REACHing for the Right Solution

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There are strong voices on all sides of the debate which has been triggered by the European Commission's White Paper Strategy for a Future Chemicals Policy and in particular on REACH.

REACH (Registration, Evaluation, and Authorisation of Chemicals) is arguably the most significant proposed development in European legislation on controlling chemicals and it will have far-reaching implications for the science and practice of chemistry within the European Union.

As an independent professional scientific society we have a duty under our Royal Charter to serve the public interest and it is in that spirit that we examined these proposals carefully and identified some key points which we think should be taken into consideration.

In principle the Royal Society of Chemistry would welcome a single harmonised regime for assessing and controlling the possible effects of chemicals on health and the environment.

REACH has some very laudable objectives. One of its key aims is to introduce laws that will provide a faster, more efficient approach to managing chemicals of high concern. The most recent version of REACH is more balanced and more pragmatic than earlier versions.

However, in common with the UK Government and many other interested parties, including the House of Commons Science & Technology Committee whose excellent report was published in May, the Society believes that more information and guidance is required if REACH is to achieve its intended objectives. Until then we have some significant concerns about the sheer workability of aspects of the proposals. Our reservations can be summarised as follows:

REACH should be based on Risk and not Hazard

We believe that substances should generally not be classified on the basis of their intrinsic hazard alone but on the risk that the hazard will cause actual harm. Intrinsic hazard is not a good measure of the actual threat that a substance poses to humans or the environment. Risk is a better measure because it is based on the likelihood that an intrinsic hazard associated with a substance will cause actual harm. The Society suggests prioritisation (to identify and deal with substances of high concern) on the basis of risk to be built in at the Registration stage. Exposure scenarios required for registration will differ on the basis of use and this will have a key impact on the risk that a chemical (substance) poses.

Volume Alone is Not Enough

There is a danger in concentrating solely on the volume of a chemical produced or imported. For example a high volume low toxicity substance like sodium chloride (common table salt) is of less concern than a small volume high toxicity substance. Using tonnage to trigger the REACH process is not ideal although it offers a pragmatic solution for new substances.

REACH and International Compatibility

We think REACH should be compatible with existing and proposed international initiatives on the control of chemicals. For example, implementing REACH should have regard to the Intergovernmental Forum on Chemical Safety [IFCS], the UNEP strategic approach to chemicals management, the OECD co-operative programme for testing and assessing High Production Volume (HPV) chemicals, and the Rotterdam Convention on Persistent Organic Pollutants (POPs). REACH should also be compatible with the proposed

Global Harmonised System for classification and labelling of substances.

Transparency and Commercial Confidentiality

Transparency is vital to enhance public confidence in chemistry and in REACH. The challenge is to create a balance between transparency and commercial confidentiality. It's not easy to do but we're not sure the balance is right yet.

All aspects of the REACH process need to be transparent so that interested parties can see how decisions are made and we wish to promote dialogue between the chemical industry and other stakeholders on this key issue. However this transparency should not extend to providing detailed commercially sensitive information which would impact on competitiveness (eg on the intermediates used in pharmaceutical syntheses or details of formulations that would allow competitors to copy mixtures or finished products) without providing any useful benefit.

REACH and Real Data

REACH should only require data that have real and proven value. Production and importation levels of chemicals are not realistic indicators of potential harm or exposure. Testing threshholds should reflect this and take account of estimated actual exposure and potential impact. There should be greater acceptance of scientifically reliable historical data and data in dossiers produced to meet the requirements of other chemical evaluation programmes. We need European Chemicals Agency guidance on using read-across toxicity data and advice on what level of information is required at the Registration stage to avoid a "tick-box" approach.

Minimise the Testing on Animals

It would be unethical to require animal testing simply to complete a bureaucratic "box-ticking" exercise. On the other hand legislators and regulatory agencies must minimise any unnecessary delay in accepting results from alternative test methods. We have a concern that if dossiers will only be checked for completeness, prior to being placed on the database, that this will encourage registrants to generate comprehensive datasets and thus the use of experimental animals for toxicity testing is likely to increase unnecessarily. Testing on animals should be minimised.

Unnecessary Bureaucracy and Cost?

The Society is concerned about the practicality of registering 30,000 substances and over 40,000 intermediates (or whatever the figures turn out to be) within the 12 years of REACH coming to force. Ideally we can see the case for one registration per chemical compound – otherwise we face the prospect of the bureaucratic nightmare of multiple registrations, but how practical this is remains to be seen.

It is difficult to quantify the cost of compliance with REACH. Current cost estimates by the EU Commission are 2.8 billion euros – mostly on testing and registration.

The biggest costs will probably be incurred "downstream in the supply chain" due to mixture and product reformulation. This in turn will depend on the number of substances that will be taken off the market. Whatever the figures turn out to be it is already clear that implementing REACH will place significant costs on industry and we share the fears that this could be a factor that affects whether the industry remains in the EU.

What Kind of European Chemicals Agency?

The Society has serious concerns about the resources and expertise within the European Chemicals Agency [ECA] and other key bodies involved in REACH. Will the ECA have the necessary skills and experience to make sure that Registration isn't downgraded to a "box-ticking" exercise? Will the ECA check the validity of data dossiers and enforce a proper sampling regime to ensure that harmful substances classified into categories not intended for rapid evaluation do not slip through because the data is not properly scrutinised? Will the ECA provide proper guidance to ensure consistency and a level playing field between Member States?

Unintended Side Effects?

Any chemicals that are withdrawn should be those that are least desirable for health, safety or environmental reasons. But REACH could lead to useful chemicals ceasing to be available due to the high cost of testing. The "best" or "safest" substances should not be withdrawn simply because economic sense dictates that the producer/importer drop that substance rather than pay for the tests. The Commission estimates that only 1-2% of substances currently on the market will be lost. But the Society and others believe that this may be a significant underestimation.

REACH mustn't inhibit Innovation

The Society welcomes the exemptions on Registration for the purposes of research and development to facilitate the introduction of new substances aimed at promoting innovation. The Commission's approach to innovation is primarily focused on substitution. Although substitution can lead to environmental benefits it is unlikely to lead to the true innovation needed to underpin sustainable development.

The Society is aware that the process of developing the proposals into legislation has only just begun and we hope that further improvements will be made to ensure the effectiveness and workability of the eventual legislation.

The new MEPs elected in June now have the task of discussing and debating these important proposals when the European Parliament gets seriously under way in the autumn.

Our Society will be ready to offer them our advice and help.