

## ENVIRONMENT, HEALTH AND SAFETY COMMITTEE [EHSC] NOTE ON :

### THE EU COMMISSION STRATEGY FOR A FUTURE CHEMICALS POLICY KNOWN AS 'REACH'

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#### SUMMARY

The European Commission has adopted a proposal for a new regulatory framework for the control of chemicals. It is arguably the most significant development on controlling chemicals in the European marketplace for many decades. Under the proposed new system called REACH (Registration, Evaluation and Authorisation of Chemicals), enterprises that manufacture or import more than one tonne of a chemical substance per year would be required to register it in a central database. The stated aims of the proposed new Regulation are to improve the protection of human health and the environment while maintaining the competitiveness and innovative capability of the EU chemicals industry. One of the key aims of REACH is to provide a faster, more efficient approach to dealing with chemicals of high concern that will need to be authorised for specific uses.

REACH will have significant implications for the European and global chemical industry. It gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on the substances and removes the distinction between 'existing' and 'new' chemicals. 'Existing' refers to chemicals listed in the 1981 EINECS inventory, in other words chemicals that have been on the European market since before current legislation was put in place. Some 'existing' chemicals have limited safety data compared to 'new' chemicals which have to undergo notification. It will be very costly to generate all the new safety and environmental release data requested. This may result in the loss of substances that generate insufficient profit to cover the costs of registration. Set against this, REACH will be a simpler and more transparent regulatory system. The proposal

has been forwarded to the European Parliament and the EU's Council of Ministers for adoption under the co-decision procedure<sup>1</sup>

## **'CONTROLLING' CHEMICALS**

Legislation to control chemicals has been in force for many years in Europe. However critics believe it hasn't worked well enough. There have been several high profile cases over the years where chemicals have been associated with or perceived as causing environmental damage or damage to human health. Examples include the effects of DDT on wildlife, exposure to asbestos fibres which can cause malignant lung tumours and leukaemia associated with exposure to benzene. An issue of current concern is the association of increases in some reproductive impacts such as testicular cancer in young men and feminisation of some wildlife species, which are perceived as being associated with exposure to certain chemicals.

Such cases are seldom simple. Chemicals have benefits as well as risks and it can be difficult to balance the two. For example banning DDT may have helped the environment but may also have led to more deaths from malaria and other invertebrate-borne tropical diseases. Nonetheless the fact remains that chemicals have caused widespread public concern and the resulting public pressure is partly responsible for the REACH proposals which are intended to control chemicals more effectively.

There are various ways in which a chemical can be 'controlled'. For example its use can be restricted, as with the proposed ban on the use of short chain chlorinated paraffins in metal working fluids and leather tanning. A chemical can also be controlled by placing limits on the amount that may be emitted when it is used by setting a limit on discharges to the air or to the wastewater system ('inputs' into the environment), or a limit on the amounts that are present in individual foods (e.g. 'maximum residue limit or level', an 'input' into the food basket). Alternatively it can be controlled by setting limits ('intake' limits) for the maximum amount in a medium (workplace air, indoor or outdoor air, drinking water, the food basket), based on simple assumptions concerning how much will be breathed, eaten, etc. One of the key aims of the REACH proposal is to ensure that adequate hazard data exists for all chemicals. This is necessary so that appropriate risk assessments can be conducted, both for human exposure and for environmental releases. In this context 'hazard' is an intrinsic property of the chemical such as toxicity, flammability and/or corrosivity, or of the interaction between the chemical and the biological system (a toxicant). 'Risk' is the likelihood of a particular hazard being realised under particular circumstances. Once the hazards of a chemical to humans and the environment have been assessed, exposure to that chemical can be examined and, if necessary, controlled in a way that is commensurate with the risks.

## **CURRENT LEGISLATION**

At present the safety and sale of chemicals on the European market is primarily controlled by the Dangerous Substances Directive (67/548/EEC), the Existing Substances Regulation (793/93), the Marketing and Use Directive (76/69/EEC).

In September 1981 a European 'inventory' of chemicals was produced. This was a list of 100106 'existing' chemicals on the European market at that time. It became known as EINECS (European

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<sup>1</sup> The European Commission is the only EU institution that can propose legislation. Draft proposals are adopted as formal proposals by the college of twenty Commissioners. The Parliament working with the Council of Ministers can adopt the legislation proposed by the Commission. The Council of Ministers is made-up of ministers from each of the Member State governments. The Council can only take a decision after it has sought the opinion of the Parliament, but it is not obliged to take this opinion into account. A co-decision procedure gives Parliament and the Council equal legislative powers and is applied to most environmental policy issues. In this procedure, after a first reading of a Commission proposal (and amendments) in the Parliament, the Council adopts its 'Common Position' (containing the Council's changes to the proposal). Parliament then holds a second reading. If it does not agree with the Council's Common Position, representatives from the Council and EU Parliament must negotiate a compromise text. Some of the practical issues are only decided after adoption. The Commission decides on these with the help of committees which are provided for in the Directive or Regulation.

Inventory of Existing Commercial Chemical Substances). Current legislation distinguishes between so-called 'existing' and 'new' chemicals; 'new' chemicals i.e. those that have been introduced after 1981.

Before any substance not listed in EINECS can be placed<sup>2</sup> on the market in the EU in quantities greater than 1 tonne it has to undergo a full notification process involving the production of physico-chemical, toxicological, environmental and eco-toxicological data (known as the Base Set), together with human and environmental risk assessments. For supply at above 10 kg per annum (but below 1 tonne), reduced notification is required, with less safety data.

The data produced is submitted to one of the national European authorities, known as Competent Authorities (e.g. the Health and Safety Executive in the UK), who assess the information and agree the appropriate hazard classification (the Risk and Safety phrases). Following this process, the substance can then be placed on the market. Further data is required as the amounts placed on the market or concern over possible effects increases.

On the other hand all chemicals that are in EINECS can be freely supplied in Europe without official notification. As a result it is claimed there are a large number of substances sold in significant volumes for which little or no safety data is available, either because it does not exist or because it is held by the manufacturer as commercially confidential information. In an attempt to address this concern the Existing Substances Regulation [ESR] was introduced in 1993. On the basis of safety information on high-production chemicals received from chemical suppliers under this Regulation, four sequential priority lists were published showing chemicals of high concern - either because they are produced in large amounts or because of their known hazardous properties.

Individual Member States then volunteered to prepare comprehensive risk assessments for the life cycle and use patterns of these priority chemicals. In the UK the Competent Authority charged with overseeing the chosen risk assessments is the Health and Safety Executive, supported by other agencies such as the Environment Agency and the Department of Health. The results of the risk assessments determine whether a substance can continue to be supplied without restriction, or whether additional controls are needed. If necessary, further control can be implemented by way of other appropriate EU legislation, such as the Marketing and Use Directive.

Despite the ESR being in force for a significant number of years, relatively slow progress has been made in evaluating all the chemicals on the priority lists, and only a small number have completed the full risk assessment process. This is in part due to the process of gathering and evaluating hazard data and assessing risk being very resource intensive and often taking considerable time to generate and refine because of the frequent need to conduct analytical studies to validate exposure models. In particular, the risk assessment requires detailed knowledge of both the intrinsic hazards of a substance, and the exposure and release scenarios during its use. This can also lead to the requirement for further hazard data as part of the iterative assessment process.

In summary, current legislation seems to be good at controlling 'new' substances that are being sold on the European market for the first time because it requires their hazards to be investigated before they can be sold. However the legislation is less good at dealing with the 'existing' substances.

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<sup>2</sup> European legislation uses the phrase 'placing on the market' which essentially means making a chemical available to a third party within the EU. This includes providing it to other companies or to consumers. 'Placing on the market' can arise from either manufacturing a chemical in the EU, or by importing it from a country that is not a member of the EU.

## REACH

In February 2001 the European Commission published a White Paper 'Strategy for a Future Chemicals Policy' [COM (2001) 88] outlining its strategy for ensuring a high level of chemical safety and a competitive chemicals industry through a system for the Registration, Evaluation and Authorisation of Chemicals, the REACH system. It sought to address concerns about the current approach to controlling chemicals and proposed alternative arrangements for evaluating chemicals so that their use could be controlled more effectively and before there was an opportunity for harm to be caused.

The Commission's proposal finally published in October 2003 after an intensive internet consultation process is for a Regulation based on Article 95 of the EC Treaty, in keeping with the objective of safeguarding the internal market, while ensuring a high level of health, safety, consumer and environmental protection. The precautionary principle (Article 174.2 of the Treaty in combination with Article 6 and Article 95.3) will continue to guide the approach in the implementation of necessary measures.

The proposed new legislation, which has yet to be finalised, will result in a Regulation once agreement has been reached. Regulations are directly applicable and binding in all Member States. Directives, on the other hand, set out the results to be achieved, and the timeframe, but leave to Member States to enact national legislation. EU Member States will then have to incorporate the requirements into their own legislation. The text of the proposal can be found at: <http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm>

## THE 'REACH' SYSTEM

At the core of the proposed system is REACH, a single, integrated system for Registration, Evaluation and Authorisation [and Restriction] of Chemicals. REACH would put an end to the artificial distinction between 'new' and 'existing' chemicals. REACH would require companies that produce and import chemicals to assess the risks arising from their use and to recommend the necessary information to their customers to enable them to take measures to manage any risk they identify. This would require industry (manufacturers, importers, and, for the first time, downstream users) to provide the safety and exposure data and risk assessments (the missing R – regulation/restriction, is still a role of Government, at EU level). Under the present legislation public authorities are required to identify and address possible safety issues for the chemicals already on the market on the basis of 'available' information, and, until recently, with little or no ability to cause industry to provide missing information.

**Registration** is the main element of REACH. Chemicals manufactured or imported in quantities of more than 1 tonne per year and per manufacturer/importer would need to be registered in a central database. Some groups of substances would not have to be registered (such as certain intermediates, polymers, some chemicals, such as pesticides, biocides, veterinary medicines and human pharmaceuticals that are already managed under other EU legislation and a very short list of commonly available natural chemicals generally regarded as safe). The registration process would include providing information on intrinsic properties and hazards of each substance, uses (and hence likely exposure levels) and safe ways of handling the chemicals. The information required would be proportional to production volumes and the risks that a substance poses. The safety information will be passed down the supply chain, so that those that use chemicals in their own production processes - to produce other products - could do so in a safe and responsible way, without jeopardising the health of workers and consumers and risking damage to the environment.

To cope with the large number of 'existing' substances a phased approach is proposed. The deadlines for registration are set according to the volume of the substance on the market or the hazard. The shortest deadlines apply to very high volume substances (above 1000 tonnes), 'PBT' chemicals (persistent, bioaccumulative and toxic -i.e. substances that are carcinogenic, mutagenic

or toxic to reproduction and, under some circumstances, substances causing chronic toxicity) and vPvB (very persistent, very bioaccumulative) substances above 1 tonne. These will have to be registered within three years. Those substances that have production volumes in the range of 100 – 1 000 tonnes will be required to register within six years and the remaining low production volume chemicals (1 - 100 tonnes) within eleven years. It is expected that around 80% of all registered substances would require no further action.

**Evaluation** encompasses two processes; evaluation of dossiers and evaluation of substances. The evaluation of dossiers is to ensure completeness. Some limited testing in animals is required for the basic registration dossier, but tests involving large numbers of animals are only undertaken following discussion with the regulators as to whether they are needed. Further, where possible, data sharing is required. This is in order to comply with the stated aim of reducing animal testing to a minimum.

Substance evaluation by competent authorities would take place either on grounds of high tonnage or where there were justified reasons to suspect that a substance poses a risk to human health or the environment. For both types of evaluation, the outcome could be a request for further information. The European Chemicals Agency would take the final decision on requests for further information if all Member States agreed. In case of disagreement, the European Commission would make a decision.

**Authorisation** of substances of very high concern for specific uses will be required. The Commission will be responsible for authorisation. Substances of very high concern include:

- CMRs - carcinogenic, mutagenic (causes damage to genes) or toxic to reproduction (causes either a decrease in fertility or problems with development of the foetus), category 1 (where the effect on man is known) and Category 2 (where the effect on man is likely).
- PBTs: Substances of very high concern that are persistent (difficult to break down in the environment), bio-accumulative (accumulate in aquatic species) and toxic (to humans and aquatic species; except when that toxicity is short term, following acute administration).
- vPvBs: Substances of very high concern that are very persistent (very difficult to breakdown in the environment), very bio-accumulative (very liable to accumulate in aquatic species).
- Substances identified as having serious and irreversible effects to humans and the environment equivalent to the other three categories. For the time being, this includes for example certain endocrine disrupting substances (substances disturbing the body's hormone system). These will be identified on a case by case basis and be subject to authorisation.

If the risks emanating from the use of such a substance are minimal (because of lack of exposure) or can be adequately controlled, authorisation would be granted. Many hazardous chemicals can be used safely if the right risk management measures are respected, such as the use of good ventilation or protective clothing. If they cannot be adequately controlled, the European Chemical Agency would look at the level of risk, whether the use of the substance was socially and economically important and if there were substitutes. Based on these factors the European Chemical Agency will decide whether the substance would be authorised. Under REACH, some substances of very high concern may be subject to a Restriction. Restrictions are the safety net of the system. The European Commission will be able to introduce restrictions at EU level for any substance that poses unacceptable risks, taking due account of socio-economic factors. Restrictions include banning uses in certain products, banning uses by consumers or even complete bans.

Under REACH only those chemical substances produced or imported in volumes of 1 tonne or more per year, per manufacturer/importer, have to be registered. This in effect means that around 30 000 marketed substances will need to be registered. Of these 30 000 around 20 000 are produced or imported in volumes of between 1 and 10 tonnes. These substances are unlikely ever to be evaluated unless they are identified as posing risks to human health or the environment. It will be six

years (from implementation) before dossiers for existing substances between 100 and 1000 tonnes have to be submitted (unless they are PBT or vPvB) and three years before dossiers for substances over 1000 tonnes and substances that are PBT or vPvB have to be submitted. Clearly, evaluation follows on from submission of the data. The number of substances that will need to be evaluated will depend on the concerns of the Member States' competent authorities. Up to 1500 substances of very high concern will be subject to authorisation.

In addition approximately 40 000 intermediates will also need to be registered although for most of them the registration requirements will be significantly lighter than for other substances.

One of the major areas of change proposed in the REACH process is the use of industry-led risk assessments. A key reason underlying the proposal to shift the responsibility for conducting risk assessments to industry is the assumption that the suppliers and downstream users of a chemical should have the greatest knowledge about how it is used and should therefore be more involved in the risk evaluation. However one of the potential difficulties is that for reasons of commercial confidentiality customers often won't tell their suppliers what they use their products for. Thus the supplier of paint may guess that his customer is going to paint with it but there's no such clue for a supplier of a common solvent for example.

Under the proposals, the producers and downstream users of chemicals would have a significant role in the whole process, from generating hazard and exposure data to conducting the risk assessments. Thus there would be a closer partnership between producers and users. However many aspects of this development still have to be resolved.

## **RSC POSITION**

Current EU Chemicals Policy is fragmented and cumbersome. In principle The Royal Society of Chemistry would welcome a single harmonised regime for assessing and controlling the effects of chemicals on health and the environment. REACH will replace about 40 Directives and regulations on chemicals and leave more than 20 others in place. It is also important that REACH should be compatible with existing and proposed international initiatives on the control of chemicals.

The Society believes that it is vitally important that REACH should be based on risk. Substances should generally not be banned on the basis of intrinsic hazard alone. Intrinsic hazard is not a good measure of the actual threat that a substance poses to humans or the environment. Risk (which requires both hazard and exposure) is a better measure because it is based on the likelihood that an intrinsic hazard associated with a substance will cause actual harm. Using tonnage to trigger the REACH process is also not ideal. By focusing on the volume of chemical produced or imported, the danger exists that effort may be misdirected on high volume but low toxicity substances such as sodium chloride – common table salt, rather than on substances of high concern used in smaller quantities. The Society therefore believes that the additional criteria of PBT and vPvB are important and that, as knowledge progresses, there may be occasions when other criteria may need to be used to define substances of high concern.

The Society fully supports the principle of transparency under REACH. Transparency is vital to enhance public confidence in chemistry. The challenge is to create a balance between transparency and commercial confidentiality. All aspects of the REACH process need to be transparent so that interested parties can see how decisions are made. However this should not extend to providing detailed commercially sensitive information that would impact on competitiveness without providing any useful benefit, such as on the intermediates used in pharmaceutical syntheses, or on details of formulations that would allow competitors to copy

mixtures or articles (finished products). Commercial enterprises should only have an obligation to declare hazardous components of mixtures and articles that could have public safety implications.

It is important that REACH should only require data that has real value. This is particularly true for 'existing chemicals' that have been in use for many years with no apparent adverse effects. Testing thresholds should, where practicable, take account of estimated actual exposure and potential impact. Furthermore, there should be greater acceptance of scientifically reliable historical data gathered for other toxicological assessments required under other regimes. Testing on animals should also be minimised. It would be unethical to require animal testing simply to complete a bureaucratic box ticking exercise. There tends to be more information about chemicals of high concern. Consequently, data waivers should be allowed where there are good surrogate measures. Annex IX of the proposal must be liberally interpreted.

Even though the Commission is proposing to allow the maximum use of existing non-animal test methods, new test methods will take time to develop, validate and gain acceptability by regulators. In the past it has taken many years of international validation studies before legislators and regulatory agencies would accept the results from alternative test methods. In addition, the test methods currently in the proposal need updating. Whilst Annex V to the Dangerous Substances Directive will soon contain details of the mouse local lymph node assay LLNA for allergy testing, it is not included in the test methods (Annex X).

The Society welcomes the simplified and reduced Registration requirements but has serious concerns about the resources and expertise within the European Chemicals Agency, Competent Authorities in member states and in testing laboratories for coping with REACH. The Society is also concerned about the practicalities of the Registration of 30 000 or so substances, including the 11500 substances of high concern requiring Evaluation and Authorization within the 12 years of REACH coming into force. In addition to these substances, 40 000 intermediates will also need to be registered even though the requirements for registering these will be significantly lighter. In view of the number of chemicals that will fall within the REACH process it seems unlikely the Competent Authorities will have the resources to devote sufficient time to chemicals of lower concern, i.e. those requiring Registration and Evaluation but not Authorisation.

One particular concern is that REACH could lead to useful chemicals being withdrawn unnecessarily due to the high cost of testing. Any chemicals that are withdrawn should be those that are least desirable for health, safety or environmental reasons. The 'best' or 'safest' substances should not be withdrawn simply because they generate insufficient profit to cover the cost of testing. The Commission estimates that 1-2% of substances currently on the market will be lost. The Society and others believe that this may be a significant underestimation. This situation is likely to arise in those cases where a producer would have to spend a large amount of money to test a low economic value substance for the purposes of Registration. In such cases economic sense dictates that the producer / importer drop that substance rather than pay for the tests. A similar situation has already resulted in a loss of around 60% active substances in plant protection products and probably an even larger proportion of active substances in biocidal products.

It is difficult to quantify cost of compliance with REACH. However the current cost estimate from the Commission for complying with the proposals is 2.8 billion euros with most of this being for testing and Registration. It is likely however that the biggest costs will be incurred downstream in the supply chain due to mixture and article reformulation and this in turn will depend on the number of

substances that will disappear. It is important to note that the quantity of material does not relate to value of a component in a formulation which may not be possible to reformulate in some cases.

Whatever the figures turn out to be, it is already clear that implementing REACH will place significant costs on industry and there are fears that this could be a factor when industry decides whether to remain in the EU. The Commission should therefore consider developing options for allowing some generic substances that do not have sponsorship to continue to be manufactured within the Community. Enforcement of REACH may be a serious problem when dealing with downstream users, and proper enforcement also represents a significant cost.

There are concerns that REACH may inhibit innovation. Innovation is essential to achieving sustainable development, and chemistry can provide a range of 'solutions' to support sustainable development. There is some concern that innovation as envisaged by the Commission is primarily focused on substitution. Although substitution can lead to environmental benefits it is unlikely to lead to truly innovative articles (products) which contribute to the economic profits needed to underpin sustainable development. At present there are no rules concerning substitution, and this is an area in which criteria will need to be developed.

The RSC finds the latest version setting out the proposed regulations to be more balanced and more pragmatic than earlier versions. However, the Society still has significant concerns about the workability of some aspects of the proposal, and believes that more information and guidance is required if REACH is to achieve its intended objectives. The Society is also aware that the process of developing the proposals into legislation may jeopardise the latest improvements and these changes will need to be monitored during the passage of this proposal. The full text of the Society's position on REACH can be found at: <http://www.rsc.org/lap/rsccom/ehsc/reach.htm>

## **INFLUENCING PROPOSALS**

The Royal Society of Chemistry Charter obliges it to serve the public interest by acting in an independent advisory capacity. It is in this capacity that the Society has made an input into official UK and EC consultations and inquiries with an interest in the proposed policy and legislation. The RSC Environment, Health and Safety Committee [EHSC] made written submissions on the White Paper to the former Department of Environment, Transport and the Regions and to a House of Lords Select Committee during 2001. EHSC also gave oral evidence on the Society's behalf to the House of Lords Committee. The RSC submissions are available from the Society's website [www.rsc.org](http://www.rsc.org) and evidence to the Select Committee is in the public domain. The EHSC has also given written and oral evidence to the Royal Commission on Environmental Pollution Study into long-term effects of chemicals in the environment which deals with many issues related to the White Paper. More recently the Society responded to a European Commission Internet Consultation on REACH (July 2003) and submitted evidence to the House of Commons Science and Technology Committee Consultation of the in January 2004. In addition the Royal Society of Chemistry has a representative on the UK Chemical Stakeholders Forum, coordinated by Department for Food, Environment and Rural Affairs, that is concerned with aspects of REACH.

Although the general philosophy and approach of the proposed REACH regulation is clear and is unlikely to change, much of the detail has yet to be finalised. Since the proposed REACH regulation was published there have been many discussions between the Commission and stakeholders such as the chemical industry and non-governmental organisations (NGOs). In general there seems to be support for the aim of increased evaluation and control of existing chemicals. However concerns have been expressed about the means proposed for achieving this aim.