for 'margin of safety'.

In seeking to examine a series of substances, absolute numbers for the margin of exposure for a specific key impact can then be compared by setting them against a reference value (the substance being subjected to authorisation). Alternatively, if the data permit, comparison may be undertaken without determining absolute numbers. In the cases of persistence and bioavailability the presence of the material in the environment is the problem. In this case, presumably, the 'margin of exposure' would be determined by taking the numerical value for the parameter in question, comparing it with the criterion value for that parameter, and then setting that number against the actual exposure value (e.g. obtaining the PEC/PNEC ratio. The TGD methods should be applied in a comparative mode).

At present there is a need to deal with the question of potency when dealing with carcinogens; the current classification system deals with carcinogens in terms of quality of evidence, not in terms of potency. The 'margin of exposure' approach is applicable to non-genotoxic carcinogens, but, for genotoxic carcinogens, the UK principle hitherto has been to jump immediately to risk management and to propose avoidance of exposure to the general public where possible and otherwise to reduce exposure 'as low as is reasonably practicable'. Comparative risk evaluation for genotoxic carcinogenesis (which may be required for workplace operator exposure) will require that a comparative risk evaluation is conducted, so the UK Committee on Carcinogenicity will have to provide advice to the UK Government on how to undertake the associated risk assessment.

Within a 'key impact' it should be possible to rank a series of chemicals on the basis of their 'margin of exposure' (to the NOAEL). If the 'margin of exposure' is deemed insufficient, it may also be necessary to deal with the question of dose-response and hence the relationship between the maximum level that could be deemed 'tolerable' and the theoretical, predicted or determined exposure. It should be possible to comment upon the quality of the exposure data available for the particular use for both the substance subject to authorisation and the alternatives. There may be inequalities in the quality of evidence concerning hazard for the alternatives that should be commented upon – for example carcinogenicity and reproductive toxicity data may not be available for particular alternatives if they are currently low tonnage chemicals not subject to authorisation or chemicals not placed on the market.

Risk ranking also requires consistent choices regarding how the attributes of chemical substances should be grouped; unfortunately there are no objective criteria for determining the best method to do this for ranking purposes. Perhaps the best approach is to define the risks in a manner that is most useful to stakeholders.

Every substance has its own hazard profile and although it is possible to rank substances in order of their toxicity to man or their global warming potential it is not possible to rank substances in order of generic 'hazard' in order to select a 'safer' alternative. Consequently, replacing one substance by another in order to reduce one specific hazard may increase one or more different hazards. The decision maker therefore needs to balance the risks posed by these independent hazards in order to determine the optimum substitute material. A crude example of this is in the attached table. However, it should be noted the table only contains broad headings for areas of 'key effects', not individual 'key effects'.

### **Step 3: Describe the impacts**

Risk profiles detailing the type and scope of risks for each candidate substitute chemical substance should be summarised, according to agreed criteria, by an expert group equivalent to the UK Advisory Committee on Hazardous Substances. This is the comparative risk assessment. These profiles should then be considered by a (primarily) stakeholder group with input from interested parties, i.e. the stakeholders take part in a risk evaluation. Ideally output of

Decreasing>	<i>TOXICITY</i>	<i>ECOTOXICITY</i>	<i>VOLATILITY</i>
	Dichloromethane	Monochlorobenzene	Dichloromethane
	Trichloromethane	Trichloromethane	Acetone
	Monochlorobenzene	Toluene	Trichloromethane
	Toluene	Dichloromethane	Toluene
	Acetone	Acetone	Monochlorobenzene

**Table 1. Chemical Substances Ranked by Hazardous Property**

the first stage could be a matrix of alternative substances scored against the same set of criteria. This would serve to facilitate the comparison of alternative chemical substance. The expert group should also identify and explain all uncertainties and assumptions inherent in the information. Concerns that can not be adequately described in terms of summary criteria should be made explicit so that they can be factored into the risk evaluation process and subsequent follow through. This should involve a consideration of socio-economic matters and any other relevant considerations.

Socio-economic considerations include:

1. Availability of effective alternatives nationally and globally
2. Impact of loss of economic goods and services if substance withdrawn
3. Effectiveness of reformulated products for specific uses
4. Costs of reformulating products that contain active substances

Other considerations include:

5. Unique properties specific to a particular chemical substance (not dealt with above)

The above list of considerations is not comprehensive and has been provided to highlight some of the properties that will need to be agreed upon when undertaking comparative risk evaluation.

**Step 4: Ranking the alternatives**

A key question that needs to be asked before 'choosing' between the best alternative among negative impacts of different chemical candidates for substitution is 'Do we need the chemical for this product or would society be better off without it?' Ideally society would like industry to deliver a desired property or effect of a chemical substance without negative side-effects, e.g. flame retardant clothes are desirable but not flame retardant chemicals with bio-accumulative properties. If the answer to this question is 'yes' then there is a need to rank alternatives. However, one alternative may not be appropriate in all circumstances, and, as with medicines, it may be necessary to authorise several alternatives, all of which meet appropriate criteria.

To date it appears that the main driver in making substitution decisions has been human health. Concerns for the health and safety of the workforce have resulted in the 'substitution principle' being built into occupational health and safety guidelines. This view that human health appears to be more important than the environment is supported for example by recent decisions to re-introduce DDT for malaria control.

Although various attempts to produce ranking scores (see e.g. Shillaker, R 'Priority setting and risk assessment of chemicals: Human health effects' in Risk Management of Chemicals, edited by M L Richardson, Royal Society of Chemistry, 1992 and references therein) have been made, none have been successfully adopted. This is because these systems have been trying to impose a technical process on what is properly a societal judgement.

Where possible, the process of weighing dissimilar risks has to be based on scientific evidence. This should be based on risk profiles of the list of chemical alternatives with a particular outcome in mind i.e. desired effect (optimum outcome at with the lowest impact). Stakeholders should first individually rate and rank the impacts of each end effect for each chemical substance making use of factors such as: severity of effect (irreversibility); probability of effect (use/exposure); groups affected (vulnerable groups, the young and the old); the affected environment (aquatic, terrestrial and atmospheric); sustainability (and hence life cycle analysis); and societal attitudes to different classes of risks ('voluntary'/'involuntary', 'dread', etc.).

It is likely that each group of stakeholders will judge some risks and benefits to be more important than others e.g. flammability vs. damage to the ozone layer. Summary sheets should be used to record individual stakeholder rankings of each chemical substance for the common desired outcome. Individual stakeholders should then seek to develop group rankings, for chemical substances in discussion with other stakeholders. Although consensus is desirable it is not always possible or essential. The outcome of this process could produce a majority view as to which chemical substance is the preferred either for use directly or for incorporation into products based on achieving the desired effect at the lowest impact.

Assuming that it is possible to identify one or a number of substitutes which is, or are, on balance, 'safer' than the currently used material, it would be inappropriate to proceed without examining the sustainability impacts of making such a substitution. A 'safer' chemical may be used in larger amounts, require more energy or water to be used and/or may generate more waste. For example the transistors and silicon chips that began to replace the thermionic valve from the 1960's onwards contain semi-conductor materials that are Persistent, Toxic and Bioaccumulative (PBTs) but they utilise only a fraction of the resources and energy. The decision maker must therefore again balance the safety of the substitute against any potentially negative sustainability impacts in order to determine the optimum substitute material.

Where the differences in terms of the gains by substituting one chemical substance for another (for a specific use) are clear, then substitution should be required. Difficulties arise in those situations where the comparative risk assessment process highlights differences between two candidate replacement substances in terms of their predicted impacts. In such cases, where no satisfactory methods exist to make a reliable comparison possible, substitution should not be required. For example a chemical substance with a higher risk to aquatic organisms, would not normally be substituted by another with a lower risk in that area but a higher risk in a different area e.g. to birds. In such cases the outcome of the process would be information that could be used to aid users make choices about which chemical substance to use in different situations, according to their risk profiles. Such information could also be incorporated into the labelling of products.

## **7) SUBSTITUTION AND AUTHORISATION**

Substitution is at the heart of the proposed REACH Authorisation process for the control of chemicals in the EU. If a substance needs to be authorised for a specific use and its exposure during use cannot be controlled to acceptable levels, a formal examination of possible substitutes must be submitted to the Competent Authority.

The 'Authorisation' process is essentially a risk management process. As substances enter the Authorisation process on grounds of hazard, once likely exposure is examined it may be that, for one or more specified uses, control is such that the risks are deemed 'broadly acceptable'. This is the circumstance for which Article 57(2) applies and the substance can be authorised without further consideration. Alternatively, if exposure to the original substance cannot be controlled to 'broadly acceptable' levels of risk, then further risk evaluation is needed. If society has a need for the chemical/use and risks from exposure are not unacceptably high, they can be deemed 'tolerable' on socio-economic considerations. If available substitute chemicals also exhibit a number of hazardous properties that lead to risks which are deemed worse than the original, it may be appropriate to continue a particular use on socio-economic grounds. Article 57 (3) of the proposed REACH regulation makes provision for 'Authorising' some potentially hazardous chemicals for specific uses, even though the risks will not be 'broadly acceptable', but only after making the socio-economic case and examining possible substitutes, and only for a limited period of time.

But what constitutes an acceptable increase in risk? Using the example of the almost non toxic and non flammable CFCs which were introduced to replace refrigerants that were either very toxic to humans, such as ammonia, or were extremely flammable such as propane. When this substitution took place the impact of CFCs on the ozone layer was unknown. However when this effect was discovered, the older refrigerants were reintroduced with a very significant increase in risk to the population. Who is going to determine when this is acceptable?

There is therefore a need for clear Authorisation requirements in this area so that legal certainty and market rights can be established. Trade barriers could also result if the same criteria not applied in all member states. Furthermore, poorly defined authorization criteria would erode the willingness of industry to develop business opportunities or encourage continuous investment in innovation and the search for solutions to existing problems.

In a free market, customer behaviour will determine the appropriate level of cost and benefit and this ceases to be a challenge. However, if substitution becomes a legal obligation, the legislator will need to establish appropriate cost benefit guidelines e.g. should substitution be required if it costs £100k to improve safety by 0.01%? (or any other combination of numbers you choose to insert). Similarly rules will need to be established about the weight to be attached to the views of those stakeholders who are customers. For example, the use of contraceptive pills leads to the release into the environment of an endocrine disrupting substance, whereas the condom provides a non-chemical substitute. In this case consumer preference clearly outweighs the requirement to adopt the substitution principle, but under what circumstances does this occur?

## **8) SUBSTITUTION SEPARATE FROM THE AUTHORISATION PROCESS**

Authorisation only applies to substances exhibiting certain specified properties. Substances are also classified as 'dangerous' on grounds of other human health hazards, such as acute toxicity. Substitution may also be appropriate for uses in which the risks arising from these other human health hazards are not 'broadly acceptable' – i.e. the use is not 'safe'. The decision on when and what to substitute in a particular application may reside with the manufacturer/importer or may reside further down the supply chain. The buying power of informed users/consumers and suppliers could be an effective mechanism for driving substitution as they are in the unique position of being able to exert pressure on those higher up the supply chain. Product formulators need to be responsive to user/consumer demands or they could stand to lose their markets. A real example of this approach being adopted successfully are the series of supply chain voluntary UK agreements which were developed to manage the phase out in certain applications of nonylphenol and its ethoxylates. There is thus a case for arguing that alternatives based on this approach may deliver equivalent or even better outcomes

than the use of the regulatory system. Such a system could be enhanced by using market incentives, such as subsidies to encourage the use of preferred chemical substances. Inclusion in a positive EU database of substances that have undergone comparative risk assessment and been approved for specified uses, would also serve to encourage substitution.

## **9) ADDITIONAL COMMENTS**

Generally substances not requiring Authorisation should be preferred to those that do and the benefits would have to considerably outweigh the risks if a chemical requiring authorisation is to be preferred to one that does not for a particular use. However, on specific occasions, it may be better to continue to use a hazardous chemical by 'tightening up' on how it is manufactured, used and disposed of. Annex XIII of REACH should be divided into two parts. One part should list chemicals that meet the criteria for Authorisation but for which market forces could act as a sufficient driver for risk reduction. This part would be a division for those uses that can be continued as posing a 'broadly acceptable' risk. The second part should identify the uses of chemicals for authorisation that are accompanied by regulatory restrictions and mandatory encouragement of replacement as the risk, even when controlled, is still only 'tolerable'. Consideration should also be given to a positive list of those substances and uses which emerge as suitable when an examination of substitutes is undertaken for 'dangerous' substances not subject to authorisation.

## **10) SUMMARY**

- Substitution should be based primarily on risk rather than hazard
- Substitution is a multi-component process designed to reduce the overall risk to one that is broadly acceptable
- Substitution should be goal-orientated rather than prescriptive
- Substitution requires considerable stakeholder involvement, including regulators, informed users/consumers, and suppliers
- To be effective, the substitution processes must be transparent
- Substitution is the outcome of comparative risk assessment and evaluation, incorporating health, wildlife and environmental concerns.
- Risk evaluation involves:
  - identification of a group of chemical substances considered as possible substitutes
  - development of risk profiles of candidate substitutes
  - expert group summarisation of risk profiles for each candidate
  - risk evaluation of candidates by stakeholder group
  - choice of best alternative candidate by majority stakeholder view (or consensus if appropriate)
- Authorisation provides the risk management processes in a regulatory context. Substitution may also reside down the supply chain via informed users/consumers
- Normally, substances not requiring Authorisation should be preferred as replacement candidates to those that do
- Annex XIII of REACH should be divided into 2 parts; one part listing chemicals meeting Authorisation criteria but for which some or all of the uses are controlled sufficiently to represent a 'broadly acceptable' risk and for which market forces can be used to drive risk reduction. The second part should identify uses that are accompanied by regulatory restrictions (i.e. tolerable risk).

The members of the REACH Task Force: Mr P Whitehead [Chairman], Dr J Duffus, Mr D Hart, Dr J Hoskins, Dr P Illing, Dr N King, Dr D Knight, Mr K Prior, Mr P Reeve, Prof D Taylor, Dr S Lipworth [Secretary]

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