

## Environment, Health and Safety Committee Report on

### ROYAL SOCIETY OF CHEMISTRY STAKEHOLDER WORKSHOP PRACTICAL ASPECTS OF CHEMICAL SUBSTITUTION

Held on 14 December 2004



The Royal Society of Chemistry held a one-day workshop to explore how chemical substitution could work in practice within the context of the proposed REACH Regulation. In order to get an overview of the issues of concern in relation to substitution and how some of these could be resolved, participants were drawn from a wide range of organisations including Government, Industry and NGO's. The meeting at the Royal Society of Chemistry was opened by the Minister of State for Rural Affairs and Local Environmental Quality the Rt. Hon Alun Michael MP. Professor David Taylor chaired the meeting and presented the keynote address. Every effort has been made by the RSC to summarise the range of views expressed by workshop participants without bias, thus the report cannot be represented as the opinion of any particular stakeholder.

#### Executive Summary

- Substitution is a principle with wide application across society; not solely an issue for REACH.
- A broader debate is needed on the nature of risk; greater understanding of risk is required at all levels.
- Substitution decisions require considerable stakeholder involvement and the role of stakeholders in the substitution process needs to be carefully defined. There is also a need for good information so that stakeholders can make better informed decisions about possible substitutes.
- Substitution decisions will involve tradeoffs between risks and benefits of different chemical substances that go beyond the scientific evidence. Such decisions are very difficult because they involve both objective and subjective judgements which have societal implications.
- Rules on substitution would be desirable to ensure consistency and transparency, but are only likely to evolve with experience.
- Substitution is not a simple process of replacing one chemical with another since it is necessary to ensure that the overall risk is reduced and that a decrease in one risk is not overshadowed by the increase in another. It is important to note that risk is not eliminated in this process.
- The general view expressed was that 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.
- The 'substitution principle' should be applied to all chemicals, not just those requiring authorisation.
- Generally substances not requiring authorisation should be preferred to those that do. 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. The other part should identify chemicals for authorisation that are accompanied by regulatory restrictions in respect of the uses to which the chemical is put.

This report was compiled by the Environment, Health and Safety Committee [EHSC] of the Royal Society of Chemistry.

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## The Workshop

For the purposes of this workshop, substitution was defined as 'the replacement of one chemical by another in order to increase safety for people or the environment'.

Substitution is at the heart of the 'Authorisation' process in the proposed REACH regulatory framework for the control of chemicals in the EU. The REACH regulation makes provision for 'Authorising' some potentially hazardous chemicals for specific uses in those cases where it can be demonstrated that the risks posed by such chemicals can be 'adequately controlled' or by 'time limiting' the use of those that can not.

The aim of this workshop was to move the debate on REACH forward by considering some of the practical aspects of 'substitution'. This meeting was not aimed at seeking consensus but at an exploration of views and sharing of concerns. This workshop was not about whether substitution is desirable or about the adequacy of the requirement for substitution within the REACH proposal. The purpose of the workshop was to consider the 'how' rather than the 'why' of substitution.

Workshop participants were asked to consider the following practical issues before addressing specific questions.

- Availability of Comparative Data. Effective substitution of a 'problem' chemical by an alternative requires an 'adequate' set of data for the alternative.
- Which is the 'key' hazardous property? Chemicals can not be ranked in order of 'safety' - they have 'hazard profiles' whose ranking differs.
- How to weight different impacts? Should substitution be required for 'safety' or for 'sustainability'?
- How do you assess cost/benefit? Should substitution be required, if it costs £100000 to improve safety by 0.01%? What about the views of the end user?
- What is 'adequate control'? A substitute chemical will still exhibit a number of hazardous properties, some of which may be worse than the original. What constitutes an adequate degree of control?

Workshop participants were divided into breakout groups and asked to address the following questions in order to stimulate debate.

- Which are the key impacts upon which comparative assessments to determine the requirement for substitution should be based e.g. toxicity to fish, impact on users etc.?
- How should dissimilar hazards (e.g. ecotoxicological impact vs. human cancer risk vs. climate change) be weighed?
- How should an 'acceptable level of risk in relation to societal benefit' be defined? How much better does the substitute need to be to justify a change?
- How should issues like 'adequate control' be defined when making substitution decisions?

Participant responses to the specific questions were presented and discussed in the plenary session. The responses and the output of the discussions have been summarised and combined to reflect the main views expressed. All workshop proceedings were under the Chatham House rule in order to facilitate an open discussion. Consequently, no views expressed have been attributed to any individuals present.

## Risk and Substitution

In an ideal world it would be preferable not to use hazardous chemical substances for which 'less harmful' substances exist. In reality, hazardous chemicals have been 'authorised' for use in those cases where the perceived benefit to society is disproportionate in comparison with the risks.

Substitution is a principle with wide application across society, and is not solely an issue for REACH. Chemical substitution is one of many options in the process of reducing risk. Substitution is a practical outcome of comparative risk assessment. Comparative risk assessment 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.

A broader debate is needed on the nature of risk; greater understanding of risk is required at all levels. Substitution decisions require considerable stakeholder involvement and the role of stakeholders in the substitution process needs to be carefully defined. There is also a need for good information so that stakeholders can make better informed decisions about possible substitutes.

## Stakeholder Participation

Substitution decisions will involve trade offs between risks and benefits of different chemical substances that go beyond the scientific evidence. Such decisions are very difficult because they involve both objective and subjective judgements which 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, green organisations, etc.). These decisions require the engagement of all stakeholders with an interest in the trade offs that could result from choosing between alternative chemical substances. At present, no established mechanism for dealing with these complex issues exists but will need to be in place in the future.

Rules on substitution would be desirable to ensure consistency and transparency, but are only likely to evolve with experience. The requirement to substitute needs ground rules but this is problematic as chemical substances and the ways they are used are inherently variable. Rules setting out the criteria for substitution and defining the thresholds of acceptability need to be developed. 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. A 'Manual of Decisions' (as is currently available for decisions concerning new substances) may be the way forward. 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 CSF experience on how to consider and give just weighting to all factors.

A key question will be 'who decides or initiates substitution?' This might be the "Authorisation body" which could decide that some or all of the uses of a substance are no longer 'acceptable' and 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 downstream user of a chemical may seek a substitute e.g. in response to pressure from a risk-averse customer. It could be argued that these types of substitution are outside the scope of REACH but many of the arguments that urge caution in the application of the 'Substitution Principle' are just as relevant in these cases and the same principles should apply.

The view of the chemical industry is changing as it adjusts to societal expectations. Industry is becoming more aware of responsibilities towards downstream users. In this regard professional chemists also need to take a more pro-active interest in substitution, particularly those working in industry.

## Assessing the Impacts

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.

A key question that needs to be asked before 'choosing' between the 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.

Substitution is not a simple process of replacing one chemical with another since it is necessary to ensure that the overall risk is reduced 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. However, it is important to note that risk is not eliminated in this process. Substitution can involve changes to both manufacturing process and product specifications.

The general view expressed was that 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.

The relative importance of different impacts, such as human carcinogenicity, reproductive toxicity, pre-senile dementia, environmental ozone layer depletion or fish kills in rivers is an issue that will also have to be addressed. It was also accepted that some of the consequences of substitution may be unforeseen at the time substitution decisions are made.

The process of weighing dissimilar risks has to be based on scientific evidence, where possible. Weighing should make 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.).

### **Substitution and Authorization**

The 'substitution principle' should be applied to all chemicals, not just those requiring authorisation. For the substitution to be triggered it may be necessary to demonstrate that the alternative active substance or substances can be used with similar results without significant economic and practical disadvantages for the user and without an increased risk to health or the environment.

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.

At present it may be easier to treat all chemicals of very high concern (CMRs and PBTs) as a group requiring authorisation and not to try to rank these chemicals for the purpose of substitution. Although this goes counter to considering each chemical substance on a case-by-case basis, it would serve to prevent serial substitution of one substance by others in this group.

The view was expressed that 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. The other part should identify chemicals for authorisation that are accompanied by regulatory restrictions in respect of the uses to which the chemical is put.

Many of those present also expressed the view that regulations for chemicals in imported products should be the same as for manufactured chemicals.

### **Invited Organisations**

Advisory Committee on Hazardous Substances	English Nature
Association of the British Pharmaceutical Industry	Green Alliance
British Association for Chemical Specialities	Greenpeace UK
British Chambers of Commerce	Health and Safety Executive
British Union for the Abolition of Vivisection	Institute for Environment and Health
Cardiff University Chemistry Department	International Council on Mining and Metals
Centre for Ecology and Hydrology	Non-Ferrous Alliance
Chemical Industries Association	Pesticides Safety Directorate
Confederation of British Industry	Royal Society of Chemistry
Crystal Faraday Partnership	UK Chemical Stakeholder Forum
Department for Environment, Food & Rural Affairs	World Wildlife Fund
Department of Trade and Industry	