

EUROPEAN UNION

INDUSTRIAL CHEMICALS: BURDEN OF THE PAST, CHALLENGE FOR THE FUTURE

**A stakeholder workshop on the development of a future
"chemicals" strategy for the European Union - 24/25 February
1999**

**WRc Ref: EU 4719
APRIL 1999**

3. DISCUSSION AND RECOMMENDATIONS

In this section an attempt has been made to draw together elements which may offer a way forward for the European Commission when developing a Chemicals Strategy. We have drawn heavily on the discussions during the stakeholder workshop but the recommendations should not be taken as conclusions of the workshop itself as a wide variety of views were expressed and inevitably some parties would not agree with all aspects.

Main areas of concern

The current EU chemicals legislation has established a comprehensive framework for the control of industrial chemicals in the EU. However, a number of major areas of concern were identified at the workshop.

The main concern relates to the slow progress in assessing existing chemicals and the burden of proof required by the authorities to institute risk management measures.

There appears to be general support for the system of assessing new substances, although industry are still concerned that the current notification procedures stifle innovation and might be able to be simplified for some substances, such as intermediates, if limited environmental exposure could be assured. Simplification of notification procedures could enable more effort to be targeted on existing substances.

Legislative issues

EU chemicals legislation is complex as it has evolved in response to the changing needs of the European Community. There was general recognition that the system is cumbersome and burdensome and whilst some short term improvements to the current system could be made, they would be limited in scope. Therefore, whilst a concerted effort should be made to optimise the current system, there was broad support in the long-term for a fundamental review of the legislative framework for chemicals and associated structural changes. This should take account of economic, social and environmental drivers.

Currently disparate systems are used for the assessment of 'new' and 'existing' chemicals. There was broad, but not unanimous, support for these two systems to be eventually merged into one system.

Institutional issues

Regulatory authorities are currently not sufficiently resourced to be able to make rapid progress on existing substance assessments within the current system. This raises two lines of questioning:

1. What resources are needed and who should provide them (an institutional issue)?
2. Are risk assessment procedures always appropriate and are full risk assessments always necessary (a technical issue)?

The current system was described (J van der Kolk) as an inverted triangle with unassessed chemicals comprising the bulk of existing chemicals, fewer on priority lists and very few as regulated chemicals after risk assessment. It was suggested that the triangle should be turned around to provide a tiered system with very few chemicals requiring strict EU control, a greater number being controlled under a harmonised EU

approach and the vast majority becoming the responsibility of industry within a clear framework.

The need to work in partnership was widely accepted at the workshop and industry expressed a willingness to take more responsibility for chemicals assessment. All parties accepted the need for independent peer review and recourse to regulatory action where necessary. Environmental NGOs, however, preferred risk assessment to remain with regulators. There was also a call for better coordination of activities within the Commission and several parties suggested strengthening the role of the European Chemicals Bureau (ECB). The option of strengthening the ECB to act as a focal point within a new system with a coordination and peer review should be considered. Increased resources are needed for risk assessments which could be provided from regulators but this would require significantly more commitment from Member States and agreement on burden sharing. An alternative approach would be for industry to take responsibility for producing risk assessments for most chemicals with perhaps regulators retaining responsibility for chemicals of particular concern. If this approach is adopted, it will be important that there are adequate regulatory safeguards. For example, there should be a clear framework with transparent procedures and independent peer review. Information which forms the basis for any decisions should be transparent and accessible to the public.

During the workshop, it was suggested that there is a need to better relate environmental policies to environmental improvement and a role was seen for the European Environment Agency in providing feedback on environmental improvement.

The need for a Stakeholder Forum was raised several times during the workshop and this may provide a mechanism to involve all major stakeholder groups in the review of chemicals legislation to keep them informed of progress. However, there is also a wider issue of public access to information which needs to be addressed (this includes, for example better risk communication and information on which substances have and have not been assessed).

Exposure assessment currently represents a significant gap in the process and it is important to involve downstream users in the process so that chemicals can be managed during their whole life-cycle not just at the production stage.

Technical issues

Hazard and risk are a continuum. Both are part of the risk management process and their roles should be reconsidered and clearer guidance given on when and how to use them.

In some cases hazard is already used as the first basis for risk management and there may be a case for temporarily restricting the marketing of some substances based on their hazard until a risk assessment has been completed. For such substances, the burden of proof could be reversed to enable industry to demonstrate acceptability of these substances through more detailed risk assessment (i.e. bans would ultimately still be based on risk assessments). This would imply the development of appropriate criteria to select such substances, reconsideration of the burden of proof and how the precautionary principle is applied.

Risk assessment should remain the main basis for risk management but there should be scope to apply it more intelligently. The requirement to undertake full risk assessments, even when it is obvious that they will not change the outcome, is burdensome and fast-track and targeted risk assessments should be more widely used. However, clear criteria would need to be developed to indicate when such approaches would be appropriate.

As regulatory resources are limited it would be best to concentrate regulatory effort on substances whose risk assessment/management would have a high expected regulatory outcome (e.g. where regulatory controls are needed and likely to substantially reduce risk).

The aim of zero emissions was seen as a helpful aspiration to encourage the continuous reduction of emissions of hazardous substances but not generally as a realistic target. A wider role for the application of the substitution principle was discussed during the workshop. However, the need for further development of the approach was identified if it is to gain wide acceptance and consistent application.