

THE WHITE PAPER ON THE NEW CHEMICALS POLICY

There is a great deal of activity associated with the formulation of the New Chemicals policy. This legislation introduces a significant change to the regulatory process for chemicals of all types supplied into the EU market. Conscious of the high level of regulatory control already in the world, the Commission has noted the requirements of other approval processes such as, ICCA and the U.S. EPA - HPV programmes, particularly with regard to the collection and use of test data.

Not only does this piece of legislation bring potential expansion in the number and range of chemicals for which some kind of approval will be necessary, it also transfers the burden of responsibility for the performance of risk assessments from the authorities to industry. Furthermore, it places obligations for the assessment of risk on downstream users, a situation that undoubtedly will lead to problems for many suppliers. On the positive side, there will be an increased emphasis on the use of exposure data, which should allow for a more flexible testing programme.

In keeping with the stated aim of the Commission to reduce the amount of animal testing, group applications will be encouraged. The Commission is considering the assignment of "property rights" to data submitted in the hope that it will ensure all suppliers contribute fairly to the cost of product registration.

The policy introduces the REACH system, bringing together the assessment of risk for both new and existing chemicals. The components of REACH are:

Registration - this is applied to substances on the market at > 1 tonne;

Evaluation - for chemicals supplied at >100 tonnes; and

Authorisation of Chemicals - for substances classified as carcinogenic, mutagenic or reproductive toxins and for POPs. This section includes accelerated risk management and restrictions of chemicals causing the greatest concern.

Initially, the risk assessments for approximately 2600 substances supplied at 1000 tonne or more, or substances classed as CMR/POPs, will be evaluated by the authorities. With a proposed completion date of 2005, the Commission would like to see these chemicals in the evaluation phase as soon as possible.

Between years 2005 to 2008, close to 3000 chemical substances supplied at tonnages between 100 and 1000 will be assessed. The remainder of 25,000 substances will enter the system starting in 2008, with a completion date of 2012.

A degree of flexibility will be applied to the testing programmes for the higher tonnage products requiring evaluation in the first part of the programme. The level of use and exposure will be a factor in the choice of data necessary for the risk assessments.

In general, there will be a move to phase out and replace substances classified as CMRs and POPs unless the industry can show there is a definite need for a particular substance or prove that the risk to health and the environment is negligible.

This degree of flexibility also allows for the use of:

- *in vitro* test methods;
- existing technical information;
- test data generated for the support of chemicals in review under other regulatory programmes; and

- predictive techniques such as QSARs.

There has been a call for the establishment of a central agency to administer the work associated with the operation of the new policy. This could take a significant amount of time to set up, staff, and come up to speed on the requirements of the REACH system, such that it could impact the proposed timescales outlined in the White Paper.

The chemicals industry, through Cefic, has stated its support for the objectives outlined in the White Paper. However, it is sceptical about the deadlines set for the REACH system.

Cefic put together a "thought starter" on how it believes the REACH system could be modified in order that it might achieve the goals of the White paper.

The findings of a pilot trial using the principals outlined in Cefic's "thought starter" showed that the objectives set out in the White Paper could be achieved more cost effectively than with the proposed REACH system. Furthermore it highlighted a number of potential problems, such as difficulties in bringing together primary and downstream users, pulling together accurate information on the tonnages of chemicals in use and the lack of a process for accounting for non-EU manufacturers and suppliers.

Inevitably, the introduction of a new policy for chemicals will necessitate an increase in the workload of industry. There are a number of actions that can be taken by suppliers in order to prepare for what could be a substantial amount of work once the new policy comes into force. At this stage, companies should review their product ranges to determine which products will be covered and at what level, which other suppliers will be affected and start to look at the requirements for downstream user risk assessments.

How can Steptoe & Johnson help?

Should you want to talk about the set up and management of these initial work programmes in order to allow for a smooth entry into the REACH system, please contact: Graham Lloyd

Telephone No: +44 1902 851 425

Fax No: +44 1902 851 188

E-mail: glloyd@steptoe.com