

Environment Council 28 June 2004 – Authorisation and the role of substitution

Introduction

The European Commission's proposals for the new system of chemical regulation – REACH (Registration, Evaluation, Authorisation of Chemicals) – ought to lead to real improvements in the environment and to human health. For many of the chemicals currently marketed in the EU, we do not have the necessary information to allow adequate assessment of the potential risks these may pose. However, the proposal also has implications for the competitiveness of one of the EU's key manufacturing sectors as well as the potential to affect the competitiveness of the many downstream users of chemicals.

It is vital that the right balance is struck between protection of human health and the environment from hazardous chemicals, maintaining the competitiveness of EU industry and stimulating innovation.

Authorisation

We support the aim of the authorisation process to ensure that the risks from substances of high concern are properly controlled and that these substances are eventually replaced by suitable substances or technologies with the aim of reducing risks to human health and the environment.

A workable and efficient system of authorisation will lead to:

- rapid identification of substances of most concern based on sound scientific criteria;
- a shift in the burden of proof to industry to demonstrate that the use of these substances should be continued;
- tighter controls on the uses of substances of concern; and
- a framework to stimulate innovation into substances and technologies that reduce risks.

We support the Commission's proposal for the scope of authorisation and the inclusion of chemicals that are:

- carcinogenic, mutagenic, and toxic to reproduction (CMR) categories 1 or 2;
- persistent, bioaccumulative and toxic (PBT);
- very persistent and very bioaccumulative (vPvB); and
- substances of equivalent concern such as endocrine disruptors when scientifically validated test methods have been developed and criteria established.

Substitution of substances of most concern

The concept of substitution – that chemicals of most concern should be systematically replaced by safer alternatives – is supported by the UK. The view of

Member States was set out in the Council Conclusions on the EU Chemicals White Paper:

“The Council recognises that chemicals that are dangerous should be substituted with safer chemicals or with safer alternative technologies not entailing the use of chemicals, with the aim of reducing risks to man and the environment;”

However substitution is not a straightforward process. There have been a number of examples where an apparently safer substitute has been introduced in response to human health or environmental concerns only to turn out to have unintended or unexpected effects of equal or greater concern to those of the substituted substance. It will therefore be important that REACH facilitates a long term strategy on substitution by increasing our knowledge about the properties, uses and potential new applications of chemicals.

The UK considers that REACH should be designed to create a framework to stimulate innovation into finding safer substitutes to complement, as far as possible, the commercial pressures that already apply within markets, but especially where such pressures are weak.

The UK considers that the role of substitution in REACH should be guided by the following key principles:

- the legislation should be designed in such a way that innovation to develop safer alternatives is encouraged as far as possible;
- the legislation should ensure that regulatory decisions on substitution are based on a consideration of relative risks; and
- the legislation must be workable and, as far as possible, provide clarity and predictability for regulators, suppliers and users of chemicals.

The UK would like the Working Group to explore possible mechanisms to strengthen incentives for finding and developing safer substitutes, such as:

1. **A clearer definition of “adequate control”** to reflect commitments under existing occupational health, public health and environmental legislation.

This would be consistent with the World Summit on Sustainable Development’s 2020 chemicals goal, and with the Council Conclusions on the White Paper that:

“the policy should aim to achieve that, within one generation (2020), chemicals are only produced and used in ways that do not lead to a significant negative impact on human health and the environment, which is also in line with the Water Framework Directive and with commitments that Member States and the Community have undertaken in international fora;”

2. **Mandatory review periods for all authorisations.**

This would be intended to create a clear timeframe within which industry could focus its efforts on innovation and development of new and safer alternatives once an

authorisation has been granted. Review periods would need to be set on a case-by-case basis, and involve an assessment of the risk management measures that apply, the availability of substitutes or alternative technologies and socio-economic factors.

3. A requirement for **an independent review of available substitutes** (potentially as part of the socio-economic analysis) paid for by industry but carried out by a third party.

This recognises the difficulty manufacturers may face in identifying substitutes (especially if these fall outside the manufacturer's products range) particularly as the decision on whether an alternative is suitable is reliant on the decision of downstream users. Given the importance of the downstream user in the substitution process, consideration could also be given to encouraging downstream users to consider substitution when choosing appropriate measures to control risk.

Conclusion

- The UK supports the aim of the authorisation process to ensure that the risks from substances of high concern are properly controlled and that these substances are eventually replaced by suitable substances or technologies with the aim of reducing risks to human health and the environment.
- We consider that REACH should be designed to create a framework to stimulate innovation in finding safer substitutes to complement, as far as possible, the commercial pressures that already apply within markets.
- We would like the Working Group to explore possible mechanisms to strengthen incentives for finding and developing safer substitutes that help ensure that we continue to enjoy the benefits of chemicals while avoiding harmful effects on human health or the environment.