UK REACH COMPETENT AUTHORITY (CA)

FINAL NOTE OF THIRTEENTH MEETING OF THE STEERING COMMITTEE FOR THE UK REACH DELEGATED COMPETENT AUTHORITY

Thursday 27th January 2011
Nobel House, London and via Teleconference

Attendees

In person

Chair:	Arwyn Davies (Defra)
Members:	Keith Bailey (Defra) Steve Dungey (Environment Agency) Tim Harris (HSE)
Secretariat:	Andrew Smith (HSE – REACH CA) Martin Ball (HSE – REACH CA) Philip Ryland-Jones (Defra)
In attendance:	Amanda Cockshott (HSE – REACH CA) Rob Mason (HSE – REACH CA)

Via telephone

Members:	Martin McVay (Welsh Assembly Government) Paul Holley (Department of Health) Susan Scott (Scottish Government) Anne Conrad (Scottish Environmental Protection Agency) Richard Hawkins (Environment Agency)
In attendance:	Stavros Georgiou (HSE – REACH CA) Christine Northage (HSE – REACH CA) Richard Davis (HSE)

1.Welcome, Apologies and introductions

Apologies / non-attendees

Members:	Alison Edwards (Local Government Regulation) Wendy Thornton (Scottish Environment Protection Agency) Angela Rabess (Business, Innovation and Skills) Jim King (HSE NI) Robert JT Williams (Welsh Assembly Government)

The secretariat reported that they had been informed by Nick Cartwright that due to a change in role at EA that he had left the SC and starting from the current meeting would be replaced by Richard Hawkins. The SC welcomed Richard.

2. Note and actions arising from last meeting (23rd July 2010)

Subject to a few minor amendments the minutes of the last meeting (Paper 1 – REACH SC 2011/1/2/1) were agreed. On the actions, the key points to note were:-

- The minutes from a number of outstanding REACH CA Steering Committee (SC) meetings have been placed on HSE's publically available website and the secretariat had sent copies of recent SC meetings minutes to Defra to be posted on their website.
- Defra had sent a copy of the agenda for the upcoming CARACAL meeting to SC members. Defra acknowledged that the timescale for comments was limited for this current meeting but anticipated that there should be more time available for comment in future.
- It was agreed that the SC should meet twice yearly.

Actions: Secretariat to circulate an availability matrix in time to arrange the next meeting due to be held mid-July.

3. Review of UK REACH CA Activity April – December 2010

HSE–REACH CA provided a summary of the second and third quarter progress (REACHSC 2010/1/3/1). Some key points were as follows.

The helpdesk is still a high priority, with response targets continuing to be met and feedback received from enquirers continuing to be consistently positive. The Committee work is increasing in complexity and enforcement remains important.

There continues to be routine work to be carried out such as commenting on Restriction dossiers or test methods, and the approach being taken is to focus on quality rather than go for quantity.

HSE and WAG commented that they were satisfied with the work being carried out by the CA.

HSE–REACH CA asked whether the SC were happy with the paper in that it was an update of the paper presented to the July 2010 meeting, to which HSE commented that the final end of year paper could perhaps contain a note on budget to account for resourcing. HSE–REACH CA responded that this would be useful to explain where the CA had not done an activity due to resource limitations but otherwise would not be necessary, but was open to SC suggestions on this issue. Secretariat suggested that this might help provide context, such that a short summary of the resource situation might focus where the priorities have been. HSE–REACH CA indicated that a 'crude' pie-chart has been used previously and could be provided in future. Secretariat considered that this might provide the broad context as to the constraints that the CA faces.

HSE considered that this was more for interest than reporting or monitoring. HSE questioned who this report was aimed at, and suggested that if the intended audience is wider than the SC, it might be beneficial to focus the document. HSE–REACH CA confirmed that the document was for the SC and a defined form had never been established.

The Chair considered that this will be a useful addition to the final report and provide a more complete picture.

Action: HSE–REACH CA to add budget information in the form of a pie-chart to the final end of year review of CA activity.

HSE–REACH CA explained that the work of the CA was not just about high profile substances but that there was a lot of routine maintenance and background work that the CA carried out (and which is important to cover for maintaining the CA's reputation). It is important that this work is not overlooked. DoH questioned whether this CA progress report document should be made available on the internet, to which HSE–REACH CA answered that there was nothing sensitive or confidential in the document. Defra considered that as there was nothing sensitive it would be useful if it were made available. HSE–REACH CA indicated that it could be placed on the internet as a stand-alone document (rather than an agenda item from this meeting). HSE asked whether progress reports from previous meetings would also therefore be posted similarly. HSE–REACH CA indicated that the CA could start by posting this document initially.

Action: Secretariat to confirm with SC members that they are happy with the text in the CA progress report document, and following confirmation post the document on HSE's REACH site.

4. Forward planning for 2011/12

In introducing this agenda item, Defra indicated that the REACH CA budget for 2011/12, and subsequent years, was likely to be cut in line with the general budget reductions anticipated for DEFRA and HSE. However, it was yet to be decided how this would be spread over the 4 year period of the Spending Review.

4.1. General Discussion

HSE–REACH CA presented the Forward Look document (REACHSC 2011/1/4/1). In view of the uncertainty surrounding the budget, this document offered a perspective on where the priorities for resource allocation might lie. The planned work of the CA in 2011/12 could be divided into several sections: Helpdesk &communications; ECHA Committees; Evaluation of dossiers and/or substances; Management of CA; Support to the Defra REACH-policy team; Enforcement & compliance, etc.

There were several key points drawn out by the discussion of this agenda item.

(i) Unlike some of the other larger EU MS CAs, the UK CA has not yet indicated whether it will be taking forward any restriction or SVHC proposals during 2011/12. Work on a small number of Risk Management Option papers will be taken forward,

and this could lead to further proposals. However, resources will be targeted towards ensuring the regulatory systems in REACH are being progressed well, e.g. by commenting on the dossiers of other member states, engaging in ECHA-led discussions about the Authorisation and Substance Evaluation processes, etc. It was thought that ECHA would value this approach, as had been seen already in relation to the work CA staff had done for RAC and SEAC (including on the classification of substances). Another example was the work that had been done in relation to "substances in articles".

(ii) The CA will continue to operate the helpdesk and anticipates the relative complexity and variety of enquiries to continue, even if the overall numbers decline post-registration. The CA is unlikely to produce a lot of new guidance or to host many seminars/workshops during 2011/12.

(iii) The CA's continued relatively high-level involvement with the ECHA committees and CARACAL and its subgroups were seen as being important.

During further discussion, DoH questioned whether other Member state CAs might question why the UK has not already indicated intentions to propose more SVHCs. The CA thought this unlikely, given that numerous UK intentions had been provided for classification and labelling and the UK was engaging at a more general level on PBT and vPvB issues.

Defra noted that on human health it had to be borne in mind that in relation to Annex XVII of REACH that once a substance is classified as a Carcinogen, Mutagen or Reproductive toxicant (CMR) that there is already a general restriction prohibiting supply to the public, and therefore questioned the extra benefit from going for an SVHC listing.

The CA would be preparing a Risk Management Options paper on decaBDE, following advice from the Advisory Committee on Hazardous Substances (ACHS). Their final view in September 2010 had been that the existence of strong qualitative evidence, together with some quantification in experimental systems was sufficient to conclude that deca-BDE has the potential to undergo environmental degradations to SVHCs. The ACHS were also of the opinion that if qualitative evidence was considered sufficient for regulatory purposes, then deca-BDE meets Article 57(f) criteria for classification as a Substance of Equivalent Concern.

Regarding other substances of concern for the environment, it was noted that EA will consider further candidates for possible SVHC identification. EA confirmed that there are likely to be some, and that other EU MS seem to expect those that are PBT to follow this route. However, there are other (non-REACH) methods available to regulate such substances, and these will also be considered.

WAG noted that some other EU MS appear to be deliberately aiming to produce relatively high numbers of SVHC proposals, as a matter of policy. WAG would have been uneasy if the UK took a similar approach where quantity rather than quality seemed the approach. WAG considered that the scrutiny of documents from other Member States was important. Defra agreed that assessment and communication on OMS papers is considered to be important, and highlighted the proposal from

Denmark to deal with four phthalates as a group with combination effects as an example of the importance of the UK's interaction. WAG confirmed that they were happy with the approach being taken, i.e to aim for scientific rigour in the REACH processes.

Overall, the Steering Committee welcomed the opportunity to discuss the Forward Plan and agreed that it formed a sound basis for the work of the CA in 2011/12.

4.2. Substance evaluation: Strategic thinking in relation to UK CA involvement

HSE–REACH CA explained that the paper REACHSC 2011/1/4/2 was to provide information to the SC on what is planned in relation to substance evaluation and the development of the CoRAP, and asks questions intended to help the CA plan strategically for when substance evaluation starts in 2012. The ECHA has requested that MSCAs provide precise numbers of substances for the next 3 years by 1 March 2011. HSE–REACH CA questioned what relative importance should the CA give to substance evaluation and sought views on the number of substances that the CA should propose. HSE–REACH CA added that the reason for asking is that the people conducting the evaluation may well be the same as those who sit on the committees or produce RMO papers, and therefore the CA has a need to prioritise work and people.

The Chair questioned whether the proposal to work on three substances was a tentative approach by the CA to gauge the practicalities of the system. HSE–REACH CA indicated that the ECHA Management Board Working Group had made assumptions that an average of 3 - 3.5 substances would be evaluated per year per Member State. At a workshop in October 2010 on substance evaluation discussion between OMS indicated that the range would be 1 - 4 substances per year. This is a new area of work, the formats for the work are not confirmed, and hence the UK CA are erring on the side of caution. However, it is possible that the number of substances may change after the first year.

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The Chair questioned whether OMS and ECHA would be surprised if the UK only nominated 3 substances. HSE–REACH CA replied that 4 would seem to be the upper number. As noted previously, the UK may increase the number after the first year but experience from previous regulatory programmes indicates the need for a careful initial approach. Therefore 3 substances should not be seen as an indicator of the UK's long term ambition. The Chair asked if this proposal for 3 substances was for 2012 only. HSE–REACH CA indicated that this was not intended to set a precedent for the period between 2012 – 2014, and in response the Chair asked if the CA could give an indication of its plans for 2013/14 without necessarily committing to a number. HSE–REACH CA indicated that the CA were looking to increase the number of substances in line with OMS but were taking the first year as an example.

Defra indicated that they support this approach and that 3 substances seems a reasonable beginning, and that there are issues in relation to the funding of this work by fee transfer from ECHA that need to be addressed with ECHA (such as the profile for when the fee transfer happens).

The Chair questioned what figure the CA would give if pushed. HSE–REACH CA indicated that whilst a figure does not have to be provided, if pushed to do so the UK

could perhaps say 4+. The Chair considered this approach reasonable, particularly with the questions that need to be addressed with ECHA. HSE noted that this issue is critical to HSE's Chemicals Regulation Directorate (CRD) which houses the CA since although CRD are keen to be involved the first substances need to be realistic.

DoH noted that it is good to be able to prioritise the substances that are of most relevance to the UK and is attractive in that it offsets possible criticism in relation to the approach taken by the UK in relation to SVHC. HSE indicated that the UK approaches substances on a risk proportionate basis, with the current spotlight being on risk. It is better to do a good job on a few substances rather than take on too many (particularly in the first year). Defra questioned whether the evaluation would identify if the substances were high risk, however HSE confirmed that they would not be nominating substances if they did not think that they were high risk. Defra confirmed that the money to carry out this work is associated with it (and hence is additional to money which is already provided).

The Chair questioned how the CA intended to identify substances. HSE–REACH CA explained that ECHA may find issues with substances while carrying out dossier evaluation and put these forward but is also developing IT tools to search the dossier information for potential candidates which will then form a list. MS can also propose substances for evaluation. The UK was in general looking to the ECHA list, as MSCAs do not yet have full access to the IUCLID database (the interim solution of an excel file provided by ECHA is not ideal) but would need criteria to choose from those substances .

Defra questioned whether there would be an expectation that MS who propose a substance would also carry out the work on that substance. HSE–REACH CA agreed that this was the likely position but that there would be discussions before CoRAP to agree who does what. EA noted that they had substances ready to take forward, and that they may want to share this list with OMS to investigate whether any OMS would be interested in progressing any of these substances. Defra commented that whilst there are substances on a list that could be taken forward that there are some issues that need to be borne in mind. It is necessary to consider substitutes for SVHCs, in that there are often large amounts of data on the SVHC substance but far less on possible substitute substances, (ie potentially replacing a substance which we know is of high concern with one about which we know far less).

Nano-forms of bulk substances were also considered to be a potential reason for prioritisation: if the UK were to volunteer to evaluate some of these it may be possible to address some of the issues that surround such substances.

HSE re-iterated that chemicals are controlled by legislation other than REACH. There are occupational exposure limits already, and BIS/DoH could comment on public health/consumer protection. CMR are well covered but what about equivalent concern, for example endocrine disruptors?

HSE questioned whether it was too early to be involved in evaluating nano-materials in that it was not clear how they would be covered at EU level. Therefore, it may be best to prioritise based on environmental issues first, although recognising that presentationally it might seem strange if human health is not targeted. DoH agreed

that there may be presentation issues if the focus was on the environment rather than human health.

Defra noted that in relation to nano-materials, if the UK were to do a few substances it would give some specific information that may be of some value. HSE agreed that the substance evaluation work may resolve some issues that have been around for years and could have a final outcome. However, would the UK want to pick up substances that the UK have dealt with before eg. Bisphenol-A (BPA)? HSE–REACH CA questioned whether the UK should begin by working on less controversial substances in order to work out the system rather than risk getting bogged down with controversial substances that have been discussed in a number of other regulatory schemes but continue to raise issues. HSE–REACH CA added that ECHA has suggested that MS choose 'easy' substances to get started. EA noted that there is only 12 months to evaluate the substance. HSE–REACH CA commented that a substance such as BPA is a big international issue and therefore there is a danger of being overloaded with competing information, but that if after the first few years the evaluation process is a success then such a substance could be considered.

WAG noted that it would be interesting to see which substances OMS picked up. Defra considered that the UK has been dealing with challenging substances so the cost of processing a less challenging substance would need to be determined. The Chair asked whether in relation to human health issues, the CA were intending in the near future to propose substances for years 2 and 3? HSE replied that the CA does not have a compelling need to suggest substances upfront. HSE–REACH CA added that there may be other substances outside REACH (eg pesticides / biocides) where data are available to suggest classification and labelling to achieve significant outcomes.

Defra suggested that it would be useful for the CA to access the ECHA list of substances.

HSE–REACH CA confirmed that the CA now has a good steer on this issue as a result of these discussions.

4.3. *REACH Enforcement by the Chemicals Regulation Directorate*

HSE–REACH CA introduced the paper on REACH enforcement REACHSC 2011/1/4/3. It was explained that the first regulatory deadline for substance registration had now passed. Regulatory enforcement is a priority and the paper focused on suggestions (along with rationales) as to possible ways forward in relation to this.

HSE–REACH CA made clear, that given the resources available, enforcement operations cannot be fully comprehensive but must be prioritised. Duty holders' compliance is considered to be good compared to some OMS. The proposal therefore is to carry on as currently, with re-active enforcement (which helps to maintain confidence in the CA) but also carry out pro-active enforcement on individuals who have done the least to comply with the legislation. However, HSE–REACH CA were

clear that enforcement needs to be proportionate, and noted that companies should be given time to comply with requirements.

HSE–REACH CA indicated that CRD's enforcement section could provide a support and co-ordination role for the supply chain, through guidance, training and advice to other units and the Enforcement Liaison Group (ELG). However, there must be a realistic understanding as to what is achievable through these routes/groups.

In terms of regulatory enforcement there are some risks that need to be managed. In particular the expectations of external stakeholders such as ECHA need to be realistic and this needs to be managed to ensure that this is the case. The CA and Defra continue to work closely together since the work that is carried out by the CA feeds back into policy issues.

WAG considered that the perception of REACH enforcement is extremely important since it would be very damaging to both the reputation of HSE and confidence in the REACH system if industry lost confidence that REACH would be adequately enforced.

EA noted that information had been supplied to HSE regarding compliance in relation to particular substances, and questioned whether this should continue. HSE–REACH CA replied that the CA were starting campaigns based on these reports, but needed to evaluate their outcomes. It was re-iterated that the CA wants to continue to be pro-active. HSE pointed out that UK industry will be a key stakeholder, as responsible dutyholders expect that competitors who have not complied with their duties under REACH are enforced against. HSE is also aware of concerns from big business about the supply chain as any breaks in their supply chain could have significant consequence for production upstream. HSE noted that the first registration requirement is typically for big companies that have a more thorough understanding of REACH, and that it will be important to draw lessons from both first-tranche registration and enforcement of these duties, in order that smaller companies can be effectively supported and monitored at later registration deadlines. Therefore, insofar as there are presentational risks associated with enforcement, they are more relating to dutyholder concerns than, for instance, ECHA.

Defra agreed that although the relationship with ECHA is important, the most important stakeholder is UK industry, and that industry wants to see a level playing field across the EU. This relates to the work of the Forum and how the UK interfaces with the Forum and still encourage a UK approach across the EU.

HSE expressed concerns which were noted by the Chair over the suggestion in the enforcement document to focus only on Article 5, and proposed a discussion of how the proposals to achieve efficiency gains go forward. Defra noted that in relation to Article 5, this goes back to internal discussions and list of enforceable duties. There is a lot of individual information providing duties and these did not need to be listed as enforceable duties. If information that a company is meant to be supplying to ECHA has not been provided then it is in breach of Article 5. HSE clarified that the concern that was being expressed was in relation to the word 'only' in relation to Article 5.

HSE–REACH CA noted the continued absence of a representative of Local Government Regulation (formerly LACORS) on the SC and asked in relation to enforcement how much co-ordinated interaction there is with LGR. HSE–REACH CA noted that an LGR representative is also missing from the ELG, although there is interaction with individual local authorities which are very helpful.

6. Reports from ECHA Committees and other fora

HSE-REACH CA explained that the short reports on the ECHA Committees and other fora had been circulated to members prior to the meeting. No comments had been received in relation to these reports.

The Secretariat confirmed that SC members had been provided with web-links to the minutes published by ECHA and the EC for the committees named in the circulated reports for further information. Secretariat highlighted that most agendas and minutes were publically available but that the CARACAL minutes might be on a site to which SC members do not have access.

Secretariat indicated that an abbreviation list had been provided.

7. Date of next meeting

The secretariat noted that the SC had expressed an interest in having two meetings a year, spaced approximately 6-months apart. As such the suggestion was that the next meeting would be July 2011. HSE–REACH CA noted that this would be just before the next CSF. The SC agreed that this would be an acceptable date for the next meeting.

Actions: Secretariat to circulate an availability matrix in time to arrange the next meeting due to be held mid-July.

8. AOB

HSE requested a written update from Defra on the legal amendments to enforcement updates on asbestos and DCM. Defra confirmed that the necessary reglegal amendment had been included in the Defra Regulatory Forward Look, and that they would be in place in tiume for the REACH deadline for these arrangements to be reported to the European Commission of 1st June 2011. Defra confirmed that they intend to circulate this document to SC members via the secretariat.

Actions: Defra to provide a copy of the intended changes in relation to enforcement updates on asbestos and DCM to the secretariat for circulation to SC members.

Summary of actions

Actions: Secretariat to circulate an availability matrix in time to arrange the next meeting due to be held mid-July.

Action: HSE–REACH CA to add budget information in the form of a pie-chart to the final end of year review of CA activity.

Action: Secretariat to confirm with SC members that they are happy with the text in the CA progress report document, and following confirmation post the document on HSE's REACH site.

Actions: Defra to provide a copy of the intended changes in relation to enforcement updates on asbestos and DCM to the secretariat for circulation to SC members.