

Submission to the House of Lords European Union Commission's White Paper "Strategy for a future Chemicals Policy"

This is the Royal Society's response to the call for evidence by the House of Lords European Union Committee for their enquiry into the European Commission's White Paper 'Strategy for a future Chemicals Policy' (COM(2001)88 final). The following submission was prepared by a working group chaired by Professor John Enderby CBE FRS (Physical Secretary and Vice-President, Royal Society). The other members were Dr Andrew Cooper (Department of Chemistry, University of Liverpool); Dr Michael Festing (MRC Toxicology Unit, University of Leicester); Professor Ian Fleming FRS (Department of Chemistry, University of Cambridge); Dr Nicholas Leadbeater (Department of Chemistry, King's College London); Professor John Pickett FRS (IACR Rothamstead); Dr Richard Sharp (MRC Human Reproductive Sciences Unit); Professor John Sumpter (Department of Biological Science, Brunel University); Miss Marisa Goulden (Secretary); Dr Nicholas Green (Secretary). This response has been endorsed by the Council of the Royal Society.

2. How strong is the case for having a single regime for dealing with new and existing chemicals?

There is a very strong case for a single regime to deal with new and existing chemicals. A single regime will simplify the registration requirements for international chemical companies, which need only conform to a single EU standard. Simplified registration requirements would benefit research, development and commercialisation by reducing the total effort involved in registration. Increased harmonisation is an opportunity to reduce the use of higher animals for tests of toxicity. For example, the International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was initiated in 1990 to bring together the regulatory authorities of Europe, USA and Japan. Part of their ongoing work has been to investigate animal testing methods for pharmaceuticals. Their experience shows that the numbers of animals used for testing can be reduced to about half the numbers previously used if authorities in different countries can reach agreement on testing methods and accept each others results.

3. Are the proposed procedures for testing chemicals justified and proportionate?

There is cause for concern about the number of untested chemicals to which humans and the environment are exposed. The strategy of devolving responsibility for testing down to the manufacturers is sensible because this links production with the responsibility. The proposals appear to offer some flexibility by taking account of existing information and by tailoring the testing of individual chemicals according to their use, volume and probable level of human and environmental exposure. For example, some chemicals produced in small quantities are of higher risk than some bulk commodity chemicals. The indirect economic costs may be high, but the early identification of potential problems should stop even higher costs in the longer term.

4. Are the overall timescale and deadlines for registration of chemicals realistic?

Because of the large numbers of 'existing' chemicals and the implied cost of registration, the process will take longer than anticipated. The extent to which there is delay will, of course, depend on the resources available.

5. What are the implications for animal testing?

As stated above it is desirable to reduce the amount of animal testing and the proposal to avoid the duplication of testing would help to achieve this. Nevertheless, implementation of the proposals is likely to lead to a sustained increase in animal testing for the foreseeable future.

To reduce the amount of animal testing, more emphasis needs to be placed on the development of alternatives. For example, carcinogen testing in mammals previously required considerable numbers of mice and rats. Now, following ICH, the mice may be replaced by an alternative involving transgenic models. Given that alternatives are usually cheaper than testing in animals, it is cost-effective to start a programme of research into alternatives as part of the over-all strategy, using the European Centre for the Validation of Alternative Methods (ECVAM) as a coordinator. There is a problem with the development of alternatives, at least in the UK, in that it is not usually 'cutting-edge' research, so is unlikely to attract Research Council funding. This makes it unattractive for academic researchers. If this opportunity to reduce animal testing is to be taken, then the EU needs to offer some substantial additional funding for research into alternatives as part of the over-all strategy.

There are, however, examples where only *in vivo* experiments (or exposure) have demonstrated unpredicted adverse effects of chemicals. For example, tributyl tin (TBT) has been seen to cause a type of inter-sexuality (imposex) in molluscs, leading to major population declines and extinctions. This is the only well-documented example to date of an identified endocrine disrupting chemical (EDC) causing abundant, undisputed and world-wide population-level effects in wildlife. In cases like these only *in vivo* testing will give us the information required.

6. Should a requirement to conduct life-cycle risk assessment of the use of chemicals form part of the strategy, or should it be addressed separately?

Conducting life-cycle risk management is a long and involved process. Consequently, the additional time and expense required to undertake such studies need to be included in the strategy. At present there is little information about the risk to humans and wildlife from most chemicals, as pointed out in the White Paper. Without better data sets it is not possible to undertake reliable risk assessments.

7. How effectively will the proposed authorisation procedures meet the objectives of the strategy?

Essentially, the aim is to bring the 30,000 old, untested, substances into line with new substances introduced since 1981. The rules for new substances appear to be working reasonably satisfactorily, so the proposals have a good chance of success. However, some adverse effects will be missed, and will only become apparent once the chemical is in use. For example, it is highly unlikely whether any plausible strategy, current or new, would detect the effects of TBT on molluscs.

8. What balance of effort and responsibilities should be struck between the Commission and Member States under the proposed Registration, Evaluation, and Authorisation (REACH) regime?

The EU is ideally placed to administer this kind of international programme, with member states providing expertise for the regulatory committees. Industry in each country should be responsible for the testing of new chemicals for human, animal and environmental risks.

9. Where will the costs of implementation principally fall? Has there been a realistic assessment of the likely costs to industry and regulatory authorities in the Member States?

The strategy will be expensive to implement with the costs falling mainly on industry and the regulatory bodies within the member countries. There is already concern within industry about the effects of the White Paper in terms of the requirements for dossiers on 'existing' chemicals. The lengthy evaluation procedure will be another cost to be borne and may impact indirectly on productivity by delaying commercialisation. The proposed exemption for substances used in research and development (Action 3D of the White Paper) is to be welcomed as this will give scope for innovation.

One cost that does not seem to have been addressed is that associated with legal liability. No chemical is safe at all dose levels. Industry will be required to state publicly the hazard posed by each chemical that is sold. The hazard might be high, but the risk may be low because the chemical is well contained. This information on hazard will be readily available to the public, who may not understand the difference between *hazard* and *risk*. There is a danger that industry will be exposed to substantial legal action costs if, for example, an employee gets cancer having worked in a factory producing a known carcinogen, even though the chemical itself was well contained.

10. Have the responsibilities of downstream users been adequately addressed?

Manufacturers must supply full details of any testing undertaken when selling a chemical, allowing downstream users to take on responsibility for the chemical after the sale. This will help to extend the responsibility along the manufacturing chain, as proposed in the White Paper.

11. Do the proposals meet the needs for transparency and public access to information?

Giving the public access to information about chemicals to which they are exposed should improve the public perception of the chemical industry. However, this would require very carefully definition of terms such as 'harmful' in order for the public to make informed decisions about products containing chemicals deemed to be harmful.

The proposals may lead to a conflict of interest between intellectual property and the need for transparency and public access to information. Some of these problems could be alleviated to a great extent by the proposed exemption of research and development (as outlined in Action 5E of the White Paper: property rights for test data).

12. How far should the strategy be concerned with providing safeguards in relation to chemicals (especially imported chemicals) as constituents of finished products, or are these requirements dealt with adequately in other community legislation?

It is essential that data obtained outside of the EU be accepted and special attention must be given to products from developing countries (see page 10, paragraph 3 of the White Paper). This seems to be adequately covered (e.g. 5.3, Action 5C of the White Paper: obligation of downstream users to inform authorities) regarding any downstream use that has not been envisaged by a manufacturer or importer.

13. What are the implications for enforcement?

The policy will be self-enforcing, providing companies want to be seen by the general public and their shareholders as both transparent and safety conscious. Countries with smaller capabilities and capacities for managing chemicals would benefit from the improved administrative capacity and infrastructure of these proposals. These countries are also predominantly net chemical importers so the regulation of the imported chemicals will provide the necessary regulation. Downstream users will need to be regulated in a similar manner to manufacturers.

14. What criteria, methodology and administrative systems are appropriate for identifying chemicals, particularly existing chemicals, of concern and for setting priorities for action?

Criteria

It is uncertain in the White Paper whether 'chemicals' will include ill-defined mixtures of chemicals like oil, tar and asphalt that are almost certainly hazardous to health, and difficult to replace. There are also issues of the form in which a substance will be tested or classified. For example, nicotine is clearly dangerous, but is less dangerous as a patch than as a cigarette.

Criteria for identifying chemicals of concern should include consideration of the effects of related chemicals on animals and the environment because many classes of compound have similar toxicity. For example, many years ago it was learnt that heavily chlorinated chemicals were hazardous. Yet, despite knowing that these chemicals are very persistent and bioaccumulate, a series of new brominated chemicals were introduced (primarily as flame retardants) and there is now a realisation that these brominated chemicals are also persistent. Adverse effects caused by these chemicals are likely to be documented. Why was this course of events not seen as inevitable, given our knowledge of a closely related group of chemicals (the chlorinated organics), and the brominated chemicals therefore avoided? The use of established chemical safety databases may prevent similar mistakes in the future. This raises the important question of the accountability and ownership of databases generally.

There is often an incompatibility between the required characteristics of a chemical and its 'friendliness' to people and the environment. For example, almost by definition flame retardants, which save lives, have to be very 'tough' chemicals, as they need to resist fire. Such 'toughness' will probably mean that they are very difficult to degrade in the environment or metabolise in organisms.

The biodegradability of chemicals needs to be addressed. Non-biodegradable chemicals or substances that degrade into toxic substances must now be studied as a matter of urgency. Chemicals that are in direct contact with animals, humans or could enter the food chain should be accorded the highest priority for investigation. This investigation needs to include chemicals, though manufactured for non-human

consumption, may be disposed of in a manner such that they may contaminate the land and so enter the food chain.

Methodology

As previously mentioned in relation to the question regarding animal testing, experimental methodologies have to be *in vivo* animal tests coupled where appropriate with *in vitro* assessments. Endocrine disruptors indicate how reliance on *in vitro* screening alone can lead to problems going undetected as with the effects of TBT on molluscs.

As a general rule, data on chemical toxicity or environmental damage should be subject to vigorous peer review and published in the open literature. Studies leading to such data should refer to likely exposure situations. Highly hazardous agents can be used safely by regulation and monitoring in order to reduce the risk. For example, ectoparasiticides have few restrictions when used in human health under strict guidelines but are covered by extreme restrictions when used as pesticides.

Administration

We agree with the proposal in the White Paper that expert committees must be responsible for the administrative systems.

15. What lessons can be learnt from overseas experience?

There are lessons to be learnt from the situation in the US, where litigation is extensive. Europe is likely to follow in this direction. Industry could be induced to adopt the new testing regime in order to avoid potentially costly legal action. Rigorous testing of a chemical is likely to reduce legal costs in the long term and will provide a sustainable defence against expensive litigation.