

**New EU Chemicals Strategy
Position Statement by the UK Government and the
Devolved Administrations**

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Contents

1	Introduction	3
2	Overall objectives.....	3
3	Key themes.....	4
3.1	A simplified and transparent system	4
3.2	A phased approach.....	5
3.3	Minimisation of animal testing.....	5
3.4	Innovation and the competitiveness of the chemical industry	5
3.5	Provision of Information	6
3.6	Role of downstream users	6
3.7	WTO and other international commitments.....	7
3.8	Chemicals in products.....	7
3.9	The Central Entity	8
3.10	Scope of the system	8
3.10.1	Interface with other regimes.....	8
3.10.2	Intermediates	9
3.10.3	Polymers.....	10
3.10.4	Scope of authorisation	11
4	The REACH system.....	12
4.1.1	Pre-registration	14
4.1.2	Registration package	15
4.1.3	Evaluation/risk assessment	17
4.1.4	Authorisation process	18
4.1.5	Decision making process.....	19
5	Background and Description of REACH.....	20
6	Glossary of Terms.....	21

New EU Chemicals Strategy: UK Government Position Statement

1 INTRODUCTION

This paper sets out the UK Government's and the Devolved Administrations' overall objectives in relation to the European Commission's forthcoming legislative proposals for a new EU chemicals strategy (NECS) and its views on a number of key themes (see section 5 for background). The latter part of the paper sets out some ideas the UK Government and the Devolved Administrations (collectively referred to in the rest of this document as "the Government") have developed on how the key elements of the REACH¹ system might operate in a practical and workable manner. The ideas in this paper have been developed through a process of stakeholder consultation within the UK (especially with the Chemicals Stakeholder Forum collectively and its members individually) and discussion with other Member States and the Commission. This process is not complete and further comments and contributions are welcome. This paper is not a definitive statement of the Government's negotiating position, not least because the Commission has still to publish proposals for legislation and those proposals will require a complete regulatory impact assessment. The Government intends to consult formally once the Commission's proposals are actually produced – currently expected early 2003– before establishing its final position. Thorough consultation will be essential to ensure all interested stakeholders have an opportunity to comment on the detailed legislation.

2 OVERALL OBJECTIVES

The Government supports the overall aim and approach set out in the Commission's White Paper. In negotiating the resultant legislation, the Government will have three overarching objectives:

- Creating a fast, efficient and workable process of testing, screening and assessing chemical substances to provide the information necessary to control those substances of concern, starting with the most harmful, because of their impacts on human health or the environment;
- Keeping animal testing to the minimum necessary to protect human health and the environment; and
- Maintaining or enhancing the competitiveness of the chemical industry.

In addition, the Government will want to see a system that is transparent to all interested parties in its operation and that provides consumers, workers and users of substances with the level of information they require about the substances with which they come into contact. The Government also fully supports the need for industry to assume responsibility for managing the risks from substances as far as possible. Finally, the Government considers it essential that the new system be compatible with Member State and EU commitments under the World Trade Organisation (WTO), relevant multilateral environment agreements such as the Stockholm and Rotterdam Conventions, the Globally Harmonised System of classification and labelling and with other existing complementary legislation.

The White Paper recognised the vital contribution of chemicals and explained that the overriding goal of future chemicals policy is to achieve sustainable development. This requires the integration of environmental, societal and competitiveness policy objectives. In seeking to improve the existing regulatory regime for chemicals, it is essential to assess the macro-economic impact of new legislation (which involves both direct costs on the chemicals industry itself, and the indirect costs on other manufacturing sectors that rely on chemicals) and balance this with the benefits to health and the environment.

In May 2001, the Government prepared a partial regulatory impact assessment to consider the impacts of the White Paper. A full regulatory impact assessment, with a more detailed cost benefit analysis, taking into account the wider economic impacts will be carried out once the Commission publishes its proposal. The results of this additional work will need to be taken into account before developing a final view.

The following sections set out the approach the Government is currently developing. As stated above, these do not represent a fixed position as the entire regime is still under development within the Commission.

3 KEY THEMES

3.1 A simplified and transparent system

The new EU chemicals strategy should provide a streamlined, transparent and, where possible, simplified system that effectively identifies and prioritises substances of concern and takes early risk management action. This should ensure that risk assessment is used in a targeted way to deal swiftly with identified uses of concern. It is therefore essential that implementation follows a realistic and achievable timetable and that the system is not overloaded by inclusion of large numbers of lower priority (i.e. low exposure or low production volume) substances from the beginning.

The recommendations made in and lessons learned from recent initiatives such as the Simpler Legislation for the Internal Market (SLIM) report on the Dangerous Substances Directive should be enshrined into the new legislation. This will ensure the resources required by Member State authorities are used where they will have the greatest effect, and minimise the demands on business.

A simplified and transparent system is also important, from a competitiveness perspective, such that REACH and other key components of the new regulatory regime conform to the latest EU regulatory best practice.

Finally, the UK Government does not object to the idea that the main legislative elements of the new EU chemicals strategy should be in the form of Regulations rather than Directives as they are well suited for this particular area. Since Regulations are directly applicable in Member States without the need for transposition into national law, they help ensure uniform application and legal certainty, thereby providing a level playing field across the EU for what is a multinational industry.

3.2 A phased approach

There should be a phased approach to the implementation of the legislation to ensure the workload is manageable for both industry and enforcing authorities. The approach taken by the White Paper to have the highest tonnage, and hence those with the likely greatest exposure, registered first is a suitable way forward. However the timescales will need to be realistic and achievable. It will be necessary to review the implementation timetable for the different production volumes proposed in the White Paper given the delay in producing the proposed legislation. The move to the new system could include:

- The Commission piloting the proposed system preferably during the development of the proposals or shortly after their adoption prior to implementation. By running a trial of the system on a limited number of priority substances experience could be gained to ensure the system is workable. Piloting of existing programmes such as the Existing Substances Regulations (ESR) could have anticipated the delivery problems subsequently encountered.
- Making best use of the resources spent on existing programmes such as the ESR, for example using substances assessed under ESR to pilot authorisation and rapid risk management and not putting great effort into re-assessing substances that have been previously assessed in great detail (e.g. lead). This approach should free up resources for other, less well-known substances of high concern; and
- Giving priority to tackling substances that have a wide dispersive use.

3.3 Minimisation of animal testing

Vertebrate animal testing should be kept to the absolute minimum necessary to ensure that sufficient information is available for decision-making on health and environmental protection. This can be achieved by structuring the required information packages for substances to require the right level and kind of data, ensuring wide-spread data sharing between companies, accepting high-quality data even if not meeting the strictest of Good Laboratory Practice (GLP) standards and using validated non-animal tests where available.

It should also be emphasised that a key part of minimising animal testing is to achieve mutual international recognition of non-animal tests (e.g. OECD validated alternatives) and adopt a consistent EU approach to animal testing. The EU should also support research into alternatives to animal testing specifically designed to meet the requirements of REACH, building on existing work being conducted in international fora including, inter alia, work in the OECD. There is time available for this to yield results when REACH is due for implementation.

3.4 Innovation and the competitiveness of the chemical industry

The new EU chemicals strategy should encourage innovation and maintain or enhance the competitiveness of the chemical industry whilst addressing the urgent need to obtain information on existing substances. REACH must be streamlined, workable and place the minimum regulatory burden on industry necessary to ensure

the adequate protection of human health and the environment. It should ensure a level playing field is maintained with non-EU producers and should not result in a disproportionate impact on discrete sections of the industry, particularly Small and Medium-sized Enterprises (SMEs).

Like some other Member States, the UK has a strong speciality chemicals sector, consisting mostly of SMEs, which are highly innovative and which add great value in the chemicals supply chain. It is generally recognised that their competitive position is most vulnerable to REACH. It is therefore important that new legislative proposals enable the EU chemicals industry scope to develop new, safer and more sustainable chemicals. Such an approach will enable the industry to continue to meet the requirements of a multiplicity of other manufacturing sectors that rely on speciality chemicals (e.g., electronics, pharmaceuticals) and help supply the range and quality of products available to consumers.

The new legislation must guard against the scope for companies to 'piggy-back' on data gathering, testing and registration carried out by other companies under REACH, whilst at the same time avoid the creation of undue barriers to market entry and prevent the consortia envisaged under REACH from acting in an anti-competitive manner (e.g. by forming cartels). Market access is an issue that applies to non-EU manufacturers wishing to trade with the EU as well as to intra-EU manufacturers. Furthermore, the new EU chemicals strategy must avoid creating incentives for companies to move manufacturing out of the EU to circumvent the controls, thereby losing the environmental benefit and damaging EU competitiveness

3.5 Provision of Information

The Government is committed to having a transparent system and would expect to see as much information as possible made publicly available. However, adequate controls on access to commercially sensitive data are essential to avoid stifling innovation. The system must respect intellectual property rights (IPR) arrangements as a vital element of competitiveness whilst recognising the right of the public to have access to relevant and meaningful information on hazards and risks.

There should be a greater provision of useful information (e.g. on risks of substances) to the public and workers, not only via a central database, but also by suppliers and formulators themselves. Consumers should have access to relevant and meaningful information.

In addition, there is a need for an effective system for providing information to downstream users about chemicals in products that they buy and use, so that they can take responsibility for managing the risks to the environment and to human health for the part of the life-cycle of the substance where they are responsible.

3.6 Role of downstream users

The principal responsibility should be placed on the supplier of a substance to provide a risk assessment for categories or classes of use, rather than relying on 'postcard' systems as envisaged in the White Paper. The risk assessment supplied at registration stage should cover the whole life cycle. This will place an obligation on the downstream user to ensure that the risk assessment covers their category of

use. If their general use category is not covered by the risk assessment and they wish to continue to use the substance, they must either notify the producer to get it included or prepare a risk assessment themselves. This approach should help contribute towards better information flows along the often complex chemicals supply chain and thus improving upstream suppliers' knowledge of downstream requirements, including retailers and consumers.

As registration should be open to any legal entity wishing to register a substance regardless of whether they are supplier or user, some large users may wish to be formally part of consortia registering a substance. In any case, there may be scope for a generalised duty on all suppliers and users to co-operate with registration and to pass on information further down the supply chain to end consumers and others. This would be within the requirements to comply with the provisions on data sharing, consortia formation and cost sharing outlined in section 4.

3.7 WTO and other international commitments

The EU should ensure that its proposals are consistent with its international obligations under the WTO and other multi-lateral agreements. The EU should also work closely with international organisations and seek to negotiate a global approach to managing chemicals as rapidly as possible.

It is important that the new EU chemicals strategy takes EU commitments under WTO agreements fully into account. Legislative proposals should be WTO-robust and must not leave the EU either exposed to challenges by our main trading partners in the WTO, or, in the light of the WTO Doha Development Round Agenda, and the principle of trade benefiting developing countries and poverty reduction, aim to minimise problems for exporters in developing countries. It should not create barriers to imports to the EU, or disadvantage indigenous EU producers against imports and, equally important, should not create competitive disadvantages for EU exporters.

The EU chemicals strategy should be consistent with commitments under the Stockholm Convention (i.e. concerning POPs and transport through the environment), the Rotterdam Conventions (i.e. concerning exports of substances banned or severely restricted in two or more regions) and OSPAR agreements. It should also contribute to the 'Priorities for Action Beyond 2000' of the Intergovernmental Forum on Chemical Safety (IFCS) and the 2020 chemicals target set at the Johannesburg World Summit on Sustainable Development.

REACH should also recognise and make maximum use of data and assessments produced under the OECD HPV Programme or the ICCA initiative, whilst investigating the use of bilateral agreements with other major trading blocks to bring forward mutual recognition of tests, data and good practice, in advance of agreement through other international fora, in order to maximise resource efficiencies and reduce the need for animal testing.

3.8 Chemicals in products

Chemicals used in the manufacture of products in the EU are already adequately covered by existing legislation. The use of restricted substances in imported articles is also covered by legislation, but it is difficult to prevent substances entering the EU

when imported as constituents of products. The Government believes that future EU legislation should have clear definitions of product and article. Controls could be based on a self-declaration system whereby the importer states that the article complies with REACH, which will be subject to enforcement by Member States. The details of such a scheme would need to be carefully constructed to avoid affecting production and process methods in non-EU countries in a way that would infringe the EU's WTO commitments.

3.9 The Central Entity

The Commission's White Paper sets out the need for some kind of Central Entity to run part of the REACH system. It will fulfil a critical role in the implementation of the REACH system and therefore needs to be fully operational in good time to ensure successful transition to the new regime and to avoid bottlenecks. The UK Government is strongly inclined to the view that this should be an independent agency along the lines of the European Medicines Evaluation Agency, funded primarily through fees charged to registrants under REACH. However, this does not mean that the Government would expect it to be a large organisation employing large numbers of expert staff – rather, it would see much of the expertise being bought in from existing experts in the Member States, especially given the constraint of a relatively limited number of suitably qualified and experienced people.

3.10 Scope of the system

The REACH system should in time create a database of information on the hazards and risks of all manufactured chemical substances, whatever their intended use. However, it is clear that in the medium term the practicalities mean that the system must focus on the substances of highest concern that are otherwise not being addressed, in order to tackle them quickly. Even coping with the 30 000 existing substances estimated to be in use in the EU will be a mammoth task requiring rigorous prioritisation of effort. Groups of substances such as pesticides and biocides that are currently subject to a positive approval regime should therefore not be priorities for the earlier stages of REACH, and substances produced or imported in volumes less than 1 tonne per year (per supplier² respectively) should not require registration. Substances already registered under the current regime for new substances should not require re-registration. And as noted under section 3.7, workability of the new regime will be greatly assisted by maximising use of existing data and assessments, such as the ICCA/HPV programme.

3.10.1 Interface with other regimes

The new EU chemicals strategy should both build on and further inform current regimes such as those for Occupational Health and Safety (OHS), transport, major accident hazards (Seveso), environmental protection (e.g. IPPC) and consumer protection whilst not creating overlapping or contradictory requirements. The interaction with existing legislation such as that on pesticides, biocides, medicines, cosmetics and food additives also needs to be carefully considered. Bearing in mind that in some sectors (i.e. Cosmetics) the EU's key policy objective is to ensure the phasing out of animal testing in the EU and the prohibition on the marketing of goods that have been tested on animals, it is important that the additional testing requirements for chemicals in the Commission's White Paper do not result in EU

manufacturing industries being caught between conflicting Community regulatory regimes. Where environmental or human health protection is already adequately covered by existing regimes such as for pesticides, biocides and veterinary medicines, REACH should not attempt to replace or duplicate the requirements of those regimes, but rather should use the information already collected and only seek to fill in substantive gaps where there is a clear need to do so.

3.10.2 Intermediates

Four main categories of intermediates³ can be identified for the purposes of the scope of REACH:

Type 1. Non-isolated intermediates;

Type 2. Isolated intermediates stored and used on-site;

Type 3. Isolated intermediates transported between sites of one legal entity or supplied to a limited number of sites under strict contractual control (including toll or contract manufacture); and

Type 4. Isolated intermediates supplied other than within strict contractual controls between the original supplier and recipient.

It is not known exactly how many intermediates are in use in the EU, but estimates vary from 50 000 to 120 000⁴. By their very nature, most intermediates tend to have low exposure and are subject to other regulatory regimes such as the Chemical Agents Directive, the Carcinogens Directive and the Young Workers and Pregnant Workers Directives. These Directives place the responsibility on employers to ensure that appropriate risk assessments are carried out for workers who handle chemicals, including intermediates. Many of the Directives also have a requirement to substitute high risk substances with one of lower risk where possible.

There are also substantial safeguards in place to protect workers, drivers and the public when an intermediate is transported between two chemical sites. A risk assessment must be carried out for the transport of chemicals by road, air, rail or sea to ensure safe handling and transportation.

In the light of the low risk of exposure, and the availability of existing safeguards, the Government does not consider that the registration of all intermediates under REACH should be a priority. Furthermore the inclusion of such a large quantity of additional registrations would overwhelm the system and stop it from addressing substances of much higher concern. The UK Government therefore considers that in each case, a pre-requisite is that any human or environmental exposure is already controlled by existing regulatory regimes for worker or environmental protection. All intermediates would be expected to have rigorous measures to prevent or adequately control exposure from them. For each class of intermediate the following would apply:

- **Type 1** intermediates should not be within the scope of REACH.

- Intermediates of **Types 2 and 3** should not require registration under REACH. However, a very basic form of notification could be considered to enable the Member State enforcing authorities to assess compliance. This need be no more than the submission of a list of the substance names and CAS numbers. The supplier should also hold on site, for inspection by authorities, a set of core information to provide a consistent and transparent level of information to assist in compliance with existing legislation.
- **Type 4** intermediates should be treated as any other commercial substance under REACH and be subject to the full registration and other requirements.

It is recognised however, that there will be differences in the data available for intermediates as compared to supplied substances. There should therefore be a commitment to review the need for registration of Type 2 and Type 3 intermediates after REACH has been in operation for several years and the majority of commercial substances registered.

3.10.3 Polymers

Currently 'new' polymers – those containing 2% by weight or more of a non-EINECS (European Inventory of Existing Commercial Substances)⁵ listed monomer – must be notified under the rules on new substances. Polymers are subject to the full notification requirements unless they are considered non-bioavailable in which case a 'reduced test package' (RTP) applies. Existing polymers are subject to classification and labelling requirements. However, for the large number of 'existing' polymers in circulation, some of which potentially pose a hazard to human health or the environment, there is very little publicly available hazard data. The hazard of a polymer is likely to be determined by the intrinsic properties of the monomer from which it is made, though a polymer's properties may be different due to structural differences of the oligomeric molecules or indeed its physical structure.

Including all polymers in the REACH system could add at least 10 000 substances. Registering and testing every new and existing polymer would overburden the system. We therefore need to develop a proportionate approach to regulating them which focuses on those polymers which have specific characteristics which may make them potentially hazardous to human health or the environment (once criteria have been agreed), while allowing non-hazardous polymers to be exempted. Consideration should also be given to degradation; those polymers that readily degrade to their constituent monomers would assume an increased importance.

The proposal is to limit the regulatory burden to only those polymers of concern by approaching the issue in three stages:

- **Stage 1** – industry to identify polymers of concern based on agreed criteria. If the polymer is likely to exhibit specific characteristics that make them potentially hazardous, register and test the polymer. Testing should be proportionate to the risk.
- **Stage 2** – if the polymer is not of concern, only the constituent monomer(s) need to be registered. If the constituent monomer is not manufactured or imported in to Europe, the polymer should be tested.

- **Stage 3** - if the risk assessment of the monomer identifies the need for risk management, the polymers derived from it may need to be tested and risk assessed but there is a need to look at both the monomer and polymer use profile thus taking the risk into account, rather than the hazard.

In order to identify high risk polymers, consideration needs to be given to developing an appropriate methodology to predict the polymer hazard. The toxicity of the polymer can in part be assessed by considering the structural and physical characteristics of the polymer such as the presence of reactive functional groups (such as sequestrants), bioavailable metals, aerodynamic particle size, and anionic and cationic density. Reactive functional groups may be capable of reacting with tissues or have other adverse effects. If those groups are present in the polymer, there is a high possibility of them inducing these adverse effects. These polymers should therefore be subject to the full REACH process.

By focusing on those polymers of highest concern, the system would in effect be exempting the lower hazard polymers from the REACH system. As well as the benefit of reduced regulatory burden, having an exemption rule should also encourage innovation in the manufacture of lower hazard polymers.

When registering a monomer, an outline of the polymers that would be constructed from it would also need to be provided. For potentially low hazard polymers, it should be possible to predict the intrinsic toxicological and eco-toxicological properties of the polymer from the monomer data. The information provided at the monomer registration phase should therefore be sufficient to assess the properties of the polymer without further testing.

If after evaluation the monomer is highlighted as a candidate for risk management, testing may be needed on the polymer. This approach will provide a back up measure to ensure no potentially hazardous polymers are left untested.

Where the monomer is not registered under REACH, the system should be flexible enough to allow the manufacturer or importer to register the polymer instead.

There should also be wide use of a family type approach to deal with both registration and exemptions. The concept of grouping polymers into families is based on the assumption that, in principle, the members of a family of polymers possess a similar hazard potential. Although it is recognised that the effects might not always be linear throughout a family, testing polymers on a family basis is accepted in order to reduce tests to a reasonable and yet sufficient number. The decision to group polymers should not be mandatory but left to the notifier. The concepts of data sharing should still apply.

3.10.4 Scope of authorisation

It is already accepted, both in the Commission's White Paper and in the Environment Council's Conclusions of June 2001, that authorisation under REACH should apply to persistent organic pollutants (POPs) and carcinogens, mutagens and reproductive toxins (CMRs). The UK is strongly supportive of adding substances that are persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (VPVB) to the group of substances subject to authorisation as soon

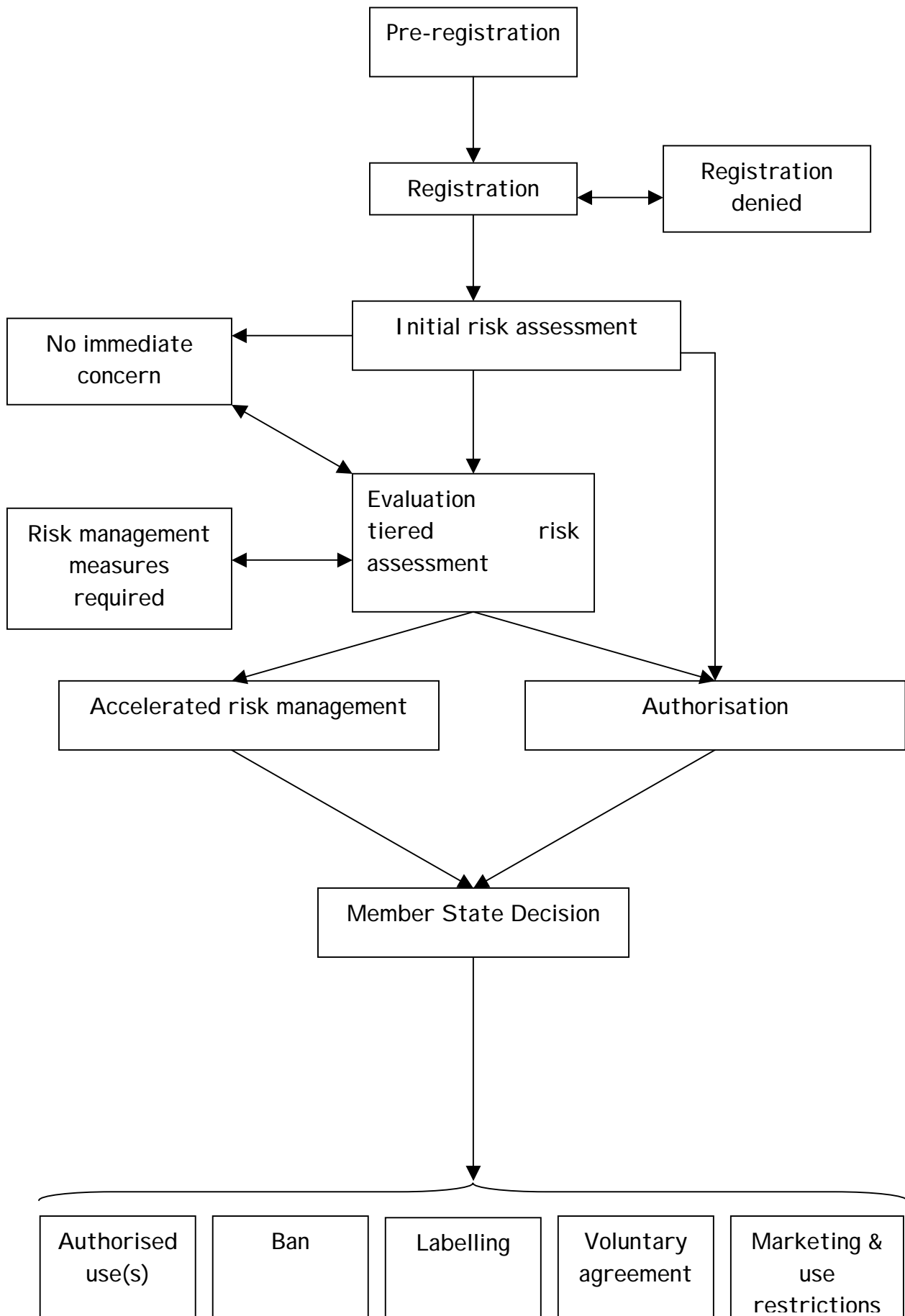
as the necessary criteria for their identification are established. In addition, we believe that certain targeted respiratory sensitisers (those classified with R42 and recognised as major causes of asthma in the workplace) should also be included. When scientifically validated test methods have been developed and criteria established, endocrine disruptors should be subject to authorisation. However, where endocrine disruptors have already been agreed within the EU these too should be included from the outset. The Government would also like to see a mechanism for bringing into the scope of authorisation other chemicals of equal concern for human health or environmental protection.

4 THE REACH SYSTEM

The Commission's White Paper leaves a number of issues unresolved or unclear as to how REACH will function in detail. This section of the paper sets out some ideas on how the key elements of the REACH system might operate. Although necessarily more detailed than some other aspects of this paper, it must however be stressed again that these ideas are not the final Government position. This will not be finalised until the Commission's proposals have been produced and it has had the chance to examine them properly, consult stakeholders about the details and carry out a complete regulatory impact assessment.

Figure 1 is an attempt to set out an outline of how the Government sees the REACH process might work.

Figure 1: Possible REACH outline



4.1.1 Pre-registration

In order to promote data sharing, minimise duplicate animal testing and encourage consortia formation there should be a pre-registration phase. In this phase a supplier would indicate its intention to register a substance, probably via the Central Entity, and call for others with an interest in the same substance to join together to form a consortium. This consortium would then share existing data and the costs of acquiring any new data then required. Data gathering may include requests to users for basic information on uses that would be needed for the registration stage.

Pre-registration will be crucial for the transition to the new single system and experience shows that consortia formation takes time. That will need to be taken into account in the timetable for implementation, and consideration could be given to the Central Entity having a facilitation role in establishing consortia, e.g., by identifying suitable agents or contractors for industry to use.

4.1.1.1 Consortia formation

The Government would expect the rules of registration to strongly encourage or even require consortium formation, for example by requiring one registration per substance and only permitting those companies involved in the registration the right to produce, market or import the substance in the EU. Requiring one registration package would bring greater simplicity and transparency to the overall process. Sharing data in this way to prepare a single package will reduce testing and registration costs. It will also make compliance checks, assessments and enforcement simpler.

During the pre-registration phase, a notice of registration could be posted on the Central Entity website and companies would have a set time from this posting to contact and join the consortia. There should be the presumption of free access to consortia. Any company wishing to join the consortia should be able to do so. Downstream users could also use this as an opportunity to ensure that their particular use will be covered in the registration.

Subsequent applications for registration from outside the original registering consortium should be subject to an additional fee and, subject to the final arrangements on data sharing, may require the new applicant to reimburse the original registrant for a proportion of testing costs. While the regime should discourage “free-riders” on the system, it should also ensure that consortia formation can under no circumstance be used to further anti-competitive practices, and does not present a barrier to entry for new membership applicants, that they are treated in a non-discriminatory way, and that the fee charged is reasonable and proportionate. We recommend that industry present guidelines on cost sharing. We further recommend that there should be some kind of industry funded ombudsman to resolve conflicts and facilitate discussion on costs and data sharing. In the last resort, there might be a specific function within the Central Entity that could rule on unresolved disputes.

It would be up to the companies involved in the registering consortium to agree the details of their own cost sharing mechanisms, but this would need to be consistent

with EU competition law (i.e. no cartels) and WTO commitments (i.e. no discrimination against non-EU companies).

As much of the REACH process as possible should be automated. For the registration process, dossiers should be completed electronically (which will automatically ensure that all information is supplied) and signed by a nominated signing officer for the registering company or consortium. The required format of dossiers should be compatible with international data collection programmes. Collective registration of well-defined groups of substances should also be allowed.

4.1.2 Registration package

The aim of the registration package should be to ensure industry has adequate data on which to base an assessment of the risks and to offer public authorities the minimum set of data necessary for prioritisation and effective evaluation within REACH. Any additional information should only be required where it is needed to ensure adequate control of the substance, not merely to complete a data set. The focus therefore should be on information required rather than tests per se.

The Government considers that it is possible to describe a registration package that will provide the required information with a minimum of animal testing. It prefers a "Basic Information Requirement" approach (a basic set of information is required unless the registrant can justify exemptions to the public authorities) to a "Minimum Information Requirement" one (a very small set of information is compulsory, but public authorities can request more from the registrant upon justification). The use of data proxies should be encouraged; this could include waiving a specific information requirement where equivalent data is already available in a slightly different form. In addition if certain endpoints are demonstrated, then others of lesser concern may not need to be examined (e.g. if a substance is a mutagen there may be no need for other human health endpoint information). In general, any new testing should be carried out to the standards of Good Laboratory Practice (GLP). However, it should be possible to use older, non-GLP data where this is appropriate, particularly for screening, using a weight of evidence approach for example as in the OECD. Chemicals could also be grouped for the purpose of assessment where appropriate and scientifically justified.

The information on uses only needs to be sufficient to allow an initial assessment at registration. Exposure information should include tonnage and categories of use/intended use based on those identified in the Technical Guidance Document. Estimated human and environmental exposure should be based on proxies (e.g. solubility, vapour pressure, miscibility etc.) and the registrant should propose 'Occupational Exposure Limits' which then can be prioritised by the Commission for harmonisation. The package should include full substance identification (including CAS number and EINECS number, where appropriate) and a justified proposal for classification and labelling.

4.1.2.1 Environmental and human health endpoints

The focus in the legislation should be on environmental and human health endpoints (carcinogenicity, persistence, etc) rather than on actual tests. This focus helps avoid particular tests being proscribed in an inflexible manner, potentially adding

unnecessarily to animal testing and requiring regular amendment in the light of technical progress. It also makes the use of equivalent data more straightforward, again reducing unnecessary testing, delay and cost. It is essential that the system deals with substances in an intelligent way and that in vivo testing is done only when the information is essential to determine the risk management strategy required. In vivo testing for mutagenicity (if indicated by positive in vitro data), reproductive toxicity or carcinogenicity should be done sequentially since a positive in one alone is sufficient to require a substance to be authorised.

Since the production/importation tonnage can be used as a proxy for environmental and indirect human exposure (high tonnage substances are likely to result in more widespread exposure than lower tonnage substances) there should be a graduated scale of information at registration. For substances in the range 1-10 tonnes per year, the general principle should be that where suitable methodology is available, testing for registration purposes should be confined to in vitro methods only (and daphnia), sufficient to identify environmental and human health hazards. There is certainly no need for any vertebrate animal testing for environmental endpoints at this level – the requirements could be based on those in Annex VIIA of the Dangerous Substances Directive 67/548/EEC, but without the use of fish (i.e. vapour pressure, water solubility, log K_{ow} and biodegradation). If toxicity testing is appropriate it should only be on daphnia, and valid (Quantitative) Structure-Activity Relations ((Q)SARs) can be used to fill any data gaps. For human health, some information on the following endpoints is needed: acute toxicity, skin sensitisation, corrosivity, mutagenicity and reproductive toxicity (teratogenicity). Information on corrosivity and screening information for mutagenicity may be obtained from in vitro OECD test methods and an OECD guideline for screening for teratogenicity is likely to be available in the next 2 years or so. Thus only 2 of the endpoints will need to use animal tests at this stage.

For substances in the range 10-100 tonnes per year, additional environmental data should include information on analytical methods for environmental monitoring, pK_a data for ionisable compounds and consideration of the identity of any hydrolysis products. No avian tests are required at any tonnage threshold, except based on a strong need following risk assessment. For human health, additional data are needed on repeated dose toxicity and on fertility. This may be obtained from one study (OECD guideline 422) or by investigating these endpoints separately. Validated in vitro test methods for endocrine disrupters should be introduced into the basic information package for substances over 10 tonnes (for screening purposes) as soon as they are available.

For substances over 100 tonnes per year, intelligent information gathering strategies need to be developed for both environment and human health impacts, focussing on endpoints of concern based on the data already acquired and, where available, read-across, existing non-standard information, (Q)SARs or other techniques. Above 1000 tonnes per year, information may well be available from the global ICCA initiative or other testing programmes.

4.1.2.2 Coherence check and next steps

Once the registration package has been submitted it should undergo an automated completeness and coherence check to ensure the dossier contains all the

information necessary and that the information given is internally consistent and, where possible, consistent with what would be expected. Registrations that fail this check should be rejected and the registrant informed of the reasons. No extension to the registration deadline should be offered in this eventuality. There should also be a system of random spot checking, carried out by the Central Entity, to check the accuracy of the registration package. Again, registration should be denied where this check is failed and there must be some form of sanction on the registrant.

4.1.3 Evaluation/risk assessment

The primary purpose of the evaluation step should be to decide what further action, if any, is required to control any risks to the environment or human health. We believe that risk is an appropriate basis for the decisions at this stage aimed at preventing harm from chemicals to the environment and human health. For this reason we propose a phased approach for evaluation beginning from the initial registration. Further work should then be carried out principally on the basis of risk, rather than a tonnage base trigger as proposed in the White Paper, although it must be recognised that hazards identified on the basis of a simple set of tests may need further investigation as a result of expert judgement.

4.1.3.1 The outline process

Taking account of these considerations we are minded to adopt the process outlined below.

From registration there are a number of clear steps leading to chemical assessments:

- An initial assessment based on screening of hazard properties (based upon the REACH base set information requirement) and the likely human and environmental exposures. This should be computerised for consistency and simplicity;

DECISION POINT: Substances of no immediate concern are identified as requiring no further action at present. Those that meet the criteria for authorisation immediately progress onto authorisation. All others progress to the next stage of risk assessment.

- Further appropriate tier(s) of risk assessment(s) should be carried out by industry as necessary. These assessments focus on collecting data on hazard endpoints, and exposures of concern indicated by the initial assessment, rather than mandate a fixed set of "higher tier" testing or measurements. The registrant should show their proposed risk management measures adequately control the substance;

DECISION POINT: Following a tiered assessment, some substances may be identified as being of no immediate concern (requiring no further action at present). Other substances may be identified as having risks but requiring no further action by the authorities at this stage because those risks are demonstrated to be acceptably managed. Those that match the criteria for accelerated risk management or authorisation proceed to the next stage of risk assessment.

- Substances that are candidates for accelerated risk management will be the subject of a targeted or comprehensive risk assessment. Substances that are candidates for authorisation (i.e. meet the criteria and for which a specific authorisation is sought for restricted use) will be the subject of targeted risk assessment and a socio-economic analysis.

DECISION POINT: A substance that was the subject of accelerated risk management has its unacceptable uses and appropriate control measures identified. A substance undergoing authorisation has its acceptable uses (and their and appropriate control measures) identified. Completely banned substances also need to be identified in the system.

Ultimately, we would like to see all registered chemicals that appear on the Central Entity's electronic database to be coded to indicate levels of concern based on the outcome of the risk assessment. In this way, we would arrive at a publicly accessible web site that:

- Contained a list of all substances that are manufactured or imported; and
- Clearly indicated whether the substance was of low concern, whether controls were necessary to control the risk, whether it had restricted uses, whether it was completely banned or authorised for specific uses.

There should be a process that enables a substance to be re-evaluated in the light of new information or justified challenge to the existing material.

Information should be made publicly available. The exact nature of the data made available will depend on what is included in the registration package, but the presumption is that all structure information, hazard data and basic use categories will be. More detailed use information could be kept confidential for commercial reasons if that was appropriate.

To ensure fair burden sharing, Member States should each take responsibility for a certain minimum number of substances identified from the initial assessment as being a priority for evaluation. On the basis of national priorities, Member States could also take responsibility for any additional substances from elsewhere on the evaluation list. The Member State rapporteur would then work with the registrant to prepare the risk management proposals, including an analysis of the advantages and drawbacks of particular action, and submit them to the final decision making process. There should be fixed and realistic deadlines on all parties through the process.

4.1.4 Authorisation process

As with evaluation, to ensure fair burden sharing Member States should each take responsibility for a certain minimum number of substances from the top end of the priority list identified for authorisation. This could be supplemented if desired by any additional substances from elsewhere on the list, based on national priorities. Following notification of the registrant by the Central Entity, the Member State rapporteur would work with the registrant to prepare the authorisation proposals, including a full socio-economic analysis, and submit them to the final decision

making process. There should be fixed and realistic deadlines on all parties through the process.

Where uses of a substance are not supported by industry or by a Member State, they should automatically be banned for a fixed period after notice of the substance entering the authorisation process. Requests for authorisation from outside the original registering consortium or companies should be subject to an additional fee and, subject to the final arrangements on data sharing, may require the new applicant to reimburse the original registrant for a proportion of testing costs. This will be necessary to discourage “free-riders” on the system.

Authorisations should in principle be time-limited. However, the exact time period should depend on the identified risk and should in any case be subject to review in the light of new information or a justified challenge to existing material.

4.1.4.1 Criteria and prioritisation for authorisation

Subject to the provisions and qualification outlined in Section 3.10.4, POPs, CMR, PBT, VPVB, certain targeted respiratory sensitisers (classified with R42 and recognised as major causes of asthma in the workplace) and endocrine disruptors should be subject to authorisation. There should also be a safety net procedure for including substances of equal concern as these are identified (based on scientific review). The criteria for POPs and CMR are already clear. For PBT and VPBP substances, the criteria in the draft Marine Technical Guidance Document may provide a suitable basis. If this is the case it is expected to result in around 1500-2000 substances being subjected to authorisation, which will then require prioritisation on the basis of their risk. For the environment, PBT substances should be the first priority followed by VPVB. Health concerns should also receive a high priority. Substances that are already controlled under current legislation should be a lower priority.

4.1.4.2 Socio-economic analysis

A key factor in developing a socio-economic analysis (SEA) will be the apportionment of responsibility between the Member State rapporteur and industry. Although the White Paper foresees the supplier or user as being responsible for the SEA and substantiating claims that the benefits of use outweigh the potential health or environmental risks, the extent to which this can be delivered are likely to be limited as there are implications across a wide range of stakeholders. A system needs to be developed allowing the Member State rapporteur to retain control over SEA development but with industry meeting the cost.

4.1.5 Decision making process

The final decisions on risk management or authorisation should be taken at EU level and should apply across the EU unless there are specific, justified reasons otherwise. Decisions should be based on the recommendations of the rapporteur Member State, but the exact mechanisms for the decision (comitology, secondary legislation) and hence the relative roles of the Commission, Parliament and Member States need to be established and are not necessarily the same for authorisation and risk management, or even for all substances within either of these categories. In

whichever system that is finally adopted there must be a significant input from the Member States.

5 BACKGROUND AND DESCRIPTION OF REACH

In February 2001, the European Commission published its White Paper for a Future Chemicals Policy⁶, setting out an approach to the regulation of chemicals based on a system called REACH (**R**egistration, **E**valuation and **A**uthorisation of **C**hemicals). EU Environment Ministers meeting in June 2001 adopted a comprehensive set of conclusions that gave clear directions for the shaping of new legislation⁷. In November that year, the European Parliament put forward its views on the White Paper too⁸.

The aim of the new system is to cover both new and existing substances in one regulatory regime. All chemicals produced or imported into the European Union in quantities above 1 tonne per year would be registered in a central database. Chemicals deemed to be of most concern would need an authorisation. This would require industry to gain specific permission for particular uses that have been demonstrated to be safe. Other uses would be prohibited. The White Paper identifies substances of very high concern as being CMR (carcinogenic, mutagenic or reprotoxic) substances and POPs. The Council conclusions added to these PBT (Persistent, Bioaccumulative and Toxic) and VPVB substances (Very Persistent, and Very Bioaccumulative).

The Reach system as outlined in the White Paper suggests the following three elements:

Registration – of basic information on all substances exceeding a production volume of 1tonne /year is to be submitted by companies to a central database. It is estimated that around 80% of substances would only require registration.

Evaluation - by the authorities of substances exceeding a production volume of 100 tonnes/year (estimated to be around 15% of the total existing substances) and those of lower tonnage where there exists a concern. The evaluation will be carried out by authorities.

Authorisation – of substances with properties that give rise to very high concern, where specific permission will have to be given before such substances can be used for a particular purpose. In addition, the proposals provide for the accelerated risk management of substances which are not subject to authorisation but which require restrictions on their use.

The new system would place an increased responsibility on industry to provide data on substances, in particular existing substances. It also involves the provision of more comprehensive information on substances to downstream users and then places a requirement on downstream users to notify the authorities of uses not originally envisaged by the manufacturer and to undertake assessments of the risks associated with those uses.

6 GLOSSARY OF TERMS

This glossary provides explanations in the context of the main paper only and are not necessarily of general applicability. It is provided for information only.

Acute toxicity Illness resulting from a single dose or exposure to a toxic substance.

Bioaccumulation The uptake of substances from the environment, and their concentration and retention by organisms, e.g. in fatty tissues.

Bioavailable How metabolically available a drug or other chemical becomes to the target tissue after it's introduced into a person's body.

Biodegradation The [degradation](#), or destruction of, a chemical substance or substances by biological means (such as through microorganisms using it as a nutrient).

Carcinogenicity A property of a substance that causes cancer.

Carcinogens, Mutagens & Reproductive toxins (CMR) Agents physical, chemical or biological that can induce mutations or cause cancer or interfere adversely with an organism's reproductive ability.

Chemical Abstract Service (CAS) number is a numeric designation given to a specific chemical compound by the Chemical Abstract Service.

Chronic toxicity Illness resulting from continued exposure to a toxic substance over a long period.

Data proxies alternatives to precise test data on a unique substance that nonetheless can be used to provide equivalent information.

Ecosystem Living organisms, their physical environment, and their interrelationships within a particular part of the environment.

Ecotoxic Harmful to ecosystems and/or the organisms within them.

Eco-toxicology The scientific study of harmful effects caused by manmade chemicals to the natural environment, especially effects on populations, communities, and ecosystems; an essential part of ecotoxicology is the study of the movement of potentially toxic substances through food webs and through the water cycle, etc.

Endocrine disrupter Substance that interferes with the working of the endocrine (hormone) system.

European Inventory of Existing Commercial Chemical Substances (EINECS) An "Existing" chemical substance is in the EU defined as any chemical substance listed on EINECS, an inventory containing 100,195 substances. It lists and defines those chemical substances, which were deemed to be on the European Community market between 1 January 1971 and 18 September 1981. In terms of Article 1(4) of the

amended Directive 67/548/EEC, these are substances to which the pre-marketing notification provisions of the Directive do not apply.

Existing chemicals Defined as those listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) between January 1971 and September 1981- a total of over 100,000. All other chemicals are 'new chemicals'.

Family type approach Grouping together closely related substances.

Functional Group The specific atom or group of atoms that give a biomolecule a specific chemical characteristic.

Globally Harmonised System (GHS) A common and coherent approach to defining and classifying hazards, and communicating information on labels and safety data sheets, developed by the UN. Target audiences include workers, consumers, transport workers, and emergency responders. It provides the underlying infrastructure for establishment of national, comprehensive chemical safety programs.

Good Laboratory Practice (GLP) is concerned with the organisational processes and the conditions under which laboratory studies are planned, performed, monitored, recorded and reported. Adherence by laboratories to the Principles of GLP ensures the proper planning of studies and the provision of adequate means to carry them out. It facilitates the proper conduct of studies, promotes their full and accurate reporting, and provides a means whereby the integrity of the studies can be verified. The application of GLP to studies assures the quality and the integrity of the data generated and allows its use by Government regulatory authorities in hazard and risk assessments of chemicals.

Hazard assessment Assesses a chemical's potential to harm humans or the environment. This is an intrinsic property of a substance. It does not address the likelihood of harm (risk), which depends on exposure, including the way the substance is used or is likely to reach the environment. The hazard assessment is therefore only the first step towards an assessment of risk.

Hazard profile Data on physical and chemical characteristics, acute and chronic toxicity, bioaccumulation, persistence and mobility in environmental media and other properties required for a hazard assessment of a chemical. Together with information on exposure, the hazard profile is used to assess risk.

High production volume (HPV) The OECD defines an HPV chemical as one that is produced in or imported into any single country in quantities of 1,000 tonnes per year or more. The US Environmental Protection Agency terms HPV chemicals as those produced or used in quantities of over one million lb. Per year, i.e. about 444 tonnes.

There are various HPV testing programmes currently in use which are designed to provide data on HPV chemicals. The four main programmes are:

- the OECD-HPV programme;
- the ICCA-HPV chemicals initiative;
- the US-HPV challenge programme/chemical right-to-know initiative;
- the existing chemicals programme of the EU.

International Council of Chemical Associations (ICCA) A body of trade associations representing chemical manufacturers world-wide. It provides a forum for regular meetings of executives from member associations. ICCA has announced a voluntary programme of accelerated testing and hazard assessments of about 1,000 high priority chemicals, to be completed by the end of 2004.

Intergovernmental Forum on Chemical Safety (IFCS) was created by the International Conference on Chemical Safety held in Stockholm in April 1994. IFCS is a mechanism for cooperation among governments for promotion of chemical risk assessment and the environmentally sound management of chemicals. It is a non-institutional arrangement, whereby government representatives meet with intergovernmental and non-governmental organizations with the aim to integrate and consolidate national and international efforts to promote chemical safety. Intergovernmental and non-governmental organizations participate without the right to vote.

Integrated Pollution Prevention Control (IPPC) is a system following Directive (96/61/EC) which introduces a more integrated approach to controlling pollution from industrial sources, across England and Wales. The main aim of IPPC is to achieve a high level of protection of the environment taken as a whole by, in particular, preventing or, where that is not practicable, reducing emissions into the air, water and land.

Intermediates are substances used exclusively for the synthesis of another substance(s) and solely manufactured for and consumed in a chemical reaction.

In vitro means, literally, "in glass"; a biological or biochemical process occurring outside a living organism. This can include computer simulation.

In vivo means, literally "in a living thing", referring to testing taking place within a living organism.

Log K_{ow} : Log K_{ow} is a measure, established from non-animal testing, used to predict, among other endpoints, the likelihood of a substance to bioaccumulate. It can be derived by observing the behaviour of a substance added to a mixture of water and an organic solvent. This will provide an indication of how lipophilic (fat loving) it is.

A more precise technical explanation is that the partition coefficient, K (P), is defined as the ratio of the equilibrium concentrations of a dissolved substance in a two-phase system consisting of two largely immiscible solvents, usually n-octanol and water (ow). The partition coefficient therefore is the quotient of two concentrations and is usually given in the form of its logarithm to the base 10 (Log K or Log P)

Monomer A single molecule that is the sub-unit of a polymer.

Mutagenicity A property of a substance which causes mutation of the genetic material of an organism exposed to it.

New chemicals Defined as those not listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) between January 1971 and September 1981. Those on that list are the so-called 'existing chemicals'.

Organisation for Economic Cooperation & Development (OECD) The OECD groups 30 [member countries](#) sharing a commitment to democratic government and the market economy. With active relationships with some 70 other countries, NGOs and civil society, it has a global reach. Best known for its [publications](#) and its [statistics](#), its work covers economic and social issues from [macroeconomics](#), to [trade](#), [education](#), [development](#) and [science and innovation](#).

OSPAR The Convention for the Protection of the Marine Environment of the North East Atlantic (the OSPAR Convention), to which the UK is a party, agreed a strategy to 'prevent pollution of the maritime area by continuously reducing discharges, emissions and losses of hazardous substances with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances.'

Persistent Organic Pollutants (POPs) chemical substances that persist in the environment, bioaccumulate through the food web, and pose a risk of causing adverse effects to human health and the environment.

Persistence The ability of a substance to remain unchanged in the environment. Persistent substances can become distributed world-wide, particularly in the marine environment or in the atmosphere.

Physico-chemical data Physical and chemical properties of substances such as boiling point; density; molecular weight; solubility etc.

Polymers are large molecules (also called a macromolecules), which are made by joining together many small molecules. Natural polymers include cellulose, starch, and rubber. Artificial polymers include rayon (artificial silk) and all plastics.

Precautionary principle The precautionary principle is an approach to risk management that can be applied in circumstances of scientific uncertainty, reflecting a perceived need to take action in the face of a potentially serious risk without waiting for results of scientific research. The 1992 Rio Declaration on Environment and Development says: 'In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'

(Quantitative) Structure-Activity Relations [(Q)SARS] The Quantitative Structural Activity Relationship approach is a computer modelling technique used to predict a chemical's properties – such as whether they are **persistent**, **bioaccumulative**, or **toxic** – by analysing its structure. It is not considered as being as reliable as other methods of establishing a chemical's properties but can be applied rapidly according to established rules. It is generally considered suitable for screening chemicals i.e. identifying chemicals that should be subject to further analysis and testing.

Read across is the use of known data on one or more substances to predict the properties (such as toxicity, etc) of closely related substances.

Regulatory Impact Assessment (RIA) is a tool which informs policy decisions. It is an assessment of the impact of policy options in terms of the costs, benefits and risks of a proposal for intended legislation.

Respiratory sensitisers are substances which when breathed in can trigger an irreversible allergic reaction in the respiratory system. Once this sensitisation reaction has taken place further exposure to the substance, even to the tiniest trace, will produce symptoms such as asthma (attacks of coughing, wheezing and chest tightness) and rhinitis (runny or stuffy nose and watery or prickly eyes).

Risk The likelihood of the hazardous properties of a chemical causing harm to people or the environment. Risk depends on exposure including the way the substance is used or is likely to reach the environment.

Risk assessment The determination of the emissions, pathways and rates of movement of a substance and its transformation or degradation in order to estimate the concentration/doses to which people or parts of the environment may be exposed. Scientists compare the hazard profile and the exposure assessment to characterise the risk, they build in uncertainty factors to allow for uncertainty in predictions or exposures and for effects on different species. When assessing risks for humans, scientists include factors to take account of extrapolating information from tests on laboratory animals and variation in the human population. Detailed risk assessments have been carried out on relatively few chemicals.

Rotterdam Convention The Rotterdam Convention was negotiated between 1996 and 1998 and signed by some 60 countries and the European Commission at the Diplomatic Conference held in Rotterdam in September 1998. The aim of the convention is to assist importing countries (mainly developing and those in transition) to make informed decisions about the importation and use of hazardous chemicals and pesticides. The Convention's provisions will be introduced into UK law through a Council Regulation, currently in negotiation, and the Convention will be ratified by the EC and its Member States once that Regulation has been adopted.

Teratogenicity A property of a substance causing abnormalities in the embryo or foetus when administered to the mother or maternal organism.

Toxicity Harmfulness to living organisms. Toxicity is the capacity of a substance to cause toxic effects to organisms or their progeny, such as reduction in survival, growth and reproduction, carcinogenicity, mutagenicity, teratogenicity, and endocrine disruption (see separate entries for these).

Toxicology Properties pertaining to the scientific study of the chemistry, effects, and treatment of poisonous substances.

World Trade Organisation (WTO) is the only global international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments. The goal is to help producers of goods and services, exporters, and importers conduct their business.

NOTES

¹ In February 2001, the European Commission published its White Paper for a Future Chemicals Policy, setting out an approach to the regulation of chemicals based on a system called REACH (Registration, Evaluation and Authorisation of Chemicals)

² Throughout this document the term supplier is used to mean the manufacturer of the substance or, in the case of substances produced outside the EU, its initial importer

³ As defined in the Manual of Decisions for Implementation of 6th & 7th Amendments to 67/548/EEC on Dangerous Substances, Ref: NOTIF/3/2001: "a substance used exclusively for the synthesis of another substance(s) and solely manufactured for and consumed in a chemical reaction"

⁴ See for example the Business Impact Assessment carried out for DG Enterprise, available via <http://europa.eu.int/comm/enterprise/chemicals/index.htm>

⁵ The EU list of substances on the market before 18 September 1981

⁶ Available via the chemicals policy pages of the DG Environment (<http://www.europa.eu.int/comm/environment/chemicals/index.htm>) or DG Enterprise (<http://europa.eu.int/comm/enterprise/chemicals/index.htm>) web sites

⁷ http://ue.eu.int/newsroom/LoadDoc.asp?MAX=1&BID=89&DID=66742&LANG=1#_Toc517083966

⁸ Adopted on 15/11/2001, text available via EP web site at http://www.europarl.eu.int/home/default_en.htm or at http://www3.europarl.eu.int/omk/omnsapir.so/pv2?PRG=CALDOC&FILE=011115&LANGUE=EN&TPV=DEF&SDOCTA=9&TXTLST=1&Type_Doc=FIRST&POS=1