

THE EU CHEMICALS DIRECTIVE AND ITS IMPLICATIONS FOR EXPERIMENTS ON ANIMALS

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Relatively uncontrolled utilisation of the use of a very wide range of chemicals in commercial products over the last 100 years, some of them potentially hazardous, has transformed the environment. The EU response contained in the REACH proposals would require a very large expansion in routine testing using animals.

Tom Blundell discusses the role of the Royal Commission in developing a more humane and pragmatic approach based on state of the art methods currently used in commercially-based environmental research and John Selborne describes how such a policy is being developed in the UK and is achieving consensus on risk assessment and management among stakeholders, ranging from the chemicals industry to NGOs, with a minimum of formal regulation.

Chemicals in Products - safeguarding the environment and human health

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Last year the Royal Commission on Environmental Pollution published its Report on Chemicals in Products – safeguarding the environment and human health. In this presentation I will explain how the Royal Commission's recommendations relate to the EU REACH proposals (Registration, Evaluation, Authorisation and Registrations of Chemicals), and what the implications of our proposals and those of REACH are for animal testing.

I would like firstly to take the opportunity to say a few words about the Royal Commission on Environmental Pollution, which I chair. The Commission is an independent environmental advisory body charged with advising the UK Government on matters both national and international, concerning the pollution of the environment, on the adequacy of research in this field; and the future possibilities of danger to the environment. The Commission was established by Royal Warrant in 1970 and comprises 12 part-time

Commission members, supported by a full-time secretariat. To date, the Royal Commission has produced 24 major Reports and we will be launching our 25th Report Environmental Effects of Marine Fisheries in October. Urban Environments is our next major study and this is in progress.

Turning to our Report on Chemicals in Products – the Royal Commission first became involved with chemicals when it recommended in its 2nd report in 1972 that new chemical products should be tested, and that a database should be set up of chemicals and their characteristics. Mandatory provision of information about chemicals with biologically active ingredients – notably pesticides – had by then been established, and the Royal Commission's proposals were to extend this sort of testing regime to new chemicals. The Royal Commission's recent return to the subject after 30 years was long overdue. Our Twenty-Fourth Report on Chemicals in Products, published last June, was a comprehensive review of the science,

legislation and public policy relating to the manufacture and use of chemicals.

The current European legislative system for chemicals has been largely unable to identify the risks posed by many chemicals and is slow to act where risks have been established. The legislation distinguishes between so-called “existing” and “new” chemicals using 1981 as a cut-off date; “new” chemicals are those that have been introduced since. New chemicals have to be notified and tested in production volumes from 10 Kg, whilst there is no such provision for existing chemicals. This has encouraged the continued use of “existing chemicals”. It has been up to the Member States to determine whether any of the “existing chemicals” need to be examined, and if so, to do it. The procedures have been lengthy and cumbersome. For example, since 1993, 140 high-volume chemicals have been singled out for risk assessment. Only a very limited number has completed the process so far. In October last year the European Commission presented proposals for a new EU regulatory

framework for chemicals, REACH. Under these proposals manufacturers and importers who handle more than 1 tonne of a chemical substance a year would be required to register it in a central database

The problems that have to be addressed are the huge backlog of untested chemicals, and the cumbersome testing methodologies that have led to what the Commission has termed “paralysis by analysis”. The Commission is very concerned about the huge numbers of animals that are required under current legislation for the testing process, and does not believe that enough has been made of the testing methods used in other areas of chemicals screening or the enormous amount of information that is available from environmental monitoring.

No matter how sophisticated the testing and assessment regime, considerable uncertainty will remain in any environmental assessment of chemicals. This arises because of:

- uncertainty in the test methods;
- the complexity of environmental processes; and
- incomplete understanding of the way in which chemicals interact with living organisms.

And it means that almost no matter how much testing or monitoring is carried out, we still will not be completely confident that any particular chemical is not causing a problem that we have not yet recognised. To address these deficiencies, the Commission has recommended a four stage process. It must be smarter and faster than existing methods, and must exploit modern technology. The four stages are listing, sorting, evaluation and approval.

The Royal Commission, whilst acknowledging that the REACH proposals were steps in the right direction, expressed a number of concerns. We thought that the procedures emerging for assessing chemicals were over complex, and would provide the more recalcitrant elements of the chemicals industry with an excuse to procrastinate, which is more or less what had happened in the case of the existing substances regulation ten years earlier.

The Royal Commission's proposals differ from those in REACH in many respects:

REACH would require detailed information and data sharing for registration and further data following evaluation. Our scheme would save time and reduce costs by making more of existing data and computational techniques and genomics towards an enhanced understanding of fate and effects of chemicals in organisms and on the environment. These techniques reduce the burden of animal testing, with the RCEP calling for all practicable steps to be taken to avoid the use of higher animals as test organisms during substance evaluation.

REACH would merge the operation of the new and existing substances schemes. RCEP want the two schemes to be separate. For existing chemicals those of concern would be identified using existing data and computational techniques; others would be available for use but monitoring would be increased. New chemicals under the RCEP scheme would come into the scheme as chemicals of concern. All chemicals of concern would be rigorously tested.

The RCEP scheme does not evaluate exposure in terms of tonnage production as does REACH. A chemical that has been selected by the sorting process should be subject to further investigation regardless of the volume of the market. But the uses to which the chemical is put, and therefore its sources and pathways into the environment, must be integral to the investigation.

The REACH proposals do not allow a fast track for risk management whereas the RCEP proposals seek to remove from the market immediately synthetic chemicals found in elevated concentrations in biological fluids and tissues of humans, marine mammals or top predators. We propose that no substances are ever considered completely safe – the situation is always kept under review.

Our approach makes much greater use of environmental monitoring, notably in triggering the re-assessment of substances previously considered as being of no concern. The Commission's approach links information and assessment to instruments that drive substitution. Substitution can involve a number of approaches. For example hazardous chemicals can be replaced

with less hazardous alternatives. Another approach could be to modify processes so that hazardous chemicals are no longer required. A third possibility could be to change working practices. To drive substitution the Royal Commission has recommended the introduction of a banded charge for the use of hazardous chemicals.

REACH will not start to come into effect this decade. We propose steps that will make an impact within just a few years.

What are the implications of our proposals and those of REACH for animal testing?

The UK's Institute for Environment and Health has estimated the number of animals likely to be required as a result of the REACH process. The lowest likely estimate for animal usage for completing testing under REACH for the approximately 30,000 chemicals produced at up to 100 tpa [tonnes per annum] is about 2.5 million animals.

Inclusion of the testing to be undertaken at Level 1 and 2 (approximately 4.27 million animals) brings the overall total to at least 6.7 million vertebrate animals (excluding offspring from reproductive studies and any additional studies that may be warranted, eg toxicokinetics, mechanistic investigations, endocrine disruption, avian toxicity studies).

The Royal Commission's proposals would result in far fewer animals being used. Only chemicals of concern would be tested on animals, and even then, only after all other avenues had been explored, including considering the question of whether the value of the chemical to society justifies animal testing. We think that it could be less than 1% of the number estimated for REACH.

In summary I believe that the recommendations in our Report Chemicals in Products – safeguarding the environment and human health, present a far smarter and faster mechanism than the REACH proposals for dealing with the massive backlog of chemicals that are currently on the market and for which there are little or no data with which to assess their risk. And the Royal Commission's proposals would result in far fewer animals being used by avoiding unnecessary in-vivo testing.

UK Chemicals Stakeholder Forum

The Earl of Selborne KBE FRS

Manufactured chemicals play a key role in the provision of goods and services on which modern society depends and the chemical industry is Europe's third largest, employing 1.7 million people directly and with up to 3 million jobs dependent on it. However some chemicals have the potential for causing serious damage to the environment and human health.

The UK Government proclaimed in its 1999 Chemical Strategy that it was "very concerned that we do not have even a basic assessment of the possible risks of most chemicals released into the environment in large quantities". The European Commission White Paper of February 2001 stated that "the lack of knowledge about the impact of many chemicals on human health and the environment is a cause for concern".

While the UK Government recognised at the time that a new EU Chemicals Regime was the preferred option, it considered that a national initiative was needed in the interim to address these concerns about industrially produced and used chemicals harming the environment and (through environmental exposure) human health.

The United Kingdom strategy had three goals:

- 1) To make full information publicly available about the environmental risks of chemicals.
- 2) To promote the reduction of risks presented by chemicals to the environment and human health while maintaining the

competitiveness of industry.

- 3) To phase out early those chemicals identified as representing an unacceptable risk to the environment and human health.

The Strategy document announced the establishment of a new UK Chemicals Stakeholder Forum to promote a better understanding between Stakeholders of the concerns which people have about chemicals and the environment. The Strategy envisaged that the Forum would, by providing advice to the UK Government and the devolved administrations, ensure that these concerns were fully reflected in the development of UK policy on chemicals and the environment. The Advisory Committee on Hazardous Substances (ACHS) was reconstituted as a expert body to advise the Forum on the technical and scientific data.

The UK Government's impatience in 1999 with the progress of the EU chemicals policy was justified. Since 1981 the EU regime had required the notification and evaluation of new (post 1981) chemicals. This had worked well and there was a useful body of data on approximately 3,000 chemicals marketed since 1981. However the EU Existing Substances Regulation of 1994 for the evaluation of chemicals introduced before 1981 had proved far less satisfactory. Approximately 30,000 such chemicals were marketed in quantities of more than 1 tonne, but little had been achieved in identifying those most likely to present a potential environmental risk, and even less in managing such risks.

By 2002 140 chemicals had been identified as requiring immediate attention. Only a handful of risk assessment and risk reduction strategies had been published by the Commission, and only two proposals had been made for banning the use of particular chemicals. This very slow progress suggested that there was a fundamental flaw in the regulation.

The Chemicals Stakeholder Forum was established in 2000 with its membership drawn from organisations representing chemical producers, industries that use chemicals, scientists, trade unions and those concerned about the use of animals in the testing of chemicals. All meetings are open to the public and all papers and minutes are published on the Internet.

The Forum was required by its second meeting to give the minister, Michael Meacher, an agreed criteria for drawing up a list of chemicals of concern. With the assistance of the Advisory Committee on Hazardous Substances the Forum defined criteria for identifying chemicals that have intrinsic properties which give cause for concern about their potential to damage the environment or human health through the environment. These criteria are based on persistence, bioaccumulation and toxicity, as well as persistence and bioaccumulation without known toxicity. These criteria were modelled closely on the EU guidelines of the time. Once these criteria had been agreed the Forum then looked at a number of specific chemicals which appeared to meet these criteria of concern and it engaged in a dialogue with the manufacturers



and distributors on what risk management might be appropriate. The Forum's consideration of medium chain-length chlorinated paraffins (MCCPs) is an example of this dialogue. The main use of these substances is in the manufacture of polyvinyl chloride (PVC). They also have significant uses in other plastic and rubber products as flame retardants, in sealants, paints, metal cutting and working fluids and carbonless copy paper. We were advised that MCCPs were likely to be found in human breast milk and cows' milk. Although MCCPs were being considered under the Existing Substances Regulation we took the view that there was already sufficient evidence to justify immediate action. In response to the Forum's concerns the UK manufacturer of MCCPs and a group of industrial users formed the MCCP User Forum to develop a targeted risk reduction plan in which they committed to a 25% reduction in emissions. The first report of the User Forum was presented in December 2003 to the Chemicals Stakeholder Forum and further plans for risk reduction will be expected.

Our list of chemicals of concern was published on our web site and this acted as a spur to manufacturers and distributors to look at their record of transparency and responsiveness to public concerns. I have always believed that there is much data on persistence, bioaccumulation and toxicity held by industry which is described as commercially sensitive. As this data relates to potential impacts on the environment, it should be put in the public arena. Any organisation or proposed regime which encourages the sharing of data and a pragmatic

approach to risk assessment and management is greatly to be encouraged. If a chemical is not volatile, there is no need to assess for inhalation. This means one less animal test is required.

As the REACH proposals have emerged we have looked at the implications and logistics of testing an estimated 30,000 chemicals currently in use in the EU and not covered by a positive approval regime. We have concluded that we have grave concerns about the potential numbers of animal tests that would be required by REACH and we wrote to the Government to urge that a different approach be adopted. Testing should only be required where it is needed to provide essential evidence, and not to fill gaps in the data. Animals should only be used when opportunities for data sharing have been exhausted, when there is no acceptable non-animal alternative test available and when all opportunities for minimisation and refinement of testing methods have been exhausted. The House of Lords Select Committee on the European Union, in its report on the European Commission's White Paper Strategy for a future Chemicals Policy, stated:

"The White paper provides a rare opportunity to generate the political will in the EU to promote non-animal testing. The United Kingdom Government must take a lead in this and should make it clear in the Council that it cannot accept a new chemical strategy that leads to significantly increased animal testing. This would be unacceptable to the public and could well cause the strategy to fail. The EU chemicals strategy must therefore be linked to an EU strategy

for minimising animal testing."

This recommendation was strongly supported by the Forum.

If REACH could embrace the concept of one substance, one registration package, then the speed of evaluation would be greatly enhanced but commercial interests mitigate against this. Where larger companies have their own testing facilities they are reluctant to share ownership of the tests with competitors. A scheme which made mandatory the sharing of core data, but excluding product information, would be highly desirable. I cannot see any justification for data on hazardous properties being withheld on grounds of commercial confidentiality.

REACH needs also to encourage countries outside the EU to share data relevant to high tonnage chemicals. Much of this required information already exists elsewhere. If this could be accessed by the new European agency it could then concentrate its activities on the specialist chemicals, which are likely to prove harder to assess. OECD has worked in the chemicals field since 1971 and much EU chemicals legislation has drawn on OECD work. The OECD has produced guidelines for mutual acceptance of data for new and existing chemicals and there is already an OECD initiative to avoid duplication of testing for High Production Volume (HPV) chemicals. There is an urgent need to agree on a common approach within OECD for non-HPV chemicals as well. Unless this is achieved REACH will prove not just impractical to implement but also a serious obstacle to Europe's competitive position in the global chemicals market.

In discussion the following points were made:

Will REACH impact more on the UK Chemicals Industry than on imports and will similar standards apply to both? These proposals risk pricing the EU Chemicals Industry out of business as US industry is in a post-REACH phase. The EU should adopt OECD standards where economic criteria form part of the evaluation. Methods require standardisation and basing on those used in drug development, rather than on REACH which requires more animal testing and ignores relative risk arising from 30,000 chemicals. The UK should put onus on manufacturers and distributors to place information in the public domain on chemicals and products containing chemicals, based on Proportionality. Since 1986 there has been a legal requirement for animal testing, which will be necessary to meet Defra requirements for REACH, but the activities of anti-vivisection groups make it impossible to hold stakeholders' meetings in the UK. Many environmental testing standards for REACH are not fit for purpose. There is scope for development of relevant testing, involving computer-based methods, to provide rapid screening and risk assessment of 30,000 chemicals. The need for REACH has arisen due to lack of response to prior invitations to disclose risk associated with historical chemicals and products, without blame implied or attached. A new Agency will be required in Europe for chemicals in the environment.