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HEALTH AND SAFETY COMMISSION

HSE's involvement in the new European system for the supply and use of chemicals

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Issue

1. The new system – REACH (Registration, Evaluation, and Authorisation of Chemicals) – will become the primary tool for delivering improved control of chemicals in the workplace. In the light of the Hampton review and other factors, how should HSE be involved in this new European system for the assessment and use of chemicals? In particular, should HSE be at the centre as part of the UK REACH competent authority?

Timing

2. Urgent. DEFRA have set a deadline of 30 September for the submission of full business cases from agencies bidding to be the UK REACH competent authority.

Recommendation

3. The Commission considers how HSE should respond – take no action, prepare a detailed business case to operate the UK Competent Authority, or open negotiations with a potential partner.

Background

4. Brief factual information on REACH is at Annex 1. It will bring significant changes to the present approach to the regulation of chemicals:

- REACH will establish an EU Chemicals Agency to coordinate European activity on chemicals; and it will provide tools for Member State regulators to impose controls on chemicals at EU level.
- REACH will be an EU Regulation putting duties directly on industry. Responsibilities for assessment of chemical safety will be shifted from employers (users) to suppliers. Suppliers will have to support uses of their chemicals, do risk assessment, set risk management measures, and communicate all this to users.
- Although REACH does not revoke the Chemicals Agent Directive (COSHH in GB), it will reduce its importance in the future as under REACH suppliers will take key decisions about when and how to use chemicals before the chemical reaches the user. Users must implement the risk management measures the supplier specifies, with the expectation they will not need to do more. HSE would then enforce this in workplaces.
- REACH will repeal the present controls on new and existing substances and transform them into a holistic, proportionate, targeted system addressing risks to people (workers and consumers) and the environment from all substances (>30,000) supplied and used in the EU.

5. The legal base for REACH is Article 95 (single market). Negotiations are currently taking place in both the Competitiveness and Environment Councils, and in Parliament. DEFRA lead, and are working hard to achieve political agreement on REACH during the UK Presidency (July to December). It is anticipated that REACH will come into force in late 2007.

6. REACH will require each Member State to appoint a Competent Authority to work with the EU Chemicals Agency and with other Member State Competent Authorities to carry out functions under the Regulation (Annex 2). In 2004 a cross-Government group (including HSE) met several times to consider the structure and functions of a UK Competent Authority. However, the group was disbanded when the Pesticides Safety Directorate (PSD) and Environment Agency (EA) independently put outline business cases to DEFRA to take the role of the REACH Competent Authority.

Argument

7. HSC/E's current position on REACH dates from November 2002 when the Commission last considered its strategy on chemicals. The policy agreed then was to keep REACH at arms length and to leave it to others wherever possible, avoiding commitment of HSE resource. This reflected the view that:

- HSE already did too much on chemicals which are not central to HSE's business, and involvement in REACH would demand even more resource
- REACH would not directly help HSE deliver its PSA targets
- REACH was driven primarily by environmental concerns
- REACH was a huge legislative project with uncertain prospects of implementation.

8. This policy has signalled to others in Government and industry that HSE intends to withdraw from work on chemicals. HSE (with the EA) leads on the current EU wide regulation of industrial chemicals, and is the Competent Authority for the present schemes for new and existing substances.

9. We believe it is now appropriate to review this position in the light of:

a) The outcome of the Hampton review, which reinforced a risk-based approach to regulation applied by fewer regulators. HSE already has a lead role in chemical regulation, which is closer to HSC/E's core business than other agencies that Hampton recommended should merge with HSE. There would be other possible homes for the chemical work within Hampton's framework, but his report does change the context.

b) The wider picture on the regulation of chemicals across Government. Annex 3 provides an outline summary of where responsibilities presently lie for the regulation of medicines, pesticides, biocides, cosmetics, etc. The picture is complex, reflecting many different EU schemes driving this work. Key points are:

   i. An integrated, holistic approach to chemical regulation does not sit easily with Hampton's broad categorisation of regulatory areas as health and safety, environment or consumer protection. Post-Hampton creation of a single chemicals agency seems unlikely.

   ii. DEFRA is currently considering options for its Agencies, and in particular for PSD. The options include merger with other regulators, or expansion of PSD's remit to include biocides and possibly chemicals under REACH. EA are enthusiastic to absorb PSD and take on REACH.

   iii. HSE is presently considering whether to transfer its biocides work (around 50 staff) to PSD. However, this decision is on hold until the arrangements for the REACH competent authority are clearer.

iv. Medicines, pesticides and biocides are regulated by Government approval of individual products. This is very resource intensive and contrasts with general chemicals where the approach is to put the onus on industry (and in future under REACH particularly on suppliers) to assess and manage risk, and to give regulators options to intervene.

c) The alignment between REACH and HSC/E's approach to chemical regulation. The European Commission made significant changes in response to consultation on early drafts of REACH. There is now greater clarity that:

- REACH is not an approval scheme. Authorisation will only apply to some 3% of the 30,000 substances in scope of REACH. Authorisation will be given at EU level.
- REACH is about ensuring "a high level of human health, especially the health of workers" as well as the environment. The approach in REACH aligns well with HSC/E's approach of putting responsibility for safe use of chemicals firmly on industry and providing regulators with tools to intervene where they judge this is necessary and proportionate.
- The broad objectives of REACH match those in HSE's Disease Reduction Programme[1], which has been developed recently as an integral part of the FIT3 programme to deliver the PSA target. Like REACH, the Disease Reduction Programme recognises the need for greater focus on suppliers to achieve ill health reductions.
- REACH has built in checks and balances providing flexibility for Member States to take forward their objectives for managing chemical risk within a targeted, proportionate approach (see Annex 4).

10. The main options for HSE are:

- To maintain the position agreed in 2002, and seek to influence the agency appointed as the UK Competent Authority as necessary to take due account of occupational safety and health, and of our priorities in the context of HSE's Disease Reduction Programme
- To seek to be the Competent Authority for REACH
- To negotiate with another agency to submit a business case with a bid to be the Joint Competent Authority.

11. Before considering the options individually, three general points need to be made:

- DEFRA has said it will only consider proposals for a single UK Competent Authority, so if the Commission prefers the third option, a fallback should be agreed in case it does not run.
- In the longer-term work on general chemicals, biocides and pesticides may be brought together. The Commission will want to consider the consequences of this for HSE in making its decision on REACH.
- It is not possible to determine yet which option would leave HSE with the most resource to devote to its (other) priorities, as explained in paragraphs 16 and 17. However, the Commission could make clear that it would not agree to proceed with any option which, on examination, required a transfer of resources currently spent elsewhere in HSE.

12. The case for HSE to bid to be the Competent Authority is in summary:

- We would be much better able to reduce occupational disease and thereby contribute to the RHS/PSA targets because we could both determine priorities and influence risk management measures (e.g. in the use of isocyanates – a primary cause of occupational asthma)

[1] Improved commitment to control hazardous substances, better control of hazardous substances, increased elimination of the most hazardous chemicals, and more effective enforcement.

- We could benefit reputationally especially if, as in the past, we provide a more proportionate counterbalance to some of the extreme environmental lobby
- It builds on our existing expertise, including bolstering the significant chemicals work currently done at HSL
- It fits with a possible post-Hampton vision of our becoming a core health and safety regulator with significant scientific underpinning.

13. The case against is:

- We risk diverting our resources to a range of environmental issues which are a long way from our core business
- We face reputational risk from being part of a wider EU system which we do not control
- It runs against a growing trend of HSE moving away from authorisation/standard setting (e.g. in railways, machinery) and focusing on duty holders.

Annex 4 sets out more fully the benefits and risks of HSE being the Competent Authority for each of the main activities under REACH.

14. Whatever the decision, HSE and local authorities will also have to enforce the outputs of REACH, e.g. restrictions and authorisations on chemicals and occupational exposure among users, in the workplaces they inspect. If HSE is not the competent authority a new set of interfaces will have to be established and managed.

15. Negotiating for a bid to be the Joint Competent Authority is likely to disperse the reputational risks somewhat, while securing considerable influence over restrictions in particular. If the Commission believes that it is important to maintain leverage here for strategic reasons, it may seem an attractive compromise. However, if DEFRA's position holds, a decision will still be needed on whether the significance of the chemicals area to HSC's strategy, and the potential loss of expertise and leverage, outweighs the reputational risks and management demands.

Costs and Benefits and Financial/Resource Implications for HSE

16. If HSE does not become the Competent Authority for REACH it is clear that the staff and resource we presently have to operate the existing chemicals schemes on behalf of Government (25 to 30 staff, ~£1.5m pa, plus some staff in HSL) will be transferred to whoever takes on this role. There would be a risk from such a loss to HSE's disease reduction, major hazards and other chemical-related programmes, which rely on toxicological and occupational hygiene expertise. HSE's Chief Scientist has indicated that this risk could be managed by a reconstituted Science Strategy Committee.

17. If we were to bid to become the Competent Authority the next step would be to develop a full business case to make clear to DEFRA the costs of taking on this work. Under REACH there is some discretion in the amount of work a competent authority chooses to do. We believe that the resource needs would be no greater than those we have now to run the existing schemes for new and existing substances. This aligns well with estimates made at EU level in the context of implementation of REACH. We understand from DEFRA's lawyers that it should be possible to charge for some REACH work, as we do now under the present chemical schemes.

Consultation

18. Discussions indicate that the European Commission would welcome HSE as the Competent Authority for REACH. The Chemical Industries Association and others in the industry would welcome HSE's proven expertise and knowledge of chemical assessment in the Competent Authority. However, industry wants one coordinated competent authority for REACH, and not a joint authority addressing environmental and health and safety aspects separately.

Presentation

19. The outcome will need to be presented in the context of the best way forward both for Government as a whole in regulating chemicals, and for HSE in achieving its mission to protect people's health and safety by ensuring that risks in the changing workplace are properly controlled.

Environmental Implications

20. REACH will be a holistic scheme covering both environment and human health issues including worker protection. HSE has well-established and effective partnerships for successfully addressing environmental concerns about chemicals. If we were the UK Competent Authority we would seek to maintain these under REACH.

Action

21. The Commission is invited to consider how REACH fits with HSC/E's strategy, and which option(s) in paragraph 10 it wishes HSE to pursue.

Annex 1

REACH - General Information

1. There are around 100,000 industrial chemicals registered in the EU, of which around 30,000 are manufactured or imported in quantities above 1 tonne. Adequate data on the environmental and health effects is presently available for only a small proportion of these chemicals. The existing system for dealing with chemicals has been very slow to assess and where necessary improve standards of control. This is one of the drivers behind REACH.

2. REACH will replace the existing regulatory schemes for new and existing substances and the system of Marketing and Use Directives with provisions for targeted and proportionate controls on the supply and use of chemicals. REACH aims to ensure a high level of protection for human health and the environment, while ensuring the efficient functioning of the internal market, and stimulating innovation and competitiveness in the chemical industry. The primary responsibility is placed on suppliers, particularly those at the top of the supply chain.

3. Under REACH all chemicals manufactured or imported in volumes greater than 1 tonne per year are to be registered in a central database. Chemicals supplied in quantities greater than 100 tonnes are subject to evaluation. Substances of highest concern e.g. carcinogens, mutagens and substances toxic to reproduction (CMRs) are also subject to authorisation for use at EU level whatever the quantity.

4. REACH takes the form of an EU Regulation that will come into force in all Member States at the same time. Member States will have to implement their own enforcement provisions to check users are correctly applying the risk management controls passed down to them by their supplier.

5. The main approaches of the new REACH scheme include:

   - **Registration:** A requirement on industry to collect, collate and submit data on the hazardous properties of all substances manufactured or imported into the EU in quantities above 1 tonne per year. In addition, industry should prepare risk assessments and provide safety information to downstream users.

   - **Evaluation:** There are two types of evaluation.

     - Dossier evaluation all substances manufactured or imported into the EU over 100 tonnes per year are subject to Dossier Evaulation. The Competent Authority of the Member State where the substance is manufactured or imported must assess and agree any testing proposals put forward by the registrant. The evaluation checks if test data for the substance is already available, and whether alternative tests could be employed to prevent unnecessary animal testing. (Note: There is a strongly emerging view in the EU Council and Parliament that this work should be undertaken by the European Chemicals Agency.)

     - Substance evaluation provides a mechanism for an individual Member State Competent Authority to review a registration packages in the light of domestic concerns or priorities. Member States may review the information provided and propose an EU wide restriction or authorisation.

- **Authorisation:** Industry will need to gain authorisation to use of substances considered to be of very high concern. Applications are made to and the process managed by the European Chemicals Agency. Substances subject to Authorisation are those identified as carcinogenic, mutagenic or toxic to reproduction (CMRs); persistent, bioaccumulative and toxic substances (PBTs); substances that are very persistent and very bioaccumulative (vPvBs); and substances demonstrated to be of equivalent concern, such as endocrine disruptors.

- **Restrictions:** REACH enables risk reduction measures to be introduced across the European Community where this is shown to be necessary. Individual Member States or the Commission can prepare proposals for restrictions.

- **European Chemicals Agency:** REACH creates an agency for managing the overall technical and administrative aspects of the REACH system at Community level. In addition it has important specific functions in relation to key aspects of the proposal; for example, Registration and Authorisation. See Annex 2 for details. The Agency will be based in Helsinki Finland.

- **Member State Competent Authorities:** Each Member States is required to appoint a competent authority to be responsible for performing tasks allocated to the authority under REACH. See Annex 2 for details.

Annex 2

The Role of the European Chemicals Agency

The Agency is responsible for the day-to-day management of technical, scientific and administrative aspects of REACH. Key tasks for the Agency are to:

- Provide technical and scientific guidance and support on the operation of REACH for Member State Competent Authorities and for industry;
- Manage the Registration process, checking the completeness of Registration packages and rejecting incomplete registrations;
- Set criteria to assist Member States in prioritising substances for substance evaluation, and co-ordinate the work of Member States' Competent Authorities to ensure harmonised approach to evaluation;
- Set priorities for substances which need to be authorised and manage the authorisation process;
- Provide scientific opinions for Commission decisions to grant authorisations or introduce restrictions for a substance;
- Deal with appeals on registration, evaluation and confidentiality;
- Publish non-confidential chemical data on a publicly accessible database;
- Provide a secretariat for the Agency committees.

The Tasks of the Member States under REACH

Under REACH it is anticipated that the Competent Authority will undertake the following tasks:

- Provide advice to manufacturers, importers, downstream users and other interested parties on their respective responsibilities and obligations under REACH (Competent Authorities' help desks);
- Evaluate any testing proposals made by Registrants who are seeking to obtain further information about their substance (Dossier Evaluation), and prepare draft decisions on industry's proposals for consideration by Member States and the Agency. **Note:** There is a strong emerging view in the EU Council and Parliament that this work should be transferred to the European Chemicals Agency;
- Evaluate substances of high concern (Substance Evaluation) and prepare draft proposals for regulatory action for consideration by Member States and Agency;
- Suggest harmonised Classification and Labelling for carcinogenic, mutagenic and reprotoxic substances, and for respiratory sensitisers (Note: the Council and Industry are pressing for the scope of harmonised classification in REACH to be extended);
- Identify substances of very high concern for authorisation;

- Propose restrictions;

- Propose members to serve on the Agency committees. The work includes resolving any difference of views following evaluation, considering proposals for restrictions and harmonised classification and labelling, and identifying substances for authorisation;

- Provide adequate scientific and technical resources to the members of the Committees that they have nominated;

- Enforce REACH in the Member State.

Annex 3

The main areas in which work on chemicals is presently undertaken across Government

Area	Work done now by	Policy lead
Human medicines	MHRA (Medicines and Healthcare Products Regulatory Agency)	DH
Veterinary medicines	VMD (Veterinary Medicines Directorate)	DEFRA
Pesticides	PSD	DEFRA
Biocides	HSE	HSE
Chemical additives, etc in food	FSA	FSA
Cosmetics	DTI (with DH support)	DTI
General chemicals	HSE (with EA)	HSE

Notes

1. Many national and EU-wide programmes influence this work. All involve the expert assessment of chemical hazard and exposure, and the management of risk to people. For pesticides, biocides and general chemicals the risks also cover the environment, though environmental factors can also arise with medicines.

2. Within these different areas there are very different approaches to regulation:

- For medicines, pesticides and biocides Government does the risk assessment, sets risk management controls, and approves individual products before they are supplied or used.
- Food additives are approved following risk assessment agreed at EU level.
- Cosmetic products do not require approval but their ingredients must either be taken from a positive list agreed at EU level, or the supplier takes responsibility for the necessary risk assessment and management.
- The great majority of general chemicals are not subject to risk assessment by Government. A very small minority are subject to risk assessment, and controls can be agreed at EU level. This is not an approval.

Under REACH, suppliers will do the risk assessment and set the risk management controls for general chemicals. Member State regulatory authorities will check users are correctly applying the risk management controls and Member State competent authorities will pursue chemicals of high concern as appropriate, with the options of restriction or authorisation at EU level.

Annex 4

Table 1 - Potential benefits and risks for HSE in taking the role of the UK Competent Authority for REACH

REACH Activity	Benefits	Risks	Relevant factors
Registration Registrants submit data on hazardous properties of their substances. They prepare Risk Assessments and provide safety information to Downstream Users.	HSE would be able to engage with registrants of substances recognised as contributing to ill health to ensure that appropriate risk management measures are being proposed.	HSE resource is diverted by debate with stakeholders about aspects of the registration not related to occupational health.	The work of the Competent Authority will be set within the context of Government priorities and objectives (e.g. DEFRA for environment). Stakeholders are likely to aim to influence Department's agendas rather the Competent Authority. HSE has successfully managed the present EU schemes for new and existing substances for more than a decade. We have well-developed web-sites, web-tools & guidance in place. HSE has developed a range of partners who respond to routine queries on chemical management.
Dossier Evaluation. The Evaluation of Registrants testing proposals at >100 tonnes. **Note:** There is a strong lobby in the Council & European Parliament for this work to be undertaken by the European Chemicals Agency.	This work will assist in the identification of knowledge gaps for high volume chemicals.	HSE is overloaded with testing proposals to evaluate.	With much experience in this area through its work on existing regulatory programmes and on animal alternative test methods HSE is well-placed to efficiently and effectively do this work contributing to Government objectives on minimising the number of animal tests and reducing regulatory burdens on business.

REACH Activity	Benefits	Risks	Relevant factors
Substance Evaluation. Identifying and undertaking evaluation of substances identified by the UK as priority substances.	HSE is well placed to influence decisions about substances that are a UK priority for evaluation. For example, substances such as asthmagens, where improved knowledge and control could contribute the Disease Reduction Programme. The evaluation is likely to be the basis of any UK restriction or Authorisation proposal to improve control of the substance. HSE will maintain its ability to influence the European Agenda on chemical priorities and approaches. HSE retains toxicological and occupational hygiene resource to input into HSE's chemicals, major hazard and other programmes.	HSE is pressured by stakeholders or from within Government to evaluate particular substances as a priority. HSE's evaluation results are challenged and its reputation damaged.	As the Competent Authority, HSE will be well placed to contribute to the development by the Chemicals Agency of the criteria for prioritising substances for evaluation. HSE has a lot of experience in successfully negotiating appropriate priorities for action within EU fora. Although the Competent Authority drafts proposed action following its evaluation, the action is subject to agreement by a Committee of all Member States. Any appeal about the decision by industry is made to the Agency not the Competent Authority. We understand from DEFRA's lawyers that it should be possible to charge for evaluation work.
Authorisation for the use of substances of high concern e.g. carcinogens.	The programme for managing substance authorisation will be developed by the Agency. Through its evaluation work the Competent Authority will be able to propose substances for authorisation. This is a key mechanism by	HSE is pressured by stakeholders or from within Government to recommend authorisation of particular substances as a priority e.g. environmentally damaging chemicals.	As the Competent Authority, HSE will be well placed to contribute to the development by the Chemicals Agency of the proposed Annex of substances requiring authorisation. HSE has a lot of experience in successfully negotiating appropriate priorities for action within EU fora.

REACH Activity	Benefits	Risks	Relevant factors
	which HSE could influence improved controls for substances and uses we identify as a particular concern under the Disease Reduction programme eg carcinogens. With a wide experience in framing conditions for use in developing EU-wide chemical risk reduction strategies and using inspectors front-line knowledge we can ensure that the controls required are proportionate and practical.	HSE is criticised by stakeholders for decisions made.	Although the Competent Authority may propose the authorisation of a substance on the basis of its evaluation, the proposal is subject to agreement by a Committee of all Member States. Industry has an opportunity to comment to the Agency on its proposed conditions for authorisation prior to the final decision. Under REACH authorisation is given at EU level by the European Commission and not by the Member State competent authority.
Restrictions A mechanism for addressing unacceptable risk to human health or the environment on a Community wide basis.	This is a mechanism by which HSE could seek to restrict the marketing or use of a substance we identify as a particular concern. As in the case of Authorisations, HSE is well placed to ensure that the agreed restriction is proportionate and achievable.	The Competent Authority is pressured by stakeholders or from within Government to recommend restrictions for particular substances as a priority. HSE is criticised for decisions made	The comments above about the Authorisation procedure are also applicable to the Restrictions process.
Classification of dangerous substances – mechanisms to ensure that the classification	Classification is the foundation for the regulation of risks arising from chemicals. It impacts more on HSE than on any other part	HSE is drawn increasingly into disputes with suppliers about substance classification.	Classification is a sensitive issue because of its potential business impacts. However, the proposed classification system under REACH is

REACH Activity	Benefits	Risks	Relevant factors
adequately reflects the hazards associated with the substance.	of Government. Classification changes may directly impact on workplace controls or on the number of sites subject to COMAH. As the Competent Authority we would retain our direct input into the classification system.		not sufficiently different from the existing system that HSE enforces, and which already covers health and safety as well as the environment.
Enforcement & Advice – mechanisms to ensure that the provisions of REACH are complied with.	Through its inspection and information networks HSE is well placed to secure compliance with REACH throughout the chemical supply chain – securing benefits in the workplace without major shifts in current levels of enforcement activity.	Resource is diverted from other priority areas because HSE is drawn into enforcement of consumer and environmental issues	HSE leads on implementation of EU classification and labelling legislation. This contains consumer and environmental requirements. HSE manages these areas effectively in partnership with the LA Co-ordinators of Regulatory Services, the Environment Agency & other providers of environmental services e.g. Envirowise. We anticipate that these partnerships will continue under REACH.