

UK REACH COMPETENT AUTHORITY (CA)

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

Monday 29th September 2008 – via Teleconference

1. Attendees

John Roberts – Defra; chair
Keith Bailey – Defra
Steve Fairhurst } – representing the two groups (HSE & EA) collaborating to deliver
Steve Robertson } the UK REACH CA function respectively
Tim Harris – HSE Policy Group; contributor to REACH CA function
Stavros Georgiou – HSE Economic Analysis Unit; UK REACH CA socioeconomic expert
Chris Mawdsley – HSE, UK REACH CA
Susan Scott – Scottish Government
Garth Broomfield – Scottish Environment Protection Agency (SEPA)
Wendy Thornton – Scottish Environment Protection Agency (SEPA)
Katie Willis – Scottish Environment Protection Agency (SEPA)
Martin McVay – Welsh Assembly Government
Robert JT Williams – Welsh Assembly Government
Nick Cartwright – Environment Agency
Jim King – representing Northern Ireland Assembly interests
Chris Barrell – BERR
Alison Edwards – LACORS

Sue Hambling – HSE; Secretariat to UK REACH CA Steering Committee (UK REACH CA SC)

Apologies / non-attendees / substitutes:

- Richard Bishop – HSE; UK REACH CA enforcement
- Rhodri Griffiths – Welsh Assembly Government
- Simon Dyer – Department of Health

2. Note and actions from last meeting (20th May 2008)

2.1 Minutes

The minutes of the last meeting (Paper 1) were agreed subject to the following changes:

- inconsistencies between the use of REACH CA and REACH SC to be removed
- the Water Framework Directive to be correctly and consistently described throughout
- a footnote to be added to indicate that for diethyl hexyl phthalate (DEHP) ‘Sweden had nominated DEHP and hence the need for the UK to consider doing so was now unnecessary’

The agreed minutes are then to be placed on the UK REACH CA website.

Action: Sue Hambling to amend the minutes

Action: Tim Harris to arrange for agreed minutes to be placed on UK REACH CA website

The following observations were made whilst checking on any outstanding actions:

a) the spreadsheet of contact details for the members of the UK REACH CA Steering Committee was updated, but needs to be updated further to include Wendy Thornton & Katie Willis from SEPA (and remove Richard Grant & Felix Otton)

Action: Sue Hambling to update the spreadsheet and store the revised version on the Government REACH Internet Community site.

b) the UK REACH CA has not yet contacted key organisations for their experiences of the UK REACH CA website and Helpdesk; this is to be done in Autumn '08. It was noted that an EU survey had been done on the Helpdesks and was due to be published in Autumn '08.

c) it was agreed that at this time there was no need to reconvene the EA/Waste Industry/Defra forum to discuss the waste issue under REACH.

d) the EA has provided input to the 08/09 Business Plan (v.0.3) (Paper 2) and this input needs to be amalgamated into the current version of the Business Plan (v0.4)

Action: Steve Fairhurst to insert the EA input into the current UK REACH CA Business Plan (v0.4)

e) the use of the REACH Government Internet Community website as a communication tool was reviewed. It appears that most UK REACH CA Steering Committee members are receiving the e-mail alerts sent out when new documents are uploaded. However there was a request for the 'Alert' to be more obvious within people's e-mail in-boxes.

Action: Sue Hambling to investigate if the Internet Community facilities will allow the e-mail alert to be more obviously titled

3. Enforcement Update

Richard Bishop had provided an update to be given at the meeting. The key points were:

- LACORS and EA have reached an agreement on how to enforce at IPPC Part A2 & B sites
- the Statutory Instrument (SI) on REACH enforcement in the UK is near to completion
- some progress has been made to include HM Revenue & Customs (HMRC) in the regime; the final version of the SI will be circulated this week.

Some observations were made:

- the relationship between HSE and the Environment Agency on enforcement has developed well and there is to be a training day on the joint approach
- there is some concern about the metrics that will be demanded for reporting enforcement activities to ECHA. Defra aired concerns that the measures are likely to be simplistic (eg number of inspections) rather than intelligent (eg targeted inspections to achieve specific enforcement aims). It was also noted that terminology across all UK enforcing authorities is not consistent – HSE counts preliminary contacts as “inspections” whilst other bodies only count “inspections” as on-the-ground visits. At present it is not clear if this will be a problem.
- SEPA indicated that there was still an issue with offshore enforcement in the waters off Scotland, as SEPA can only enforce onshore. The SEPA lawyers are currently talking to Defra's lawyers and this matter needs to be resolved as a matter of urgency.

- UK REACH CA Steering Committee members, especially the Devolved Administrations, need to be aware of enforcement matters, so that they can keep Ministers up-to-date. Hence enforcement will become an agenda item for future UK REACH CA Steering Committee meetings

Action: Keith Bailey to ensure that the Scottish offshore issue is being addressed by Defra lawyers, to resolve quickly

4. Mid-Year report of activity of UK REACH CA (Paper 3)

Steve Fairhurst introduced the paper and referred UK REACH CA Steering Committee members to some of the key points regarding the activities of the UK REACH CA. The key points discussed were:

Helpdesk Enquires

- the volume of enquiries to the Helpdesk is still increasing (and will be about 1000 in September). The timeliness and quality of responses is being maintained, but on some days resource is badly stretched. The principal reasons for the high numbers of enquiries seems to be that pre-registration is on-going and also companies are being contacted by others in their supply chain, triggering worries about whether or not they need to do anything.
- it is hoped that the number of enquiries will steady, and possibly even reduce somewhat, when the pre-registration period finishes at the end of November. An issue that will then arise is what approach should be taken with Registration duty holders who have missed pre-registration. The UK REACH CA is to develop a position on this issue. Defra indicated that UK trade associations want to see a firm hand being taken against those who failed to pre-register.

Transitional Dossiers

Steve Fairhurst indicated that all four UK “Existing Substances Regulation” transitional dossiers are scheduled to be sent to ECHA in a defensible, logical state of completeness by the end of November 2008, but there will be some issues that cannot be completely resolved by this date (eg the result of an ongoing study on medium-chain chlorinated paraffins [MCCP] to better determine if it meets the criteria for a PBT). It is unclear how ECHA will manage the need for post-November updating to include additional data.

5. Communications

The UK REACH CA Communications Plan for 08/09 has been updated to reflect

- the work being done related to substances nominated as candidate Substances of Very High Concern for possible Authorisation
- the development of the EU REACH Risk Communications Network, RCN
- the shadowing by the UK REACH CA of two small UK companies, to establish better understanding of the needs of SMEs in respect of REACH information and advice.

Local radio broadcasts and advertisements on the web, to raise awareness of REACH, are due to go out this week; there will be a follow-up survey in December 2008 to assess their effectiveness

Tim Harris introduced the RCN:

- it is an unofficial part of the ECHA network of fora, set up to address the duty for member states (MSs) to provide general information to the public (Article 123) – ECHA provides the secretariat
- ECHA are interpreting REACH article 123 broadly, basing their conception of 'risk communication' on OECD work. They have a duty to produce guidance to Member States and it is likely that it will reflect this interpretation
- MSs have mixed views on whether the RCN should exist – Ireland/The Netherlands do not want the RCN, as there is no legal basis for it; the UK wants it for assistance when there is a need to communicate messages via mechanisms over and above those clearly defined in REACH such as Safety Data Sheets. A stalemate exists and a working group is preparing a paper for the MS Competent Authorities meeting on the possible role of the RCN.

The number of individual pre-registrations made thus far is far greater than ECHA expected, with those made from the UK being the second highest from any individual MS. Key points are:

- the REACH IT system is holding up (as of the previous week). Acknowledgement by ECHA of successful pre-registration takes a minimum of 6 hrs (ECHA IT quarantine period for virus checks) and up to 30 hours in some cases. There have been concerns in recent days that the IT system is slowing down and some reports of it being hard to log-in, the system freezing and then crashing and data having to be re-input.
Action: Steve Fairhurst to contact Peter Newport at the Chemical Business Association to establish what problems have been encountered; and then, if appropriate, discuss with ECHA
- two companies (one UK, one German) have pre-registered the entirety of EINECS and ECHA is unhappy about it. The UK company has been asked to remove those substances that do not need to be pre-registered (but this is slow as no bulk de-registration facility on the IT). ECHA have asked Companies to contact them if they wish to pre-register more than 10,000 substances.
- BERR has been receiving a few enquiries from the automotive industry recently (about 2 per week since pre-registration started).

6. UK Substance-Selection Process

Steve Fairhurst introduced the paper on substance selection. The key points were:

- the UK REACH CA would develop and maintain a log to cover
 - substance proposals made via the UK REACH CA Steering Committee.
 - all substances being contemplated across EU, eg from the Register of Intentions and other sources of intelligenceand all suggestions/comments for substances to be logged should be sent to Sue Hambling (UK REACH CA)
- the log would be reviewed at UK REACH CA Steering Committee meetings but
 - urgent issues will be handled by correspondence between meetings

- the log will be reviewed in detail in the Autumn of each year to establish substances for the following year's work plan
- criteria by which the UK REACH CA Steering Committee decides on selection/prioritisation of substances have yet to be proposed. Steve explained that EU REACH processes are still new and it would be sensible to maintain maximum flexibility at this stage; however, justifications for any individual substance would need to be robust, as industry/ministers will want evidence as to why individual substances are being proposed.

A number of comments were made:

i) wider views of possible SVHCs

The secretariat of the UK Chemical Stakeholder Forum is to ask members for their views on prioritisation of substances and any views presented should be taken into account.

ii) numbers of possible SVHCs to be proposed

The ECHA Management Board has recently expressed disappointment at the low number of possible SVHCs put forward for consideration for the first Candidate List and want larger lists in future.

- John Roberts asked that the UK should try to declare another couple of substances for the Register of Intentions and prepare the associated dossiers over the next 6-7 months
- Steve Fairhurst suggested that the UK could consider substances that would help complete groups (eg potassium dichromate, anhydrous sodium dichromate, etc, to complement sodium dichromate dihydrate that is already proposed) where hazard profiles are similar and easy to acquire. Without such group-wide treatment, no step-changes in the pattern of chemical usage are likely to occur.

Action: HSE, EA and SEPA to identify additional substances for the Register of Intentions within the next 2 weeks, and prepare the relevant dossiers within the next few months.

iii) timings for discussion

The proposed timing for detailed consideration of the log, in Autumn of each year, was supported by the Devolved Administrations as it fits with timescales for the development of business plans for the subsequent financial year, but timings will need to be aligned with ECHA timescales for work, once they are clearer.

iv) need for selection process criteria

The UK REACH CA Steering Committee will need to balance the number of substances it identifies as meriting serious concern, such that the UK should work on them, with the budget available for the UK REACH CA function. In this context there was general support for the development of criteria for the selection process to ensure the process is transparent and can be justified to stakeholders and Ministers.

- hazard and risk could be preliminary criteria, but there will then be a need to establish how to merge human health concerns with environmental concerns.
- it would be useful to have a rough idea of the extent of use of a substance in the UK, and the reliance on it, as part of the considerations prior to making a formal proposal to work on a substance.

- we need to consider how and when to make an initial assessment balancing benefits against costs. Within the EU REACH process socio-economic analysis is not needed until the point at which a company submits an authorisation request. The UK REACH CA needs to think about the feasibility, merits and timing of cost-benefit considerations at an earlier stage, to inform thinking about substance selection.
- some possible selection criteria for prioritising substances exist in RIP 4.5; and within the UK under the UK CCRMP (Co-ordinated Chemical Risk Management Programme)

v) understanding EU process

- It was noted that we need to better understand and intervene at the early phase in which Member States are developing their ideas for proposals to the Register of Intentions.
- ECHA is proposing to hold a workshop towards the end of 2008 on current issues related to making proposals and compiling dossiers for possible SVHCs.
- The reason for the European Commission's addition of several Coal Tar entities to the second Register of Intentions is unclear; consultants are to produce the necessary Annex XV dossiers, which should be available for MS comment in early 2009

John Roberts confirmed with the UK REACH CA Steering Committee that the process proposed in the paper was agreed. Further work is now needed to implement the process and to refine some of the features.

Action: Steve Fairhurst to collect ideas and available material, to then draft some potential selection criteria in a paper to be presented to the next UK REACH CA Steering Committee meeting.

7. Reports from ECHA Committees and other Fora

7.1 ECHA Management Board (John Roberts)

The key points from the recent Management Board (MB) meeting are:

- On the fringes of the MB meeting there was a meeting of the "Costing Methodology" group, looking at reimbursement from ECHA to MS REACH CAs for Risk Assessment Committee rapporteur work done by its staff, and for substance Evaluation work. ECHA has stated that there will be about 5 million euros available in the first 3 years after introduction of the reimbursement process. The amount to be reimbursed to any particular MS for such work will be set according to the stipulated average time needed for each type of work (eg 500 hours for a substance evaluation), a standard fee per hour and a factor reflecting labour costs & retail prices in the particular MS.
- Before the UK can be reimbursed HSE will need to agree a Framework Contract with ECHA

Action: Steve Fairhurst to ensure that the appropriate contact is made with ECHA, such that a contract can be set up.

- ESR transitional dossiers are to be used to trial the rapporteur role for Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC).
 - this will be a pilot with no money reimbursed
 - UK, Germany and Sweden have offered that their nominees to RAC and SEAC will volunteer to be rapporteurs. It might be sensible if the rapporteurs for the RAC and SEAC on any one substance are from the same MS, so that they can work together.
 - the pilot will define the quality expected from the rapporteurs for subsequent work, commensurate with reimbursement being made.
- The members of the Board of Appeal have been established but as yet there is no Chair. This is a concern, because from January 2009 ECHA decisions could be challenged via this Board. The position of Chair is being re-advertised, with the need for 5 years legal experience being reduced to 3 years.
- The multi-annual work programme was discussed and the key points raised were:
 - All MSs want more possible SVHCs included on the Candidate List
 - There is a priority to sort out how REACH will cover nanomaterials. An EC working group (a spin-off from the EU REACH Member States Competent Authorities forum) is looking at whether to recommend changes in the REACH regulation to better accommodate nanomaterials.

7.2 ECHA Member States Committee (Steve Fairhurst)

The next meeting is 7-9 October. Current issues are:

- First set of possible SVHCs nominated for the first Candidate List – the majority to be cleared by written procedure as no issue regarding meeting Article 57 criteria; 5 are to be discussed at the imminent meeting.
- There appears to be no formal forum for discussion of substances before they go on to the Register of Intentions. If they clearly meet the CMR or PBT/vPvB criteria in Article 57 they then appear to be going straight into the Candidate List, without further consideration. This is a concern – for example, MSs may not want them regulated via Authorisation; and will have to explain their inclusion in the Candidate List if asked by stakeholders, eg via their national REACH Helpdesks.

7.3 ECHA RAC (Steve Dungey & Andrew Smith)

There has been no meeting since July and there are no new issues.

7.4 ECHA SEAC (Stavros Georgiou)

There has been no SEAC meeting since the UK REACH CA Steering Committee last met. The next SEAC meeting is on 22-23rd October 2008 when the following topics are likely to be discussed

- Work procedures for transitional dossiers
- Stakeholder participation in meetings, as there is disagreement – the UK view is that all those with a legitimate interest should be able to attend subject to limitations on space and that there will be closed sessions as confidential data will need to be discussed (ECHA is less happy about observers).

7.5 EU REACH Competent Authorities Meeting (Keith Bailey & Tim Harris)

This is not a formal REACH committee as specified under the REACH regulation, but is acting as a policy advisory body for the European Commission.

It last met on 25-26th September and the key points are:

- The waste/recycling issue is reaching a ‘least-worst’ conclusion that should clarify the position on pre-registration of waste and classification of recycled aggregates as articles
- Test Methods Regulation: although OECD is the main route for international agreement of test methods, the EU can now proceed unilaterally if it so desires. This might be the route taken to achieve incorporation into REACH of the use of the “Episkin” and/or “Epiderm” alternatives to experimental animal skin irritation testing
- The current proposed entry for asbestos in REACH Annex XVII is creating a problem, because of its implications for the resale of potential asbestos-containing objects such as houses; this has been raised by the UK.
- There is an increasing proliferation of CIRCA sites used for disseminating REACH information and ECHA has accepted an action to clarify the situation
- The Commission and ECHA have a strong control over the agenda, and as all the meetings are now in Brussels there is little free/networking time. Meetings in future will have some such time available.

7.6 Article 133 Committee (Keith Bailey)

Although there were only supposed to be 3-4 meetings a year, they are currently running at 6-8 per year. The current topics are:

- rules for Board of Appeal have been developed
- Amendments to Annex IV and V have been agreed – the UK got glycerol added to Annex V
- Commission Guidance on Annex V is due out soon
- Provisions for exposure-based waiving of further testing, in Annex XI, have been agreed
- Review of Annex XIII on PBT criteria due to begin early next year
- First Amendment of Test Methods Regulation to be worked on.

8. Thoughts on UK REACH CA Work Plan for 2009/10

There was a discussion on thoughts for developing the UK REACH CA work plan for 2009/10. The key points were:

- The way in which the work plans for previous years has been presented is appropriate for the 09/10 plan.
- There will be even closer working between the HSE and EA components of the UK REACH CA in the coming year
- There is need to consider the “CREATE” project which is intended to integrate the HSE components of the delivery of the regulatory responsibilities for pesticides, biocides and REACH, now that Pesticides Safety Directorate has been merged with HSE. It is envisaged that in future there will still be
 - A distinct UK REACH CA work plan
 - Separate “UK CA Steering Committees” for Pesticides and REACH
- Any money received from ECHA for reimbursable work should be kept separate from HSE budgets and considered to be ‘ECHA contracted work’, from which EA will be reimbursed for its contribution.

Action: Steve Fairhurst to arrange for money reimbursed from ECHA to be kept separate from HSE budgets

- A summary table was requested to be included at the front of the 09/10 workplan.

9. Arrangements for next UK REACH CA Steering Committee Meeting

Feedback from members suggested that teleconference is preferred to video-conferencing or travelling. It was agreed that:

- the next UK REACH CA Steering Committee meeting is to be a teleconference in the middle of January 2009
- there will probably be a need for a longer face-to-face meeting later in 2009.

Action: Sue Hambling to arrange the teleconference meeting for mid-January 2009. The agenda should include (a) paper on criteria for substance selection, (b) a draft work plan for 2009/10 and (c) item on enforcement activities.

10. AOB

None.

Summary of Actions

Sue Hambling to:

- a) amend the minutes from the last meeting in accordance with 2.1.
- b) update the spreadsheet with REACH Steering Committee members contact details and store the revised version on the Government REACH Internet Community site.
- c) investigate if the REACH Internet Community facilities will allow the e-mail alert to be more obviously titled.
- d) arrange the next UK REACH CA Steering Committee meeting, via teleconference, for mid-January 2009. The agenda should include
 - (i) paper on criteria for substance selection,
 - (ii) a draft work plan for 2009/10 and
 - (iii) item on enforcement activities.

Steve Fairhurst to:

- e) insert the EA input into the current UK REACH CA Business Plan (v0.4).
- f) contact Peter Newport at the Chemical Business Association to establish what IT problems have been encountered recently in attempting pre-registration; and then, if appropriate, discuss with ECHA.
- g) draft a paper on substance selection criteria for the next UK REACH CA Steering Committee meeting.
- h) ensure that the appropriate Framework Contract between HSE and ECHA is set up for reimbursement purposes.
- i) check that money reimbursed from ECHA can be kept separate from HSE budgets.

Tim Harris to:

- j) arrange for agreed minutes of the fourth meeting of the UK REACH CA Steering Committee to be placed on UK REACH CA website

Keith Bailey to:

k) ensure that the Scottish offshore issue is being addressed by Defra lawyers, to resolve quickly.

HSE, EA & SEPA to:

l) identify additional substances for the Register of Intentions within the next 2 weeks, and prepare the relevant dossiers within the next few months.

Version 3 (11/12/08)

Agreed at REACH SC 19/01/09

Sue Hambling