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HEALTH AND SAFETY COMMISSION

ADVISORY COMMITTEE ON TOXIC SUBSTANCES

New European Chemical Strategy

A paper by Graham Tompkins

Advisor: Peter Galsworthy

Cleared by John Thompson

Issue

1 The New European Chemical Strategy (NECS): update and forward look to legislative proposals.

Timing

2 Routine.

Recommendations

3 That ACTS agrees the proposed method for keeping up to date on the latest NECS developments and notes:

- the slow progress of the European Commission (EC) with their legislative proposals
- the most recent HSC paper 12 November 02 (Appendix 1) updating the Health and Safety Commission (HSC) of the possible impacts of NECS for HSE;
- the UK position statement (Appendix 2) that sets out the UK Government's overall objectives in relation to the forthcoming legislative proposals. The statement also provides the Government's view on a number of key issues, for example animal testing and intermediates.

Background

4 The EC published its White Paper a 'Strategy for a Future Chemicals Policy' in February 2001. The paper proposed a new scheme called REACH to manage the supply, manufacture, importation, marketing, classification and labelling of chemicals within Europe.

5 The scheme would require all chemicals manufactured in quantities of greater than 1 tonne to be registered, those manufactured at greater than 100 tonnes to be evaluated and certain substances of high concern (carcinogens, mutagens, substances toxic to reproduction (CMRs) and persistent organic pollutants (POPs)) to be authorised.

6 The HSC paper – HSC/02/143 (Appendix 1) and its annexes provide further background information. At its meeting on 12 November HSC discussed and endorsed the position outlined in the paper.

Argument

7 The EC had originally planned to release draft legislation by the end of 2001 but this was never likely to be feasible and is not now expected before Easter. Despite this delay the EC claims to be committed to finalise legalisation by 2004. The EC considered an informal electronic consultation process over the winter but so far this has not taken place. DEFRA (the lead Department) intend to consult within the UK and to respond formally to the consultation if it goes ahead.

8 With the detail of the legislation still unknown, the impact of NECS for Occupational Health and Safety and HSE remains unclear (see Appendix 1 for more information). What is obvious however is that REACH will bring major change to the way chemicals are regulated in the UK.

9 To influence the EC and other member states, the UK Government has developed a UK Position Statement (Appendix 2) setting out the basic principles for the UK. The HSC was consulted during the drafting of this paper and supported the aim of at least maintaining the current standards of OHS and where possible improving them (details have been submitted in ACTS paper 48/2002/Inf).

Communication Plan

10 Not Relevant

Evaluation Plan

11 Not Relevant

Relevant Control Systems

12 Not Relevant

Consultation

13 DEFRA have the UK Government lead on the NECS and have established a 'rapid reaction sounding board' with a wide stake holder base for informal consultation.

14 HSC continues to consult its own 'rapid response group' (a sub group of SCHIP) to contribute to HSE thinking as negotiations progress.

Presentation

15 DEFRA and DTI Ministers have taken an active interest. DWP Ministers have been briefed on NECS and have formally agreed the UK position statement.

Costs and Benefits

16 An initial business impact assessment estimates the cost of implementation of the new scheme to be between 1.7 – 7 billion euros depending on the number of chemicals to be registered and the level of testing required (see Appendix 1 for more information).

Environmental implications

17 The new system should provide the information necessary to control substances of concern (starting with the most harmful) to the environment. This is a key issue for DEFRA in their considerations.

European implications

18 The proposal is likely to consist of a European Regulation(s), the most centralised and direct regulatory instrument available to the Commission.

Devolution

19 Not Relevant at this stage (although DEFRA will be working with the devolved administrations).

Other implications

20 Not Relevant

Action

21 To ensure ACTS members are kept informed of the latest NECS developments, we propose to provide an update paper for each meeting and an additional paper or an oral presentation should developments arise after the first paper is issued.

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Appendix 1

Open Government status: Fully open **Exempt material**: None.	**Paper Number:** HSC/02/143 **Meeting Date:** 12 November **Type of Paper:** Above the line. **Paper File Reference:** **Intranet embargo:** No

HEALTH AND SAFETY COMMISSION

THE NEW EUROPEAN CHEMICALS STRATEGY

A Paper by Mark Blainey

Advisors: Bob Warner & John Thompson

Cleared by Sandra Caldwell on 23 October 2003

Issue

1. The impact of the New European Chemicals Strategy (NECS) on HSE.

Timing

2. Discussions on the UK's approach are ongoing within Government, and with stakeholders. EC negotiations are possible but unlikely before the middle of 2003.

Recommendation

3. That HSC note the continuing uncertainty over the scope, and impact, of the NECS; the occupational health and safety (OHS) benefits; and costs and benefits to HSE.

Background

4. The European Commission's White Paper proposed a system called REACH that requires chemicals manufactured in quantities greater than 1 tonne to be Registered, those manufactured in quantities greater than 100 tonnes to be Evaluated, and certain substances of high concern (eg carcinogenic, mutagenic and reproductive toxic substances (CMRs)) to be Authorised. DEFRA lead for the UK on the NECS (see Annexes 1 and 2 for more detailed background).

5. HSE is heavily involved in the chemical assessment schemes the NECS replaces:
    a. New substances notification,
    b. Existing Substances Regulation (ESR),
    c. Classification and Labelling (C&L),
    d. Marketing and Use.

6. The NECS has been criticised by industry as being expensive, although they have expressed support for its general principles. Trade Unions are concerned about possible job losses. It is generally accepted that it is difficult to quantify the gains the REACH system will

provide to occupational health and safety (OHS) but at present many suspect the gains to be marginal.

7. The EC originally promised draft legislation by summer 2002. It now looks as if formal proposals are unlikely before Easter 2003, but there could be some informal consultation over the winter. There is continuing uncertainty about the legislation's content, and its impact on OHS, and HSE.

8. DEFRA are co-ordinating the development of the UK position, both to influence the European Commission in its thinking, and prepare for the new legislation. As basic principles the UK is looking to ensure:

    - 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;
    - animal testing is kept to the minimum necessary to protect human health and the environment; and
    - the competitiveness of the chemical industry is maintained or enhanced.

Argument

9. Although there is existing OHS legislation to control chemicals, evidence from ill health statistics and experience from existing chemical schemes (para 5) indicates possible gaps in the current control regime, for example:

    a. cancer attributable to occupational exposure – 6000 deaths a year,

    b. skin disease caused by work - 66000 new or existing cases seen a year,

    c. occupational asthma – 1500 -3000 new cases a year (TUC estimate closer to 7000) costing the UK between £500 and £1000 million over the next 10 years (recent RIA for asthmagens ACoP),

    d. Work under ESR showing difficulties in controlling carcinogens (both by SMEs, and in transient activities).

10. But the issues that REACH is primarily designed to address, lack of knowledge about the hazards to the environment, and from the environment to human health, could have a number of significant benefits, such as (more detail in Annex 3) better:

    a. information generally on chemicals leading to:

        i. more informed workplace risk assessment (improved application of COSHH),

        ii. more accurate classifications of chemicals leading to better application of COSHH Essentials, and

        iii. identification of chemicals that should be subject to major hazards legislation.

    b. identification and control of carcinogens (and if included in authorisation occupational asthmagens) that would only be used for activities where business can demonstrate negligible risk.

    c. intelligence on possible causes of ill health allowing quick action.

11. HSE are assisting DEFRA and DTI in developing the UK position on REACH, because much of the UK government experience and expertise lies within HSE. HSE is the competent authority for much of the current legislation on new and existing chemicals.

12. It is not clear, however, to what extent HSE should be involved in the negotiation or implementation of the new scheme. There is an expectation that HSE will be involved but there are likely to be significant resource implications at each stage of the new system (registration, evaluation, authorisation) for whichever UK agency administers it.

Consultation

13. DEFRA have continued to consult their 'rapid reaction sounding board' on a number of issues (eg risk assessment). HSE stakeholders have been updated through ACTS and its subgroups.

Presentation

14. DEFRA and DTI Ministers have taken an active interest in the review. Nick Brown has not been briefed to date but DWP will be involved in any formal agreement of a UK position.

Costs and Benefits

15. An initial RIA of the White Paper was prepared by DEFRA, in consultation with HSE. A further assessment will be made following legislative proposals.

16. The European Commission recently undertook a Business Impact Assessment showing costs of between 1377 and 7043 million euros over the life of the programme. These are likely to be considerable underestimates because they ignore the costs for downstream industry and include in the baseline forecast, costs for voluntary industry schemes.

Financial/Resource Implications for HSE

17. The financial/resource implications for HSE/UK government remain highly uncertain, as they largely depend on external factors such as actual legislative proposals, roles of the European Commission (and perhaps a central agency) and Member states. This will be the subject of a further paper when we have more details of the actual legislative proposals.

Environmental Implications

18. DEFRA have the policy lead on the EC White Paper, which covers environment and human health issues.

Action

19. HSE officials will continue to work with DEFRA and OGDs on developing the new system.

Contact

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Annex 1

Background/History

1. The European Commission (EC) launched the NECS in February 2001. Its White Paper a 'Strategy for a Future Chemicals Policy' proposes a new scheme called REACH that requires chemicals manufactured at quantities greater than 1 tonne to be Registered, those manufactured at quantities greater than 100 tonnes to be Evaluated, and certain substances of high concern (carcinogenic, mutagenic and reproductive toxic substances (CMRs) and persistent organic pollutants (POPs)) to be Authorised (a more detailed explanation of the system can be found in Annex 3).

2. The NECS will bring about major changes to existing European measures that manage the supply of chemicals (for many of which HSE is singly or jointly responsible):

    a. Directive 67/548 on classification, packaging and labelling of dangerous substances;

    b. Directive 1999/45/EC on classification, packaging and labelling of dangerous preparations;

    The above 2 measures set out the EC scheme for classification and labelling (C&L), Directive 67/548 also includes a EC new substance notification system).

    c. Directive 76/769 on restricting marketing and use (M&U); and

    d. the Existing Substances Regulation (ESR): 793/93.

3. This legislation sets up a number of programmes for the identification and control of hazards of chemicals:

    a. New substances notification- HSE are joint Competent Authority (with DEFRA) but manage the scheme for the UK (NONS). HSE currently employ 17 people to deal with the scheme (1 policy and 16 technical staff). HSE assesses the 'health' part of notified dossiers (EA assess the environment part).

    b. Existing Substances Regulation (ESR) - HSE are joint Competent Authority (with DEFRA) and share the administration of the scheme. HSE currently employ 10 people to deal with the scheme (1 policy and 9 technical staff). HSE develop 'health' risk assessments (RA) and risk management strategies (RMS) for substances assigned to the UK from the various ESR priority lists. This team also contributes to several international initiatives.

    c. Classification and Labelling (C&L) - HSE lead on the scheme with DEFRA/DTI input. HSE currently employ 9 people to deal with the scheme (2 policy and 7 technical staff). HSE are involved in proposing health and physicochemical classifications for chemicals and assessing other MS's proposals. This team also carries out work on PIC, and provides HSEs input to development of REACH.

    d. Marketing and Use (M&U) - DEFRA lead but HSE contribute where there is a specific workplace issue. HSE currently employ 1 person to deal with the scheme (1 policy with technical staff from within the above resource). HSE lead where the main issue is OHS but are often drawn into wider health issues.

4. The White Paper identified a number of problems with these programmes with which the NECS will supposedly deal:

    a. New substances notification - it has been asserted that the current system stifles innovation of new (and possibly less hazardous) substances.

b. ESR - the programme has been slow to deliver (generally across Europe, UK has been one of the few MS to deliver on its targets) with only 11 of the 141 priority substances reaching the end of the system. Of these 11 substances, 6 are currently at various stages of the M&U system.

c. C&L - although not as criticised as the new substances legislation and ESR it has been slow to deliver on some chemicals due to discussions taking place on all end points. Its direct links with downstream law using its classifications (eg COMAH) can cause problems.

d. M&U - this programme has also proved slow to deliver outcomes due to the Council procedure for proposing and adopting amendments.

5. Last November the European Parliament (EP) recommended the scope of authorisation should be limited to CMRs and to POPs. This position differs from that of the Council, which called for the inclusion of persistent, bioaccumulative and toxic substances and very persistent and very bioaccumulative substances, and proposed a study into adding sensitising and chronically toxic substances.

6. Between September and February the EC ran seven working groups (WG) with nominated experts from Member States and other stakeholders. DEFRA represented the UK in the Testing Registration and Evaluation; Authorisation and Rapid Risk Management; Risk Assessment; and Substances of High Concern WG. DTI attended Substances in Products WG, and HSE officials were engaged in the Classification & Labeling; and Information through the Supply Chain WG. It is unclear how the outcomes of the WG are being considered by the Commission when preparing their legislation.

7. HSC have been updated several times since the White Paper was published:

a. HSC 01/99 (April 2001) agreeing initial objectives for NECS negotiations,

b. MISC/01/04 (August 2001) reporting on the development of NECS European Council Conclusions.

c. MISC/02/19 (July 2002) reporting on EC working groups held to develop the new system, and attaching the (then) current HMG position paper.

Annex 2
REACH – what is known to date

Scope

1. The White Paper foresees 30,000 substances subject to REACH (currently on the market above 1 tonne), of which 5000 are above 100 tonnes, and 1500 are above 1000 tonnes.
2. This does not take into account substances currently not marketed but that will be caught by the requirement to register substances produced above 1 tonne such as intermediates and polymers.
3. The recent European Commission's Business Impact Assessment scoped the number of intermediates produced above 1 tonne at 100,000 - the accuracy of the figure is unknown (35% of them were actually placed on the market, and 15% were produced under 1 tonne, it is also not clear if the above figures differentiate between 2 different companies using the same intermediate because of confidentiality issues).
4. The number of manufactured polymers is unknown but estimates of >10,000 have been put forward
5. The White Paper identified there would be 1350 CMRs (850 already identified and a further 500 identified during evaluation). The European Commission's recent 'Feasibility Study on the resource requirements for a central entity' suggests if PBTs, vPvB, sensitisers and chronic toxic substances are added to authorisation, then approximately 3900 substances would potentially need to be authorised. The UK estimates that PBT/vPvB would add about 120 substances to authorisation and targetted respiratory sensitisers (R42 that are recognised workplace asthmagens) another 20-30.

Registration

6. Registration requires a manufacturer or importer to notify an authority of the intention to produce or import a substance, in volumes exceeding 1 tonne and to submit an information dossier for substances produced:
    - > 1,000 t - by end of 2005,
    - > 100 t - by end of 2008,
    - > 1 t - by end of 2012.
7. The registration dossier will include the following information on:
    - The identity and properties of the substance,
    - Intended uses, estimated human and environmental exposure,
    - Production quantity,
    - C&L proposal,
    - Preliminary risk assessment for the intended uses (the manufacturer or importer as well as the downstream user to carry out adequate risk assessments), and
    - Proposed risk management measures.
8. The authority puts this information into an electronic database, assigns a registration number and performs spot-checks and computerised screening of the registered substances for properties raising particular concern.

9. Authorities must be informed about any downstream use which has not been covered by a manufacturer or importer, and which has not therefore been addressed in the preliminary risk assessment by the user through a postcard notification on the 'use' to the CE.

10. The recent Feasibility Study suggests:

- Some sort of preregistration would be helpful to allow consortia to be formed to share data (reducing costs and animal testing).
- The Central Entity would handle the entire task of registration.
- 2% of substances registered will be subject to a spot check. It is likely Member States will carry this out. It is not clear how labour intensive this will be.

Evaluation

11. Evaluation requires authorities to examine carefully the data provided by industry and also requires them to decide on substance-tailored testing programmes, following industry proposals.

12. Substances above 100 t: the manufacturer or importer will be required to submit to an authority all available information and to propose a strategy for further testing. The MS authority will evaluate the information and the testing strategy submitted by industry and will decide on the appropriate course of action. Testing programmes at Level 1 (100 t) and Level 2 (1,000 t) will be substance-tailored. Level 2 testing should be completed by 2010 and Level 1 testing should be completed by 2012.

13. Substances below 100 t: substances which are suspected to be persistent and liable to bioaccumulation, substances with certain hazardous properties such as mutagenicity or high toxicity, or substances with molecular structures giving rise to concern will require an evaluation by the authorities. Based on this evaluation, immediate safety measures and/or further testing may be needed.

Authorisation

14. For substances of very high concern, authorities will have to give specific permission before such a substance can be used for a particular purpose, marketed as such or as a component of a product.

15. Substances subject to authorisation (in the white paper) are:

- Carcinogenic, mutagenic or reproductively toxic (CMR) substances categories 1 and 2.
- Persistent Organic Pollutants (POPs) – these substances will now be covered by ARM (para 18-21).

16. The June 2001 Council Conclusions also called for Persistent, Bioaccumulative and Toxic (PBT) and very Bioaccumulative and very Persistent (vBvP) chemicals to be included in the authorisation procedure. The conclusions also called for the addition of sensitisers and chronic toxic substances to be studied.

17. Implementation of the authorisation process: A two-step decision-making process is proposed:

- Step 1 - identification of the substances, or particular uses of substances, which will be subject to authorisation. Once identified, authorities will provide a precise date when all unauthorised uses of the substance will be prohibited. Furthermore, step 1 will identify, as appropriate, the scope of the uses to be exempted generally from the requirement

for authorisation. Relevant substances will be fed into the system as soon as practicable, with substances of most concern being considered first.

- Step 2 - particular uses of a substance will be authorised on the basis of a life-cycle risk assessment submitted by the applicant to the authorities. An authorisation will be granted if the use presents a negligible risk. A conditioned authorisation may be granted if this is justified by the overall socio-economic benefits arising from the use.

Accelerated risk management (ARM)

18. Specific uses of substances that do not have one of the properties listed under the authorisation system but for which restrictions are needed should be addressed in an improved and accelerated procedure (current problems include the need to carry out comprehensive RA and a slow legislative process).

19. REACH will help accelerate RA because:

    a. There will be data available on the health and safety properties of all substances marketed > 1 tonne.

    b. The manufacturer/importers preliminary risk assessment will reduce the need for further assessment.

    c. Industry being responsible for preliminary risk assessments will reduce the delays encountered under the present system.

    d. Targeted risk assessments will replace the comprehensive risk assessments.

20. To contribute to an acceleration of the legislative process it is suggested:

    a. The precautionary principle will be invoked whenever the risk assessment process is unduly delayed and where there is an indication of unacceptable risk.

    b. The Commission should be authorised to use the Committee procedure under Directive 76/769/EEC (M&U) more extensively than in the past.

21. The recent Feasibility Study now suggests ARM will cover substances identified as a concern by a MS (or by the Commission), and substances identified during evaluation. The process can be triggered at national level and will require the MS to prepare a risk assessment to demonstrate the need for Community action. For substances identified at Community level as being of concern, or where a MS has justified taking community action, then a rapporteur would be appointed to prepare a Community risk assessment and a proposal for a ban.

Classification and labelling

22. Current legislation requires that dangerous substances are either classified and labelled in accordance with Annex I of Directive 67/548 (*harmonised classification*) or, if they are not included in this Annex, in accordance with the principles laid down in Annex VI of this Directive by industry (*self-classification*).

23. Authorities' resources should be focussed on the most relevant hazardous properties, such as carcinogenicity, mutagenicity and reproduction toxicity (CMR), where classification gives rise to important risk management measures.

24. The Commission will ask Industry to provide a list containing comprehensive information about the classification and the labelling of all dangerous substances on the market.

25. The current negotiations on the elaboration of a Globally Harmonised System provides an opportunity to review fundamentally the current labelling provisions, to consider simplification and to improve comprehensibility of the labels.

Annex 3

	What HSE currently do.	What the NECS will require.	Benefits of NECS to Occupational Health and Safety.	Effects of NECS on HSE (if involved).	
				Benefits	***Costs***
Registration	HSE manage the notification of new substance dossiers where the manufacturer/importer is based in the UK. European Chemicals Bureau (ECB) manages registration of substances under ESR. HSE shares management of Risk Assessment (RA) / Risk Management Strategy (RMS) production with DEFRA.	The Central Entity (CE), rather than Member States authorities, will undertake registration but there could be a role for MS in spot checking registrations.	Better information on chemical's hazards (available in a more transparent way) leading to better: • C&L, and thus improved: o COSHH Essentials, o major hazard identification. • SDSs; • worker information. • Information on intermediates/polymers	• high quality intelligence on chemicals. • benefits to COSHH Essentials (as above). • identification of priority chemicals eg asthmagens. • reduced administration of new substances.	• HSE could be involved in MS spot checking – with some impact on HSE resources.
Evaluation	HSE assesses industry risk assessments (for health) for NONS. HSE delivers ESR programme for human health (produces RA/RMS for UK substances and assess those of other MS.	Industries RA/RMS will be assessed by MS (or less likely by an independent European Agency).	Further elucidation of the chemical's hazards especially interpretation of difficult data (with more of the benefits described above). Checking RMS can deliver 'negligible' risk of using a chemical.	• more high quality intelligence on chemicals (with more of the benefits described above). • maintenace of HSE's credibility in this work area. • maintain their	• Risk of diversion from priority work. NECS doesn't fit well with current HSC objectives/revitalising. • significant resource demands that could be transferred to other priorities

	What HSE currently do.	What the NECS will require.	Benefits of NECS to Occupational Health and Safety.	Effects of NECS on HSE (if involved).	
				Benefits	***Costs***
				hazard and risk assessment expertise. • maintain some level of influence over the evolving system. • opportunity to identify and work with other's agendas for chemical control. • influence duty holders at a more strategic level.	other priorities if HSE were involved in REACH to a lesser extent or not at all.
Authorisation	No current equivalent for industrial chemicals.	For substances of very high concern, certain uses will be authorised.	control of certain chemicals that legislation currently doesn't control well. clearer requirements for business could lead to better control.	• clearer requirements for inspectors to monitor • control at source could free up resources to be spent elsewhere. • influence over	• It is not clear what resources will be needed for authorisation but it is possible it will be a multidisciplinary (eg policy, technical (toxicologists

	What HSE currently do.	What the NECS will require.	Benefits of NECS to Occupational Health and Safety.	Effects of NECS on HSE (if involved).	
				Benefits	***Costs***
				selection, prioritisation etc, • promote new groups of chemicals to be covered, • stop possible disruption of worker protection regimes.	and hygienists) and inspectorial) team. It is clear that this could be a major activity.
ARM	HSE lead on certain M&U amendments where worker protection is the main issue.	For substances identified as a concern, a MS rapporteur would be appointed to prepare a Community risk assessment and a proposal for a ban.	quick decisions on chemicals (or groups of chemicals) of concern for which no uses are to be allowed.	• influence over selection, prioritisation of chemicals going forward for ARM etc • influence over selection, prioritisation etc of chemicals subject to ARM,	• It is not clear what resources will be needed for arm but it is possible it will be a multidisciplinary team.
C&L	HSE are involved in proposing health and physicochemical classifications for chemicals (new or updates) and assessing other proposals.	Similar to the present system but authorities' resources would be focused on the most relevant hazardous properties	better C&L will mean improved: • COSHH Essentials, • major hazard identification.	• benefits to COSHH Essentials (as above). • influence over selection, prioritisation	• resources spent elsewhere if HSE were involved in REACH to a lesser extent or not at all

	What HSE currently do.	What the NECS will require.	Benefits of NECS to Occupational Health and Safety.	Effects of NECS on HSE (if involved).	
				Benefits	***Costs***
		properties. Industry will provide a list of classification and labelling of non harmonised endpoints.	• SDSs;	prioritisation etc, • less bureaucracy surrounding the UK legislative frame work on C&L.	or not at all.

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

December 2002

If you have any comments on this document, please send them to:

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Contents

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 REACH[1] 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 supplier[2] 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 intermediates[3] 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 120 000[4]. 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 (**E**uropean **In**ventory of **E**xisting **C**ommercial **S**ubstances)[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

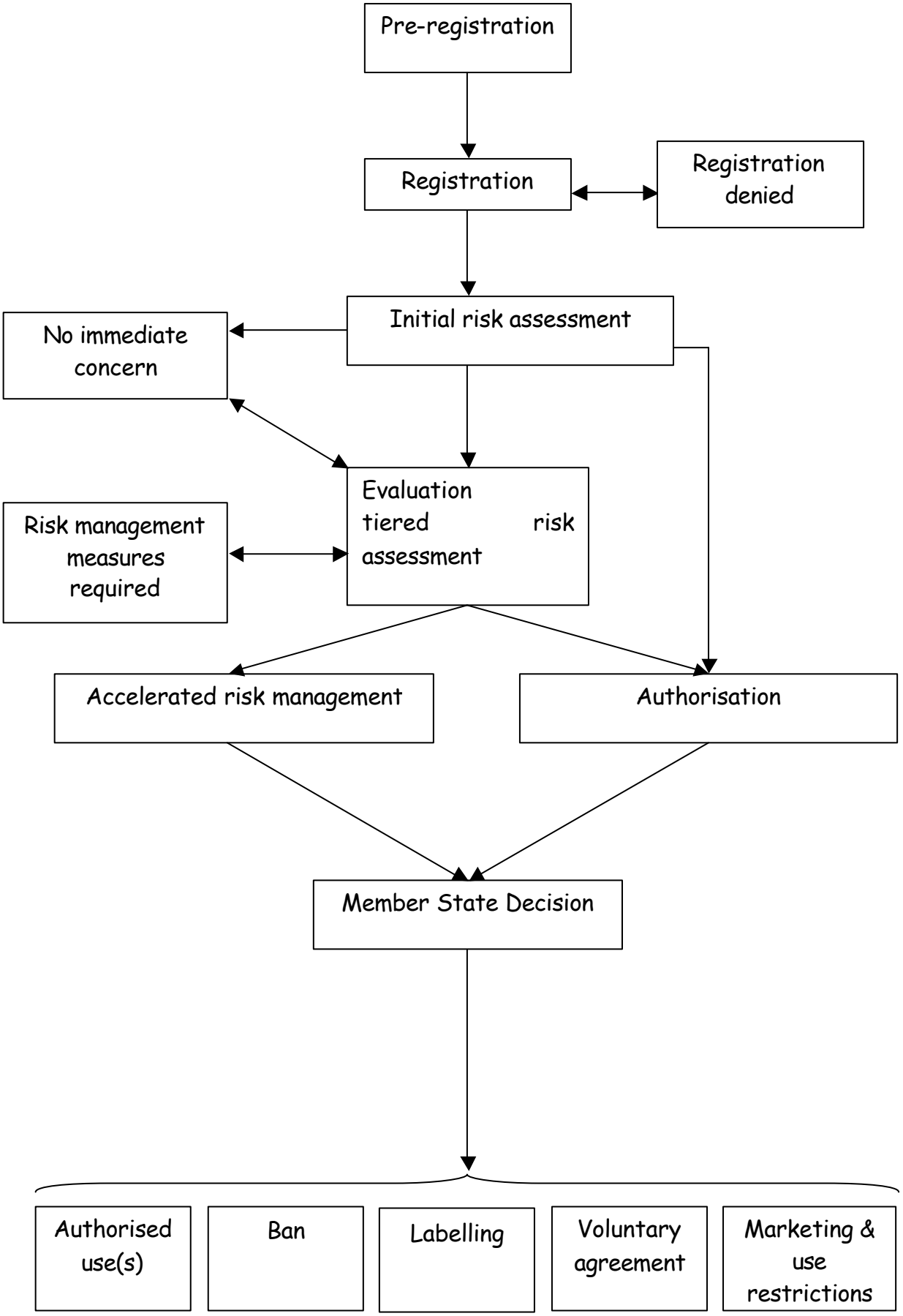
as the necessary criteria for their identification are established. In addition, we believe that certain targeted respiratory sensitisers (those classified with R42 and recognised as major causes of asthma in the workplace) should also be included. When scientifically validated test methods have been 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 Policy[6], setting out an approach to the regulation of chemicals based on a system called REACH (**R**egistration, **E**valuation and **A**uthorisation of **Ch**emicals). EU Environment Ministers meeting in June 2001 adopted a comprehensive set of conclusions that gave clear directions for the shaping of new legislation[7]. In November that year, the European Parliament put forward its views on the White Paper too[8].

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 (**R**egistration, **E**valuation and **A**uthorisation of **Ch**emicals)

[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