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HEALTH AND SAFETY COMMISSION

Update on the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH)

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Issue

1. To update the Commission on developments concerning REACH.

Recommendation

2. No action. The Commission are invited to note contents as an update.

Background

3. REACH, the new Europe-wide system for controlling chemical hazards, entered into force on 1 June 2007, with its provisions being phased-in over the next 11 years. As a European Regulation, REACH acts directly in UK law. REACH harmonises regulatory decision-making about chemical hazards across Europe, and introduces new mechanisms, such as the new 'authorisation' requirement for use of 'substances of very high concern' (e.g. carcinogens). A summary of the REACH Regulation is at Annex 1.
4. The Government nominated HSE to be the UK Competent Authority for REACH in October 2006. HSE will therefore be the principal UK technical body participating in REACH at a Community level, and will also play a central role in domestic enforcement. Details of how the Competent Authority has been established are at Annex 2.
5. REACH also established the European Chemicals Agency (ECHA) in Helsinki as the focal point for the new system. ECHA now has over 100 staff, projected to increase

to at least 500 in the next two years. ECHA will also host a number of substance evaluation committees, a forum for enforcers to share experience and co-ordinate activity, and a number of other administrative functions. HSE staff will attend several of these committees.

6. REACH should have a positive effect on the occupational health system, improving dialogue between suppliers and users of chemicals, pushing manufacturers and importers to take more responsibility for the substances they market, and giving employers a stronger steer in their duty to put in place effective risk management measures to control exposure of workers to hazardous substances. It should result in more dangerous chemicals being taken off the market and replaced with safer alternatives.
7. An important issue is REACH's relationship with existing regimes for worker health and safety – particularly COSHH. An update is at paragraphs 19-23.

Communications about REACH

8. Defra are responsible for government communications activity in relation to REACH. However, recognising that Competent Authority functions are undertaken on behalf of wider UK Government concerns, the Competent Authority has taken on a prominent delivery role in awareness-raising, under a branding scheme distinct from HSC/E.
9. Communications work is focussing on general awareness raising and key actions that dutyholders can take immediately – creating an inventory of chemicals used throughout a business, and investigating the role that each business plays in the REACH process. Pre-registration is a key REACH mechanism, and it is important for UK compliance that potential registrants are aware of the six-month window for this beginning 1 June 2008. This has been a key topic in communications to date.
10. Conference events have been successfully run in each of the four UK countries. A further event is planned in London on 5 March 2008. To date, around 20 of an ongoing programme of 'roadshow' presentations and REACH 'clinics' have been held around the UK in conjunction with Businesslink and other local partners, providing an introduction to REACH and industry perspectives, aimed at SMEs.
11. The national and roadshow events have been well received. Defra are conducting a survey to benchmark REACH awareness – Competent Authority colleagues have been closely involved in this work.
12. Basic introductory guidance aimed at the key REACH categories of dutyholder has also been published, and a range of topic specific leaflets (for example covering REACH exemptions, and the need for an inventory) are nearing publication. These being made available via the Competent Authority website www.hse.gov.uk/reach/resources.htm, as well as some paper copies printed for distribution at events and by mail. An example overview poster leaflet is included at Annex 3.

13. The Competent Authority Helpdesk, established in October 2006, has now answered over 2100 individual queries. For the period 13 September 2007– 30 November 2007, the average response time for an email enquiry was 1.53 calendar days (down 0.14 days from the preceding period). Overall response times are: same day, 43%; within 3 days, 85%; within 5 working days, 97%.

Enforcement

14. A statutory instrument is required to provide UK enforcers with the means to enforce the Regulation. This SI will apply to the whole of the UK. Defra are now preparing a draft SI, which will be complemented by Memoranda of Understanding (MoU) between enforcing authorities to establish co-operative working arrangements. HSE has worked closely with Defra in developing proposals for this 'suite' of enforcement arrangements.

15. The arrangements are based on proposals made in a Consultative Document in Spring 2007 to which the Commission responded (Annex 1 of HSC/07/035).

16. There are three broad areas for REACH compliance: registration; supply chain; and end use. HSE, as UK Competent Authority, will enforce registration issues, HSE will enforce supply chain issues, and a range of enforcing authorities including HSE will enforce at the point of use as appropriate to the remit of each authority. Although some details of these arrangements are yet to be finally agreed with Defra, HSE is satisfied that these broad principles will be reflected in the SI.

17. Because REACH covers a wide range of topics (OSH, environment, public health, consumer protection, animal welfare, etc.), a large number of enforcers have an interest. Defra proposes to place a duty on UK regulators to enforce those aspects of REACH relating to their normal vires, and for this work to be integrated with enforcement of existing systems to control chemical risk (for example COSHH, COMAH, IPPC). REACH enforcers will be:

- Health and Safety Executive and Health and Safety Executive for Northern Ireland
- Environment Agency, Scottish Environment Protection Agency and Environment and Heritage Service Northern Ireland
- Department for Business Enterprise and Regulatory Reform
- Local authorities, for health and safety, environmental protection and consumer protection (trading standards)
- Her Majesty's Revenue and Customs Service (HMRC)
- Home Office for animal testing

18. Although the listed bodies are organised in markedly different ways and have differing operational responsibilities and priorities, dutyholders, workers, trade unions and the public will expect a consistent and co-ordinated approach to REACH enforcement in the UK. As Competent Authority, HSE have been asked to co-ordinate the drafting of MoU arrangements between them as necessary. A draft is being prepared and we aim to have this available to accompany a forthcoming Defra consultation on the SI during Spring. HSE aims to use these MoU arrangements to

establish an 'Enforcement Liaison Group' to provide for close co-operation between enforcers.

REACH and COSHH

19. COSHH risk assessments and REACH Risk Management Measures will work alongside and complement each other. The additional information provided by REACH (see Annex 4, 'Discussion on chemicals risk assessment') should improve the knowledge base for developing and implementing risk controls.
20. Further, REACH should improve the standards required for controlling risks from chemical use (as opposed to the broader 'substances hazardous to health' risks controlled by COSHH) by establishing more and stricter exposure standards, and by creating a legal duty on employers to follow appropriate control guidelines when these are available. Ultimately, additional information communicated to employers as a result of REACH should help them make more informed decisions when conducting COSHH risk assessments.
21. Potential tensions between REACH and COSHH should be mitigated because:
 - REACH will be phased-in slowly (the timetable for registration extends to 2018). This allows time for those involved to learn their responsibilities and for regulators to intervene effectively if needed.
 - An example 'double system' already exists where the pesticides and biocides regimes apply alongside COSHH, and is working reasonably well. Pesticides and biocides are subject to both COSHH in the workplace and an EU driven authorisation regime controlling exposure to humans (workers and consumers) and the environment.
 - Where COSHH risk assessments need to be revised as a result of additional information under REACH, the principles of good practice set out in COSHH will still apply. Given the comprehensive nature of the principles set out in Schedule 2A of COSHH, there is limited scope for any new risk assessment to be significantly different to those required by REACH.
22. To secure 'authorisation' for use of a substance of very high concern, it is necessary under REACH to demonstrate either that risks can be 'adequately controlled' on a case-by-case basis, or that continued use is justified on socio-economic grounds. In either case, an authorisation may not be granted where there is a suitable alternative. This is in addition to 'restrictions' of the kind previously made under the Marketing and Use Directive, and registration-derived controls on exposure levels and risk management measures.
23. In particular, REACH requires that exposure of humans or the environment to 'substances of very high concern' (carcinogens, mutagens, etc.) 'is reduced to as low a level as is technically and practically possible'. This is the same standard as required now in the Carcinogens and Mutagens Directive, which is implemented by COSHH as 'reasonably practicable.' Although in theory the REACH standard is stricter as there is no consideration of 'reasonable practicability', in practice the

standards required by both COSHH and REACH for Category 1 and 2 carcinogens and mutagens in the workplace are the highest levels of control that can be applied.

Consultation

24. Across HSE, including Legal Adviser's Office and PFPD, also Defra, the Environment Agency, LACORS, and SEPA.

Presentation

25. Industry and other interested parties broadly welcomed 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

26. Defra have paid HSE £1.1m to deliver the Competent Authority for the first year, which is tied to a Business Plan and any MoU establishing the delivery parameters for 2007/08. Similar management arrangements are being put in place for 2008/09, with Defra finalising the budget soon. Defra and HSE have agreed that a PES baseline transfer will be actioned when activity levels are fully established.

27. 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 a significant issue for some years following the first tranche of registration under REACH.

28. 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.

Next steps

29. Defra will consult on formal enforcement proposals in Spring 2008.

A SUMMARY OF REACH

1. REACH will replace the existing legal framework for new and existing substances. REACH aims to ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation.
2. REACH is an EC Regulation that came 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.
3. REACH does not revoke the Chemical Agents Directive or the Carcinogens and Mutagens Directive (implemented by COSHH in GB).
4. The main elements of the new REACH scheme include:
5. **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.
6. **Evaluation** – There are two types of evaluation.
7. *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.
8. *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.
9. **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.
10. 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); substances that are very persistent and very bio-accumulative (vPvB); and substances 'of equivalent concern', such as endocrine disruptors.
11. **Restriction** – REACH adopts the existing approach to placing restrictions on the marketing and use of substances known to be of sufficient concern, although socio-economic implications must now also be taken into account.

Establishing the Competent Authority

1. HSE have been asked to form the REACH Competent Authority partly as we play a similar role under the EC Existing Substances Regulation (ESR) and Notification of New Substances Regulations 1993 (NONS) systems, which are largely replaced by REACH. HSE staff from these teams are migrating to REACH work. Other HSE occupational toxicology expertise is also being drawn upon, and an Inspector has been appointed to establish operational enforcement aspects. The Competent Authority will also be drawing on expertise from outside current HSE areas of work, in particular to deliver environmental aspects of the role such as ecotoxicology.
2. Formally, Ministers in Westminster and the Devolved Administrations hold the functions of the Competent Authority. In June 2007 (HSC/07/035), the Commission agreed to the usual mechanism for establishing the legal authority for HSE to act as Competent Authority - HSWA Section 13(1)(b) 'agency agreements' between relevant parties and the Commission, made with the consent of DWP, as is required by S.13 HSWA.
3. All five agreements have now been made. They are with Defra for matters reserved to Westminster, with the Welsh Assembly Government, with the Scottish Government, and with two relevant Departments of the Northern Ireland government. The Commission has further directed HSE to perform these functions on its behalf.
4. The following pages show an example agreement (with Defra for reserved matters) and the direction to HSE to perform these functions on behalf of the Commission.

Example agency agreement

Agreement between the Secretary of State for Environment, Food and Rural Affairs 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")

THIS AGREEMENT is made between the Secretary of State for Environment, Food and Rural Affairs ("the Minister") 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 Minister, 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 Minister the function of competent authority as referred to in Article 121 of the REACH Regulation¹, to include, but not exclusively, those functions set out in Annex 1 to this agreement, insofar as they relate to matters reserved to the Minister.
2. Nothing in this Agreement shall prevent the Minister from exercising any function assigned to him as competent authority by the REACH Regulation. Wherever practicable, the Minister shall inform the Commission that he intends 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 agrees to direct the Executive 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 1 October 2007. 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.

¹Regulation (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.

IN WITNESS whereof the Official Seal of the Secretary of State for Environment, Food and Rural Affairs has been affixed this 31st day of AUGUST 2007; and 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 27th day of September 2007.

THE CORPORATE SEAL OF THE SECRETARY OF STATE FOR WORK AND PENSIONS is authenticated by:



Authorised by the said Secretary of State

THE COMMON SEAL OF THE HEALTH AND SAFETY COMMISSION

is authenticated by:



Chair of the Commission



THE OFFICIAL SEAL OF THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS is authenticated by:



Authorised by the said Secretary of State

30 Aug 2007



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, are 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) 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 ("Defra").
- (b) 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. The nature and extent of the agreed annual estimate of costs

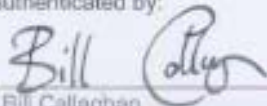
Direction

Direction under section 11(4) of the Health and Safety at Work etc Act 1974

1. In pursuance of an authorisation given by the Health and Safety Commission ('the Commission') on 5 June 2007, and on the Commission's behalf, I hereby direct the Health and Safety Executive ('the Executive') to exercise, on behalf of the Commission, the functions of 'competent authority' as set out in article 121 of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), these functions having been conferred on the Commission by agreements made with other UK authorities under section 13(1)b of the Health and Safety at Work etc. Act 1974.
2. A representative list of functions to be performed by the UK REACH delegated Competent Authority are:
 - 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.
 - Provision of adequate scientific and technical resources to those members of the Committees that have been nominated.
 - Close working with the European Chemicals Agency.
 - Performance of any other function necessary for the effective delivery of the UK Competent Authority and the regulation in the United Kingdom.
3. This Direction does not require the Executive to undertake tasks other than those for which funding is provided by mechanisms included in the agreements referred to in paragraph 1.

THE COMMON SEAL OF
THE HEALTH AND SAFETY COMMISSION

is authenticated by:



on this 27th day of September 2007

Sir Bill Callaghan
Chair, Health and Safety Commission



Example REACH leaflet (please see attached)

DISCUSSION OF CHEMICALS RISK ASSESSMENT

Risk Assessment under COSHH and REACH

1. REACH and COSHH approach the control of chemicals in the workplace in different ways. This section describes how both systems can complement one another in practice.

COSHH

2. Downstream users are required by COSHH regulation 6 to assess the risks to workers' health from exposure to the substance in question (the COSHH assessment). This should determine whether it is reasonably practicable to prevent exposure, or measures to 'adequately control' exposure where prevention is not reasonably practicable.
3. The duty to implement measures to achieve 'adequate control' for hazardous substances is captured in COSHH Regulation 7. Within this regulation:
4. Regulation 7(7) establishes 'adequate control' in terms of compliance with the 'principles of good practice' that are set out in Schedule 2A to the Regulations and with non-exceedance of a WEL, where there is one. It allows for the employer to design and implement controls that are most suitable for that particular site;
5. Regulation 7(5) further specifies that where it is not possible to prevent exposure to a carcinogen or mutagen, the employer shall implement further measures including total enclosure of the process and handling systems where this is reasonably practicable.

REACH

6. REACH approaches the control of chemical risks in a different way, passing responsibility for identifying and assessing the risks from chemical hazards up the

supply chain to those responsible for placing these substances on the European market.

7. REACH requires manufacturers and importers of chemical substances to register this activity by submitting a 'technical dossier' to a new European Chemicals Agency (ECHA). Manufacturers and importers are known in REACH as 'registrants'.
8. When the manufactured or imported tonnage of a given substance exceeds 10 tonnes per year per registrant, registrants must conduct a Chemical Safety Assessment (CSA) and submit a resulting Chemical Safety Report (CSR) to ECHA.
9. As part of the CSA, the registrant must identify Derived No-Effect Levels (DNEL) for human exposure (and PNEC environmental standards) and set out 'exposure scenarios' for substances in quantities of 10 tonnes or more per year per registrant, describing the uses that the registrant is 'supporting' (i.e. uses for which the registrant is willing to compile exposure scenarios).
10. Article 31 of REACH requires that when a 'downstream user' purchases certain chemicals, they should be supplied with a safety data sheet (SDS) that will include the DNELs and supported uses, which are represented by the exposure scenarios.
11. Article 32 of REACH indicates that where an SDS is not required, the supplier should pass certain other information to the user to inform the user's own assessment of risks.
12. If the downstream user wants to use a substance outside the conditions described in an exposure scenario, the user can ask the registrant to develop one. The registrant has to agree to support the use unless he provides reasoned arguments that the chemical cannot safely be used in that way (subject to ECHA arbitration).
13. If the downstream user does not want to make their intended use known, they can choose to undertake the CSA and CSR process themselves, including developing relevant exposure scenarios. In these cases the downstream user has to notify ECHA.
14. Article 37(5) of REACH requires downstream users to '... identify, apply and where suitable, recommend, appropriate measures to adequately control risks' that are identified in safety data sheets, in their own Chemical Safety Assessments, or information supplied under Article 32 (which specifies information to be passed down the supply chain where a SDS is not required). Article 14(6), placing the duty on registrants to identify and apply the CSR information, uses similar language.
15. Dutyholders are therefore required by REACH to identify and apply risk management measures that are appropriate to adequately control risks, i.e. they are under an obligation to comply with the recommendations in SDSs and CSAs etc.

The COSHH/REACH interface

16. An existing COSHH assessment should be compared to the measures identified in the SDS, or the user's own CSA, or any information supplied under Article 32 of

REACH. This would include information about any relevant DNELs, and exposure scenarios including risk management measures.

17. With reference to Regulation 6(2) of COSHH which details the various factors that must be taken into account in the COSHH assessment, the downstream user should then consider whether the risk management measures and other REACH conditions are sufficient to adequately control exposure.
18. In many cases, the control measures derived by application of Article 37(5) of REACH will be sufficient to adequately control exposure. In fact REACH may often impose a higher standard of control than would result from a COSHH assessment without this information, as the risk management measures are likely to be based on a more thorough understanding of chemical hazard. However, if adequate control of exposure has not been achieved (for example, should a WEL under COSHH impose the stricter standard, or should existing guidance suggest it is reasonably practicable to do more), then the COSHH assessment will go on to specify the extra control measures necessary.
19. Failure to implement the appropriate risk management measures passed down as part of the REACH process would constitute an offence under REACH and may well also contravene COSHH, insofar as these provisions apply in the circumstances. Failure to implement any further measures identified by the COSHH assessment would not breach REACH duties, but would be enforceable under COSHH.
20. For carcinogens and mutagens, COSHH requires exposure be reduced to as low as is reasonably practicable. Category 1 and 2 carcinogens and mutagens are considered 'substances of very high concern' under REACH, and may be subject to 'authorisation', where ECHA permission to continue use is required, and is only available where agreed conditions of use are applied. REACH places duties on users to follow the specific conditions of use set out where a chemical is subject to REACH 'authorisation' or 'restriction'. These mandatory conditions should drive improvements in COSHH risk assessment.