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## HEALTH AND SAFETY COMMISSION

### REACH developments

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#### Issue

1. To update the Commission on the new EU requirements for the Registration, Evaluation and Authorisation of Chemicals (REACH). It invites the Commission to agree the arrangements for HSE to fulfil the role of UK REACH Competent Authority (CA), as well as responding to Defra's public consultation on the enforcement of REACH.

#### Timing

2. REACH enters into force on 1 June 2007, and the CA arrangements need to be in place as soon as possible. Defra's consultation deadline is also imminent.

#### Recommendation

3. The Commission:
  - endorse Agency Agreements as the mechanism for delegating CA functions to HSE, as described in paragraphs 8 to 10.
  - note the enforcement arrangements proposed by Defra in their consultation, and respond as set out in paragraphs 12 to 15, and Annex 1.

#### Background

4. REACH is the new system for controlling chemical hazards across Europe. It will replace existing requirements in the European Council Existing Substances Regulation, the Notification of New Substances Regulations 1993, the European Marketing and Use Directive, and Regulation 5 of the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP), which relates to Safety Data Sheets. It also amends the safety data sheet provisions in the Dangerous Preparations Directive, and several relatively minor aspects of other domestic regulation. Although REACH will enter into force on 1 June, the

provisions are phased-in over the next 11 years. A summary of the REACH Regulation is at Annex 2.

5. As the Commission is aware, following discussions across UK government, DEFRA nominated HSE to be the UK CA for REACH in October 2006. The Commission has previously discussed REACH's relationship with existing regimes for worker health and safety – particularly COSHH. An update is at Annex 3.

### **Competent Authority**

6. HSC/E needs a legal basis for performing the functions of REACH CA, as distinct from enforcing REACH covered in paragraphs 11ff. Formally, these functions will properly be held by Ministers in Westminster and the Devolved Administrations, so it is necessary to arrange the delegation of these functions to HSC/E.
7. The CA will act on behalf of the whole UK government. REACH covers a broad range of issues, including occupational health and safety, environmental protection, public health, and consumer protection. Some of these are devolved issues, while others are reserved to Westminster, and establishing a UK-wide CA in this context has presented some challenges. A summary of REACH responsibilities and proposed arrangements for the UK, Great Britain, and each country is included at Annex 4. It is necessary to reflect this distribution in arrangements for establishing HSE as the CA.
8. HSE has worked with Defra and the Devolved Administrations to develop a mechanism for ensuring the CA function can be performed by HSE with the necessary *vires*.
9. HSE proposes to adopt the usual mechanism for establishing legal authority to act as Competent Authority - HSWA Section 13.1(b) 'Agency Agreements' between relevant Ministers and the Commission, covering functions agreed by the Health and Safety Sponsor Department (HSSD) Minister - Lord McKenzie at DWP - as relevant to the functions of the Commission. The Commission would then direct HSE to perform these functions on its behalf. An example Agency Agreement is included at Annex 5. If the Commission agrees, HSE proposes seeking approval from the Chair for the final versions of the Agency Agreements.
10. Ministers must be formally responsible for Competent Authority functions before they are able to delegate these to HSC/E. This will be achieved by:
  - a. A Designation Order in Council providing the power to make regulations under Section 2(2) of the European Communities Act, designating the Secretary of State for the Environment as able to appoint REACH CAs.
  - b. The Secretary of State appointing relevant parties as CAs.
  - c. These parties then delegating their functions to the Commission, and the Commission in turn directing HSE to perform these functions on its behalf.

## **Enforcement**

11. On 13 March, Defra published a Consultative Document on the enforcement of REACH in the UK, included at Annex 6. This public consultation will pave the way for the drafting of UK regulations to provide the legal basis for enforcement. HSE has worked closely with Defra on the enforcement arrangements for REACH generally and on the draft Consultative Document specifically.
12. There are three broad areas for REACH compliance: registration; supply chain; and end use. The Consultative Document proposes that the CA (HSE) should enforce registration issues, HSE should enforce supply chain issues, and a range of enforcing authorities including HSE should enforce at the point of use.
13. HSE currently enforces the supply chain aspects of the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP). Defra's proposal that HSE take on the supply chain aspects of REACH is based on the similarities they have to CHIP obligations, and that a single regulator is desirable for issues that are likely to involve multiple dutyholders.
14. The proposals are 'Hampton-compliant', in that they avoid creating a new regulator and as far as possible maintain the existing relationships between dutyholders and enforcers.
15. HSE is broadly content with the Consultative Document, and invites the Commission to respond positively to Defra's proposals. A draft letter is included at Annex 1.

## **Consultation**

16. Across HSE, including Legal Adviser's Office and PFPD, with Defra and the Devolved Administrations. On enforcement, there has been additional engagement with the Environment Agency, LACORS, SEPA and HSENI, as well as several trade associations.

## **Presentation**

17. Defra is leading on REACH communications, and is refining a draft strategy compiled by HSE. We anticipate that industry and other interested parties will broadly welcome the proposals in Defra's Consultative Document as they are a sensible extension of the existing arrangements and are 'Hampton-compliant'.

## **Costs and Benefits, Financial/Resource Implications for HSE**

18. Defra has agreed to pay HSE £1.1m to deliver the Competent Authority for the first year, which is tied to a Business Plan and Memorandum of Understanding establishing the delivery parameters for 2007/08, and a similar arrangement being put in place for the following year. HSE and Local Authority activity in supply-chain and end-use enforcement is outside the scope of this funding and will have to be addressed separately in considering the downstream enforcement of REACH alongside COSHH and other chemicals legislation. Practical enforcement of downstream requirements of REACH will not be an issue for 3 years following the first tranche of registration under REACH.

19. Defra has previously published an RIA assessing the impact of REACH as a whole, which estimates the total cost of REACH to UK industry as £515m over the 11 year period during which REACH provisions enter into force. For occupational health, the RIA estimates that 0.4 to 1.5% reduction in non-asbestos cancer deaths would balance the costs to UK industry from REACH.

### **Other implications**

20. None

### **Next steps**

21. The Commission is asked to:

- a. Endorse the use of the normal mechanism (the Agency Agreements) for delegating CA functions to HSE as outlined in paragraph 9, noting that the Commission will be invited to agree final versions of the Agency Agreements before signature.
- b. Agree a positive response to the Defra enforcement consultation as outlined in paragraph 15 and Annex 1.

## **Annex 1**

### **SUGGESTED DRAFT LETTER FROM HSC TO DEFRA, RESPONDING TO THE CONSULTATION**

The Health and Safety Commission welcomes the recent public consultation on the development of arrangements to enforce the new European Registration, Evaluation and Authorisation of Chemicals Regulation (REACH).

REACH is an important development in our aim to reduce occupational ill-health by improving standards of control of risks to workers posed by chemicals used in the workplace. The Commission also recognises that the REACH system brings together a number of different areas where chemicals can cause harm if not properly controlled, including the environment and wider public health.

We were pleased to learn that the arrangements described in the Consultative Document published on the 13 March have been developed in co-operation with the Health and Safety Executive and other bodies.

The Commission endorses the way forward suggested in the Consultative Document, and in particular supports an approach to establishing a penalty regime for REACH that dovetails with the current approach to breaches of health and safety law, taking account the Commission's view that penalties for such breaches could reasonably be higher in order to act as an effective deterrent.

The Commission notes that the proposed enforcement regime will require a high degree of cooperation between all the bodies taking on enforcement responsibility. We trust therefore that you will provide the necessary impetus and assistance to enable the enforcing authorities to develop the appropriate liaison arrangements.

The Commission looks forward to commenting on the draft regulations in a future consultation.

Yours sincerely,

Bill Callaghan,  
Chair, Health and Safety Commission

## Annex 2

### A SUMMARY OF REACH

REACH will replace the existing legal framework for new and existing substances.

REACH is an EC 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 ensure that manufacturers and importers meet their registration responsibilities and that users correctly apply the risk management control measures passed down to them by their supplier.

REACH does not revoke the Chemical Agents Directive or the Carcinogens and Mutagens Directive (implemented by COSHH in GB).

The main elements of the new REACH scheme include:

**Registration** - A requirement on industry to collect, collate and submit data on the hazardous properties of substances manufactured or imported into the EU in quantities above 1 tonne. In addition, industry should prepare risk assessments and provide information to downstream users about appropriate measures for controlling exposure to the substance.

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

*Dossier evaluation* involves an assessment of the information provided by the supplier under REACH, and of any testing proposals put forward by registrants. The evaluation checks if test data for the substance is already available, and whether alternative tests could be applied to prevent unnecessary testing. It applies to substances manufactured or imported at over 100 tonnes per year.

*Substance evaluation* provides a mechanism for an individual Member State Competent Authority to review a registration package(s) in the light of domestic concerns or priorities. Member States may review the information provided and the risk management controls, and propose an EU wide restriction or authorisation.

**Authorisation** - Industry will need to gain an authorisation to use substances considered to be of very high concern. Applications are to be made to, and the process managed by, the European Chemicals Agency, which will be in Helsinki.

Authorisation is restricted to substances of very high concern (less than 2% of the total) and is given at EU, not Member State level. Substances of very high concern include those identified as carcinogenic, mutagenic or toxic to reproduction (CMR) categories 1 or 2; persistent, bio-accumulative and toxic substances (PBT); and substances that are very persistent and very bio-accumulative (vPvB).

## **Annex 3**

### **UPDATE ON REACH'S LINKS WITH EXISTING REGIMES FOR WORKER HEALTH AND SAFETY**

This annex explores the links between the new REACH provisions on the use of chemicals, and existing regimes, principally COSHH.

#### **Scope**

The main differences in scope between REACH and COSHH are:

- a. REACH is a very broad ranging system, encompassing occupational health and safety, environmental safety, and public health; COSHH is focussed solely on worker health.
- b. REACH aims to control chemical hazards by restricting access to the market, providing improved information in the supply chain, shifting the responsibility for identifying risk management measures onto registrants, and a mechanism to restrict certain uses where necessary. COSHH controls any type of potentially hazardous substance in the workplace, including such materials as flour or wood dust, rubber fumes, etc., which are not within the scope of REACH.

REACH should result in more information being made available to users about the risks associated with use of chemicals, and how to control these. It includes an obligation for users to follow instructions provided down the supply chain regarding the safe use of a substance. REACH also includes an innovation on the movement of information back up the supply chain, from users via suppliers to registrants. This provides a new channel for capturing user concerns regarding chemical hazards, and passing these to manufacturers and/or importers.

REACH also introduces the Derived No-Effect Level (DNELs) concept, which will sit alongside the existing Occupational Exposure Limit (OELs) as a means of establishing the level of workplace exposure that must be achieved by risk control measures. DNELs are an innovative approach, taking account of a broader range of factors than the existing OEL system and following the fundamental REACH principle of shifting responsibility for assessing and managing risks onto industry.

#### **Risk assessment**

##### *Existing EU/GB legal framework for occupational health*

Under COSHH, employers assess the risks for chemicals they use in their workplace and put in place appropriate risk management measures.

##### *Arrangement under REACH*

Under REACH, suppliers will take key decisions about when and how their products should be used. Users must implement the risk management measures the supplier specifies, and reflect the improved knowledge of chemical hazard resulting from REACH information requirements.

The manufacturer or importer of a chemical (if greater than 10t) is required to produce a Chemical Safety Assessment (CSA), considering hazard and potential

risks, and proposing workplace measures to control the risks for all uses of the chemical he supports.

In some circumstances users down the supply chain may want to use the substance in a way not supported by the manufacturer or importer. In this case, the user can seek to have the use included in the manufacturers/importers assessment or, failing that, do their own assessment for the use.

#### *Comment on the link between the two legal frameworks*

Users of the substance will still need to carry out a risk assessment under COSHH.

REACH aims to take account of risks specific to a user's applications of a substance by providing for the user to feed information about that use up the supply chain to the registrant, for their support in provision of risk management measures.

REACH should result in more informed COSHH risk assessments, by providing specific risk management measures and more generally improving the amount of information available to employers about chemicals and risks resulting from their use. It will also establish a baseline for risk control against which COSHH assessments can be made, although with the long phase-in periods it may be some years before these effects are widely seen.

#### **Occupational Health & Safety and Environment perspectives**

Links between, on the one hand, standards of worker protection in the use of chemicals and, on the other, developments in the regulation of environmental hazard, have been the subject of a recent paper to the Commission (SR012 HSE Horizon Scanning report).

As indicated in that report, REACH provides a broad framework aimed at reducing risks to both the environment and workers. It includes a mechanism ('substitution') which will oblige registrants to seek feasible alternatives to the use of 'substances of very high concern' (SVHC), be they hazardous to human health or the environment (or both). Substitution plans must be submitted as part of a request for authorisation to use a SVHC, and will be considered by both Member State Competent Authorities (HSE in the UK) and committees considering Risk Assessment and Socio-economic importance of substance use at the European level. Substitution plans that could increase risk to either human health or the environment will not generally be in line with REACH objectives.

Generally, effective management of chemicals benefits occupational and public health as well as the environment, but there are limited circumstances where these two goals are not fully aligned.

Paper SR012 refers to a dilemma in the use of PerfluoroOctane Sulphonates (PFOS), and indicates that potential conflicts of this kind warrant detailed consideration within HSE. PFOS chemicals have properties that make them especially effective in suppressing a highly carcinogenic hexavalent chromium mist that can evolve during chrome-plating operations. The same properties also render PFOS very persistent in the environment. A usual response in environmental regulation is to seek a ban on the use of a substance of this nature, and HSE have

worked with Defra to successfully secure a derogation from this ban for use of PFOS in chromium plating.

This issue is unusual in that worker protection and environmental considerations have countered one another, and this is not an aspect of the REACH system in itself. As a holistic system taking equal account of human health (public and in the workplace) as well as environmental concerns, REACH should help ensure worker health considerations are taken into account at the earliest possible stage, where this has not previously been the case in environmental regulation. HSE continues to monitor cases of this nature for any potential negative impact on worker protection.

## **Annex 4**

### **SUMMARY OF REACH MINISTERIAL RESPONSIBILITIES AND PROPOSED ARRANGEMENTS**

Every effort has been made in discussions with the Devolved Administrations and in drafting the Agency Agreements to fully reflect the devolution of power over certain aspects relevant to REACH, and so take into account Devolved perspectives.

**Great Britain** Occupational health and safety and consumer protection matters are reserved to Westminster for Great Britain (the UK excluding Northern Ireland), Secretary of State for the Environment, Food and Rural Affairs will be appointed as Competent Authority for these matters.

**England** All REACH topics are managed from Westminster for England, and the Secretary of State for the Environment, Food and Rural Affairs will be appointed as Competent Authority for these matters.

**Wales** Welsh environment matters are split between Westminster and the Welsh Assembly Government. Public health matters are devolved to the Welsh Assembly Government. Welsh Ministers will be appointed as Competent Authority for matters falling within their competence.

**Scotland** Environment and public health matters are devolved to the Scottish Parliament. Scottish Ministers will be appointed as Competent Authority for matters falling within their competence.

**Northern Ireland** All REACH topics are managed from Belfast for Northern Ireland. Departments in Northern Ireland are constituted in statute, and advisors from the province indicate that it will be necessary for individual departments to be appointed Competent Authorities for relevant matters.

## Annex 5

### EXAMPLE AGENCY AGREEMENT

Agreement between The Scottish Ministers and the Health and Safety Commission relating to the Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (“REACH”)

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THIS AGREEMENT is made between The Scottish Ministers (“the Ministers”) and the Health and Safety Commission (“the Commission”) under section 13(1)(b) of the Health and Safety at Work etc. Act 1974 (“the 1974 Act”). It relates to a function which the Commission has agreed to perform on behalf of the Ministers, being a function which in the opinion of the Secretary of State for Work and Pensions can appropriately be performed by the Commission in connection with its functions.

IT IS AGREED THAT:

1. The Commission shall perform on behalf of the Ministers the function of competent authority as referred to in Article 121 of the REACH Regulation<sup>1</sup>, to include, but not exclusively, those functions set out in Annex 1 to this agreement, insofar as they relate to matters devolved to the Ministers.
2. Nothing in this Agreement shall prevent the Ministers from exercising any function assigned to them as competent authority by the REACH Regulation. Wherever practicable, the Ministers shall inform the Commission that they intend to perform any such function.
3. The Commission shall direct the Health and Safety Executive (“the Executive”) under section 11(4) of the 1974 Act to exercise on its behalf the functions that it has agreed to perform under this Agreement.
4. The Commission and the Executive agree to perform the functions specified in paragraph 1 of this Agreement on the basis that the costs incurred by the Commission and the Executive in performing these functions are paid in full. Arrangements for this payment are set out in Annex 2.
5. This Agreement shall come into effect on XXXX. It shall terminate on the expiry of six calendar months’ written notice, beginning on the day the notice is sent by one party to the other.

IN WITNESS whereof they are subscribed by \_\_\_\_\_ an officer of the Scottish Ministers, on the \_\_\_\_\_ day of \_\_\_\_\_ 2007

Full name of witness:

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<sup>1</sup>Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Address of witness:

the Corporate Seal of the Secretary of State for Work and Pensions has been affixed this \_\_\_\_\_ day of \_\_\_\_\_ 2007; and the Common Seal of the Commission has been affixed this \_\_\_\_\_ day of \_\_\_\_\_ 2007.

THE CORPORATE SEAL OF THE  
SECRETARY OF STATE FOR WORK  
AND PENSIONS

is authenticated by:

THE COMMON SEAL OF THE  
HEALTH AND SAFETY  
COMMISSION

is authenticated by:

Authorised by the said  
Secretary of State

Chair of the Commission

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### Annex 1

- The provision of advice to manufacturers, importers, downstream users and other interested parties on their respective responsibilities and obligations under REACH (the competent authorities' helpdesks).
- The conduct of substance evaluation of prioritised substances and preparation of draft decisions.
- The proposal of harmonised classification and labelling for substances that are carcinogenic, mutagenic or toxic for reproduction and respiratory sensitizers, or that cause other effects, as necessary.
- The identification of substances of very high concern for authorisation.
- Proposals for restrictions relating to the manufacture, marketing and use of certain dangerous substances, preparations and articles.
- The nomination of candidates for membership of European Chemicals Agency committees on risk assessment and socio-economic analysis.
- The appointment of members for the Member State Committee, to resolve differences of opinion on evaluation decisions.
- The appointment of a member to the Forum for Information Exchange and to arrange meetings to discuss enforcement matters.
- To provide adequate scientific and technical resources to those members of the Committees that have been nominated.
- To work closely with the European Chemicals Agency.

- To perform any other function necessary for the effective delivery of the UK Competent Authority and the Regulation in the United Kingdom.

## Annex 2

- (a) Unless otherwise agreed the costs referred to in paragraph 4 shall be within the limits of an agreed annual estimate of the total of such costs for the year and shall be payable within the year in which the work is performed.
- (b) For the first financial year (2007/08) of the operation of the competent authority functions by the Commission and the Executive, the costs of such shall be paid by virtue of funding arrangements that have been made between the Executive and the Department for Environment, Food and Rural Affairs, for those functions of the competent authority relating to the whole of the United Kingdom.
- (c) Unless otherwise agreed, where the Ministers agree with the Department for Environment, Food and Rural Affairs and the Commission or Executive that a function performed by the Commission or Executive is specifically concerned with the operation of the Regulation solely within the devolved competence of the Ministers, separate arrangements will be made between the Ministers and the Commission and/ or the Executive for the Ministers to provide resources to fund this activity.
- (d) Unless otherwise agreed, where the Ministers, together with any other devolved administration agree with the Department for Environment, Food and Rural Affairs and the Commission or Executive that a function performed by the Commission or Executive is specifically concerned with the operation of the Regulation solely within the devolved competence of the Ministers together with any other devolved administration, separate arrangements will be made between the Ministers and the Commission and/ or the Executive for the Ministers and the other devolved administration(s) to provide resources to fund this activity.

*N.B. Discussions continue with Devolved Administrations about the exact wording of individual agreements, and in particular Annex 2 (c) and (d). The principal that DAs pay for work that benefits only them and not UK as a whole has been agreed to (para 26), but different wording is under consideration. TH 09/05/07.*

**Annex 6**

**DEFRA CONSULTATIVE DOCUMENT ON REACH ENFORCEMENT**