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HEALTH AND SAFETY EXECUTIVE**The HSE Board****HSE's forthcoming UK REACH Competent Authority role: its positioning within HSE****A Paper by the REACH CA Project Team (led by Steve Fairhurst)****Advisor(s): Vivienne Dews and the REACH CA Project Board****Cleared by Vivienne Dews on 2 January 2007****Issue**

1. REACH (Registration, Evaluation and Authorisation of Chemicals) is new EU chemicals legislation now destined to enter into force on 1 June 2007. HSE will be responsible for the UK Competent Authority (CA) for REACH. The issue for this paper is which part of HSE should be responsible for establishing the REACH CA on the basis of the designs and recommendations emerging from the REACH CA Project.

Timing

2. The REACH CA Project objective is to have the REACH CA arrangements established in outline, by the end of February 2007. To achieve this we need to identify who will own the function.

Recommendation

3. The HSE Board is asked to consider the analysis presented in this paper and to give a view on the appropriate option for the positioning and SCS "ownership" of the developing UK REACH CA function.

Background

4. REACH (Registration, Evaluation and Authorisation of Chemicals) is new EU chemicals legislation that will enter into force on 1 June 2007. Annex 1 is a draft document that provides a brief overview of REACH. DEFRA is the lead government department for REACH negotiation in the EU and implementation in the UK.

5. REACH requires the establishment of a Competent Authority (CA) in each EU Member State. In the period June-October 2006, agreement was reached between DEFRA and HSE that HSE will deliver the UK CA role, on behalf of ministers.

6. HSE has established the REACH CA Project, running from September 2006 to February 2007. The objective of the project, in relation to the CA function, is to create appropriate, viable and robust arrangements for the operation of a UK CA for REACH, housed within HSE, by the end of February 2007. Vivienne Dews is the SRO and Project Board chair and Steve Fairhurst is the Project Manager.

7. The Project Team has characterised what will be the responsibilities of a REACH CA, has agreed with DEFRA a vision for the scale of activity of the UK CA and has analysed the human resources needed to deliver to that vision. An agreement has been reached with DEFRA for funding to be transferred to HSE in the early years of UK REACH CA operations.

Argument

8. The Project is now at a stage where the designs for the developing UK CA need to pass to a future owner (ideally at SCS-level), who can then oversee the implementation and consolidation of the arrangements (e.g. identifying the specific individuals who will contribute to the CA and their line management; progressing any necessary training).

9. A considerable proportion of the necessary input to delivering UK REACH CA responsibilities is regulatory science. The Project Team/Board recognise that there is some uncertainty, in that HSE is considering more generally the appropriate future arrangements for its science and technology, via the Making Best Use of Science (MBUS) Project. Nonetheless, it is felt that an SCS “owner” for the REACH CA function, at least for the short-term, needs to be identified now so that the UK CA is established in time for REACH entering into force.

10. The Project Team has recently delivered to the Project Board the analysis at Annex 2. In terms of SCS/Directorate “ownership”, the analysis boils down to three positioning options – Operations Group, Policy Group or HSL.

11. The Project Team recommendation is that the UK REACH CA function would be best placed initially within FOD CHSD as this would link with HSE’s most relevant current expertise. There should, however, be a commitment to explore other options particularly relating to HSL, with a view to making best use of HSE’s capacity and capability and to reflecting the outcome of the MBUS work.

Consultation

12. The Chief Executive, the REACH CA Project Board, PEFD

Presentation

13. There may be some internal interest in aspects of the REACH CA preparations. In general staff are likely to welcome this as new funded work which will enable us to support posts not currently included in our affordable staffing plans.

Costs and Benefits

14. Details of the costs and funding arrangements are included below in paragraphs 15 and 16. The benefits of REACH and the linkages with other aspects of the regulation of chemicals are at Annex 1.

Financial/Resource Implications for HSE

15. DEFRA accepts that it is responsible for providing funds to HSE to cover the cost of delivering the UK REACH CA function. HSE’s basic premise is that the REACH CA function may only be delivered to the extent commensurate with funding received from DEFRA. While a vision of the scale of activity likely to be required of the UK CA within a fully operational REACH system has been agreed, it will be some years before that is achieved and the vision may change over time. In view of this HSE has agreed an interim resourcing position whereby HSE will deliver to a Memorandum of Understanding in each of the years 2007/08 and 2008/09. Once the vision for REACH CA operations has

stabilised (possibly, but not necessarily by 2009/10) a PES transfer of appropriate funding will be considered.

16. The first year (i.e. 2007/08) will be one of building up REACH capability and familiarity across the EU. Expenditure by the UK CA will be incurred on further development of the UK CA helpdesk function, including establishing and maintaining a website; proactive communications with stakeholders of all kinds, both internal and external; IS/IT set-up costs (REACH is envisaged as operating on an electronic basis); servicing of trial runs of REACH committees (with associated regulatory science work) and developing guidance material and working procedures. There is a view that HSE will need to bolster its socioeconomic and exposure/control expertise by external recruitment but any case for this will be submitted to the Recruitment Review Panel. DEFRA has made £1.1 million available to HSE in 2007/08 and the Project Manager is confident that expenditure in 2007/08 can be controlled and constrained within that figure. DEFRA has also agreed the sum of £1.5 million for 2008/09. HSE's Planning Resources and Finance Division (PEFD) will liaise with the nominated "owner" of the REACH CA function and agree the detail of the deployment of the DEFRA resource transfer within HSE, relevant budget lines etc. The issue of the extent and likely costs of downstream enforcement (a function beyond that of the CA) is outwith these figures and remains to be agreed.

Environmental Implications

17. n/a; a technical contribution from the Environment Agency's Chemicals Assessment Unit is built into the UK REACH CA delivery model.

Action

18. The HSE Board is asked to give a steer on the most appropriate positioning of the developing REACH CA function.

PART 1: SCOPE, CONTEXT AND BOUNDARIES OF REACH AND ITS LINKS WITH OTHER LEGISLATION

1. This is an analysis of the scope and boundaries of REACH and its linkages with other aspects of the regulation of chemicals, from the perspective of HSE's interests and responsibilities.

What is REACH for?

2. In its contribution to developing the UK negotiating line on REACH, HSE has portrayed the benefits of the forthcoming REACH legislation as having four aspects, these being to:

- secure good quality information on the properties of chemicals
- achieve good exchange of information about chemicals, up and down the supply chain
- make available to those who need to know clear, reliable information on the appropriate means of using chemicals and preventing or controlling exposure to them
- promote substitution in favour of substances and technologies posing lower risk

all directed at the overall aim of reducing the threat of adverse effects on human health and/or the environment arising because of exposure to chemicals.

3. Seen in this way, it could be argued that REACH is not particularly “new”. Rather, it is legislation that clarifies, amplifies and strengthens the drive towards achieving the objectives of current “supply-side” chemicals legislation; and indeed, REACH will subsume some of this legislation, absorbing its objectives; e.g.

- NONS – good quality data and appropriate risk management, pre-marketing, on novel chemicals
- ESR – reliable data and risk assessment/management on priority existing chemicals
- Safety Data Sheets Directive – provision of clear information along the supply chain
- Marketing & Use legislation – applying restrictions to the ability to market and use some substances and preparations with properties of particular concern

4. REACH also shifts the balance of responsibilities from where it lies within current legislation, towards increasing the demands on the industries supplying chemicals and putting obligations on users to follow suppliers' advice and provide feedback. REACH lessens the demands on national regulatory authorities to search for and compile information on chemicals and to conduct risk assessments and develop risk management positions and advice. So, while not necessarily introducing new philosophy, REACH will certainly emphasise the responsibilities of dutyholders in a way and to an extent to which some are unaccustomed. There is already evidence of “culture shock” reactions from some in the chemicals business.

What does REACH cover?

5. The scope of REACH is all chemical substances supplied in annual quantities of 1 tonne or more and not covered by more specific legislation reflecting specialist areas of use, such as medicines, agricultural pesticides, biocides or food additives. It involves:

- **Registration** of a very large number of substances, each with its own information package
- in-depth **Evaluation** of prioritised substances for regulatory purposes; a key regulatory outcome of evaluation could be the imposition of Restrictions on the manufacture, supply or use of a substance.
- **Authorisation** decisions for some substances because they have properties of particular concern

Who does what under REACH?

6. REACH involves an interaction between four players – manufacturers/importers of chemicals; recipients/users of supplied chemicals; a central European Chemicals Agency (ECA) to be based in Helsinki; and national Competent Authorities, one in each Member State (MS).

7. In outline, the responsibilities of each player are:

- **Manufacturer/importer** – register substance with information package at Helsinki ECA; also direct recipients/users in the appropriate risk management measures for any particular use of the substance; also respond appropriately to other players on other aspects of REACH (see below)
- **Recipient/User** – use substance in manner described by supplier, employing the risk management measures prescribed; and feed back to supplier experience in use
- **ECA, Helsinki** – orchestrate REACH: provide central guidance; host the Registration process including checking of dossiers for completeness, accuracy etc; operate committee processes to arrive at EU decisions following the Evaluation of selected substances (by EU MS); operate the Authorisation process for substances of particular concern
- **A MS Competent Authority** – provide a national Helpdesk; enforce compliance with Registration (at least reactively in response to “whistleblowing”); Evaluate selected priority substances; participate in EU committee processes

What outcomes can be arrived at under REACH?

8. There is the general concept that, under the Registration and associated provisions of REACH, the properties of chemicals (substances and preparations) will be well understood and clearly communicated along the supply chain, along with appropriate control advice; and that recipients/users of chemicals will heed the information, implement the controls and feed back to suppliers experience-in-use.

9. Beyond these generalities, REACH is designed to deliver more specific regulatory outcomes. These are:

- ❖ **Restrictions:** an Evaluation of a substance can be used to arrive at EU-wide restrictions on the conditions of manufacture, placing on the market or use of that substance
- ❖ **Authorisation:** for substances having properties that are deemed to be of “very high concern” (there are defining criteria – e.g. a proven [“category 1”] or probable [“category 2”] human carcinogen), an authorisation is required for their placing on the market and use. A company wishing to market or use such a substance must apply to ECA, Helsinki, for an authorisation – which of course might be granted or refused.
- ❖ **Harmonisation of Classification & Labelling:** because of particular concerns surrounding a substance it can be deemed necessary to determine a binding position on how a substance should be classified and labelled. (This will then be progressed under the envisaged new “GHS” legislation, the successor to current EU classification & labelling legislation [CHIP in UK] – see below).

What lies “out of REACH”?

(i) In terms of coverage of the world of “chemicals”

10. As a generalisation, REACH and its requirements apply to all individual chemical substances and preparations thereof (i.e. mixtures, combinations, formulations), other than those that are covered by more specific legislation that is as or more stringent, tailored for those specific areas of use. So, again as a generalisation, most or all of the requirements of REACH **do not apply** to, for example:

- radioactive substances
- waste
- medicinal products (human or veterinary)
- food additives and animal nutrition products
- cosmetic products
- biocides
- plant protection products (“agricultural pesticides”)

11. REACH legislation also focuses on marketing of substances, supplied in quantities of 1 tonne per year or more. Thus REACH **does not apply** to, for example:

- non-isolated intermediates in a chemical process; and process by-products (e.g. fume or dust arising from an industrial operation); and
- substances supplied in quantities below 1 tonne per annum are not required to be registered (although in principle such substances could still be targeted for restriction or authorisation action).

(ii) In terms of regulatory responsibilities and decision-making on industrial chemicals

12. **Classification & Labelling (C&L) rules, criteria and harmonised decisions on C&L for individual substances:** Although C&L outcomes are an important influence on how REACH deals with individual substances and preparations, the route to arriving at C&L outcomes will be under separate legislation. It is anticipated that the new “Globally Harmonised System” (GHS) for C&L will be adopted in the EU via specific new GHS

legislation, entering into force in April 2008. HSE is leading for UK government in the negotiation of this GHS legislation.

13. COSHH requirements, based on EU Chemicals Agents and associated

Directives: The protection of workers from the potential adverse health effects of chemical exposure will be heavily influenced by REACH. However, REACH will not completely supplant the requirements of COSHH. Obviously REACH will not influence worker protection for entities that are not captured by REACH (refer to paragraphs 10 and 11 above). More generally, although REACH requires suppliers of substances and preparations to recommend appropriate control measures for downstream use of the materials supplied, and requires users receiving such advice to follow the measures stipulated, nevertheless it is recognised by HSE that there are limitations to what a supplier can know about the finer details of a particular work site. There might be peculiarities about the features of a particular workplace (such as the presence of other materials; the structural features of a building; the characteristics and working patterns of a particular workforce) that in HSE's mind still render it essential that operators of workplaces fulfil their COSHH assessment responsibilities – in many cases, with REACH helping in this respect.

14. Other specific legislation covering chemicals, e.g. Major Hazards/Seveso

Directive issues: REACH itself does not impinge directly on Major Hazard/accidental release scenarios and legislation (although REACH and GHS might produce downstream consequences for how sites and substances relate to such legislation).

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ANALYSIS OF DIFFERENT OPTIONS FOR BUSINESS DELIVERY AND POSITIONING OF THE CA FUNCTION

Background

Current position

1. When the forthcoming REACH legislation enters into force it will replace some current EU chemicals legislation, including that dealing with the Notification of New Substances (NONS) and the Existing Substances Regulation (ESR). HSE, in partnership with the Environment Agency (EA) delivers the UK Competent Authority (CA) role for NONS and ESR.
2. HSE has existing staff located in FOD CHSD, based in Bootle, that deliver HSE's CA responsibilities under NONS and ESR – about 11 staff-years of resource (9 on NONS, 2 on ESR) were utilised in delivering these responsibilities for the year 2005-06.
3. The above resource is co-located with a substantially greater total body of resource within FOD CHSD that delivers regulatory science into all of HSE's chemicals (including biocides) responsibilities. There is a lot of cross-fertilisation, interaction and collaboration across this pool of staff and the work in which they are engaged.
4. To a great extent, the knowledge and skills involved in delivering NONS/ESR work (and HSE's other current regulatory science work on chemicals) are those needed for REACH. Currently, people with such skills and knowledge are not deployed elsewhere in HSE, including HSL.
5. When REACH enters into force (1 June 2007), ESR will be subsumed (with some carry-over into the REACH era of ongoing work commenced under ESR). NONS will continue for a further year. The volume of NONS work that will arise in that final year of its operation is difficult to estimate; there are arguments for it to diminish substantially, but also "better the devil you know" arguments for it to remain at its current level, with new substance dutyholders preferring to deal with the known NONS system than risking the unknown REACH system.
6. The volume of work that REACH will generate and that the UK CA for REACH will need to deliver is also difficult to assess with confidence. The "Vision" document produced earlier by the Project and agreed between HSE, EA and DEFRA sets out the best estimate that can be arrived at from current knowledge (paper REACH CA PB-OCT06-07). This represents the agreed "destination" that the UK CA will be seeking to move towards; there needs to be flexibility in timings and rates of progress towards this destination, and indeed even in the ultimate destination we are seeking to arrive at, to accommodate the potential for further REACH-related developments across the EU and also experience once REACH enters into force. Overall, REACH obligations and workloads will come in gradually rather than with a "big bang".

Type of work to be done by the UK REACH CA

7. Paragraph 4 above is a solid and dependable general statement. However, compared to the situation under NONS and ESR, there will be a significant shift in the more specific types and styles of work required from the UK CA under REACH.

8. Under NONS and ESR, the CA is responsible for assessing the compliance of submitted information on substances, the performance of hazard and risk assessments, and the generation of risk management strategies where required. Under REACH the burden of assessment work is shifted, with the responsibility on industry to provide assessments of the hazards and risk presented by the substances they produce/use and to indicate the risk management measures required to control the risks. A national CA will concentrate its efforts on taking the outputs from industry and determining the appropriate regulatory measures to adopt from a range of options, including determining the need for more information and whether or not the risk management measures proposed are appropriate and proportionate to the risks. As a consequence, the Project Team judges that the REACH CA will require in greater measure experienced staff to deliver its work, a greater proportion of which will be regulatory decision-making with a strong focus on risk control measures.

Availability of knowledge/skills

9. The availability of toxicological and exposure/control expertise in UK is limited. Further recruitment would be in a potentially very competitive market with demand from industry, the European Chemicals Agency and other EU Member States for this limited resource.

10. Positionally, there are several (flexibility, consistency, cross-fertilisation, critical mass and gap-filling) arguments that would support the placing the UK REACH CA within or close to the larger total body of “chemicals” regulatory science staff in HSE.

Positional options for business delivery by HSE of the UK REACH CA function

11. Eight options for the positioning and business delivery arrangement of the UK REACH CA within HSE have been subjected to an initial “pros and cons” analysis, presented below.

Option 1: FOD - Bootle

Pros:

- Delivery of REACH CA responsibilities is “operational” in nature - delivering regulatory decisions on chemicals control
- Some manufacturers and all distributors/users of chemicals covered by HSE occupy premises dealt with by FOD
- FOD CHSD currently delivers the regulatory science needed for the broader range of HSE’s responsibilities on chemicals
- There would be minimum disruption for existing staff already located within CHSD FOD, thus minimising human resources considerations

Cons:

- REACH CA work will not be an inspection-based function requiring “inspector” capability; positioning the REACH CA within FOD might be seen as perpetuating an existing distraction/mismatch for FOD’s mainstream business?

Option 2: HID - Bootle

Pros:

- Delivery of REACH CA responsibilities is “operational” in nature - delivering regulatory decisions on chemicals control
- Large chemicals manufacturers covered for HSE by HID
- Some similarities between the “reviewing/restricting/authorising” features of REACH and those of Major Hazards legislation
- Would require some limited organisational re-arrangements between FOD and HID but minimal human resources implications

Cons:

- REACH is not Major Hazards legislation and hence does not fit easily with much of HID’s business
- REACH CA work will not be an inspection-based function requiring “inspector” capability; positioning the REACH CA within HID might be seen as perpetuating an existing distraction/mismatch for HSE Operations Group mainstream business?
- If only the REACH CA work were to be placed in HID, this creates a fracture line with the remaining “chemicals” regulatory science group in HSE

Option 3: Policy Group – Bootle (London as a location appears untenable)

Pros:

- Maximises closeness with HSE’s “chemicals” Policy team

Cons:

- REACH CA delivery work does not fit with Policy Group’s function
- If only the REACH CA work were to be placed in Policy Group, this creates a fracture line with the remaining “chemicals” regulatory science group in HSE

Option 4: HSL – Buxton, with its current staff and capabilities

Pros:

- An additional stream of work and income for HSL
- The work is science-based, not requiring inspection functions
- REACH CA staff would also be available for involvement in a broader range of HSL activities

Cons:

- HSL does not currently have the staff capability to deliver the function; recruitment of new staff of sufficient numbers and experience seems extremely unlikely

- An “intelligent customer” function would need to be retained elsewhere in HSE for ultimate regulatory decision-making (outside of the remit of HSL)
- HSE would be left with a redeployment problem for existing regulatory scientists based in FOD CHSD
- If only the REACH CA work were to be placed in HSL, this creates a fracture line with the remaining “chemicals” regulatory science group in HSE
- There might be IT mismatch problems between HSL and remainder of HSE

Option 5: HSL – Buxton, with transfer (management and geographical) of existing “chemicals” regulatory scientists from FOD CHSD, Bootle

Pros:

- An additional stream of work and income for HSL
- The work is science-based, not requiring inspection functions
- REACH CA staff would also be available for involvement in a broader range of HSL activities

Cons

- Likelihood that most Bootle-based staff would not want to move to Buxton (“Biocides/PSD merger” project predicted around 10% would have moved to York)
- Would be Permanent Transfer (PTE) costs involved for those staff who did move to Buxton
- If geographical transfer unsuccessful, would need to recruit new staff (very challenging) and redeploy non-transferring staff
- An “intelligent customer” function would need to be retained elsewhere in HSE for ultimate regulatory decision-making (outside of the remit of HSL)
- If only the REACH CA work were to be placed in HSL, this creates a fracture line with the remaining “chemicals” regulatory science group in HSE
- There might be IT mismatch problems between HSL and remainder of HSE

Option 6: HSL – Bootle (transfer of management of existing staff to HSL, but no geographical relocation)

Pros:

- An additional stream of work and income for HSL
- The work is science-based, not requiring inspection functions
- REACH CA staff would also be available for involvement in a broader range of HSL activities
- Staff would not need to move geographically, so minimising costs and greatly increasing willingness to undergo transfer of management
- Would provide a “presence” for HSL outside of Buxton/in Bootle

Cons:

- An “intelligent customer” function would need to be retained elsewhere in HSE for ultimate regulatory decision-making (outside of the remit of HSL)
- If only the REACH CA work were to be placed in HSL, this creates a fracture line with the remaining “chemicals” regulatory science group in HSE
- There might be IT mismatch problems between HSL and remainder of HSE

- May be human resources issues with staff concerned about being transferred (managerially) to HSL and perceiving that this may affect their terms and conditions of employment

Option 7: “Risk Technologies Group”, an “HSE-HSL concordat” - Bootle

Risk Technologies Group (RTG) does not yet exist. Rather, it is a concept that has arisen and is to be pursued further within HSE’s ongoing “Making Best Use of Science (MBUS)” project. Hence the pros and cons are all based on conceptions of how an RTG might come into being; and obviously subject to HSE’s decision about whether or not to create such an entity.

Pros:

- REACH CA would be positioned as part of overall corporate S&T resource; would avoid fracture lines with similar groups of staff and their work
- Existing staff likely to retain geographical location, creating continuity with current situation and avoiding costs of moving staff
- Potential for flexible use of staff, in and out of the REACH CA function
- Minimal human resources issues specific to the REACH CA function (all would be addressed in progressing the wider RTG concept)

Cons:

- “RTG” is an aspiration; it will certainly not be in place by end of February 2007 and might not come into being at all

Option 8: External contracting out of much of the work, retaining a small core responsibility within HSE

The Project Team is advised that this could not be done; most if not all of the work of the REACH CA should be viewed as a statutory monopoly function to be conducted only by a regulatory authority. Hence no further analysis is presented.

Project Team recommendations and Project Board action (*note: v0.3 contains minor post-Project Board modifications)

12. The REACH CA Project Board is asked to:
 - consider the content of this paper
 - agree that it should be developed into an HSE Board paper to be considered at the 10 January 2007 HSE Board meeting; and
 - indicate a preferred option for the business delivery model for the REACH CA function and its positioning within HSE.
13. The Project Team considers that the above analysis suggests the following. With REACH entering into force soon (1 June 2007), then the REACH CA function would be best placed initially within HSE’s Operations Group (FOD CHSD being the most obvious

option), with a commitment to explore into the future the HSL-related options, progressing to maximise the HSL contribution to the delivery of the REACH CA function and associated regulatory science work on chemicals.

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