Understanding REACH

Date: 16th December 2009

WORKSHOP REPORT

BACKGROUND

A workshop was run to promote general understanding of the REACH legislation amongst government departments and agencies and to raise awareness of how its implementation may have downstream consequences in other regulatory areas.

OBJECTIVES

A number of objectives were identified for the workshop:

- To provide an overview of the background, aims and benefits of REACH
- To provide a description to delegates of the various facets of REACH work e.g. Registration; nomination of Authorisation candidates; Evaluation;
- To improve understanding of how REACH may have downstream consequences in regulatory areas governed by other chemical legislations through Authorisation or Restriction of Substances of Very High Concern;
- To provide an overview of the Authorisation process;
- To give an outline of the enforcement arrangements;
- To describe the main elements of a Registration dossier;

DELEGATES

Delegates from all governmental departments and agencies with an interest in REACH (scientific and policy related) were invited to attend (this included non-IGHRC membership departments). A total of 25 delegates attended the workshop, corresponding to 8 government departments and agencies.

WELCOME AND INTRODUCTION TO THE IGHRC

Professor Len Levy: Chair IGHRC Executive Committee

Professor Levy welcomed all participants to the workshop and thanked speakers for agreeing to take part. A brief introduction to the work of IGHRC was given, followed by a brief outline of the workshop programme.

INTRODUCTION TO REACH

Andy Gillies (Gillies Associates Limited)
Chair, BOHS REACH Steering Group

During this presentation, Andy Gillies gave an overview of REACH which included a description of its key features, responsibilities and milestones. Perspectives from industry, workers, the environment and consumers were given. Specific issues that were discussed concerned derived no effect levels (DNELs), exposure modelling, generic exposure scenarios, RMM efficiency and REACH and COSHH interface.
This presentation is available at http://ieh.cranfield.ac.uk/ighrc/REACH.htm

REACH: THE ROLE OF THE UK COMPETENT AUTHORITY
Helen McGarry (HSE)

Dr Helen McGarry detailed the role of the UK's competent authority (CA) for REACH, with the role of other players also described. The involvement of the UK CA with each of the main REACH processes was outlined.

This presentation is available at http://ieh.cranfield.ac.uk/ighrc/REACH.htm

REACH ENFORCEMENT
Richard Bishop (HSE)

During this presentation, the REACH enforcement regime in the UK was outlined. Further issues relating to enforcement strategy, UK REACH CA enforcement activities and enforcement liaison across the UK and EU were also detailed.

This presentation is available at http://ieh.cranfield.ac.uk/ighrc/REACH.htm

UNDERSTANDING REACH: REGISTRATION
Nigel Tuffnell (RPA Ltd.)

An overview of the REACH registration process from an industry perspective was given by Nigel Tuffnell from Risk and Policy Analysts Ltd. During the presentation, issues of information sharing, chemical safety assessment, submitting a Registration, supply chain issues and guidance through the process were detailed.

This presentation is available at http://ieh.cranfield.ac.uk/ighrc/REACH.htm

REACH AUTHORISATION
Elanor Ball (HSE)

Mrs Elanor Ball presented an overview of the REACH authorisation process. Within the talk, a number of issues relating to the authorisation process were discussed including, how substances are chosen, the Registry of Intentions (ROI), the Candidate list, Annex XIV and proposing a substance for authorisation.

This presentation is available at http://ieh.cranfield.ac.uk/ighrc/REACH.htm

QUESTION AND ANSWER SESSION
Chair Professor Len Levy

The speakers were asked the following questions:

How much data is available to fill in Risk Management Option forms (which support the case for proposal of a substance for further regulatory action)?
Elanor Ball replied that RMO analyses are intended to help Member States decide which of all the available legislative instruments (including legislation other than REACH) will be the most appropriate to address the concerns that have been identified. At present, this can be tricky where there is insufficient information on the range of uses for a particular substance and the risks presented by each use. It is expected that better information will be available once registration dossiers have been submitted.

***Is the derivation of DNELs (derived no effect level) the manufacturers responsibility*?**
Nigel Tuffnell responded that although the information used for the derivation could come from other sources, the manufacturer would need to 'own' (have legal access to) the data supporting the DNEL for the chemical it produces.

***Will the data used in the REACH process be biased in favour of the manufacturer*?**
Nigel Tuffnell informed the audience that this was not possible as any data used would need to be valid and justified. However, the use of that data could potentially be biased.

***How will enforcers pick up whether selective information has been used*?**
In addressing this question, Richard Bishop replied that the technical completeness check of all registrations is followed by a compliance check carried out by ECHA. Only 5% of submissions are required to be checked by law for compliance and so the burden of compliance is on the registrant.

***If I have public health concerns regarding, for example, a chemical in land fill, would I have access to the dossier for that chemical and would I be able to question dossier information*?**
Richard Bishop informed the audience that ECHA is very sensitive about protecting dossier information. As a member state, the UK can access data held by ECHA but there are very strict security requirements associated with this. However, certain information that is held by ECHA will be made publicly available, in line with the requirements of REACH. Examples of information on substances that will be made available includes physicochemical data, classification and labelling information, and guidance on safe use.

Is it possible that a member state could oversee a document for a chemical that was economically important for their country, and if so, would it be biased?
Helen McGarry replied that any Member State could elect to evaluate any substance on the Community rolling action plan. However, draft decisions will be monitored by ECHA to ensure a harmonised approach, and will also be sent to other Member States, who are able to propose amendments.

Are local authorities enforcing the regulations already?
Richard Bishop responded that marketing and use restrictions are currently being implemented, with the focus on restriction. However, enforcement is tending to be reactive at the moment.

Is the final decision by the Commission on the list of substances to be included in Annex XIV (based on a recommendation made by ECHA) just a 'rubber stamping' exercise?
Elanor Ball replied that as yet the Commission have not published Annex XIV so it is not clear whether or not there will be any additional scrutiny of the recommendations made by ECHA before proposals are put before Member States and the European Parliament for voting.
That it was difficult to say but ECHA will probably do more than just basic data checking as they are likely to be asked to look at certain aspects in detail but this will be on a case by case basis.

CHAIRMAN'S SUMMARY
Len Levy drew the workshop to a close by thanking all speakers for their very informative talks. In summarising, Prof Levy concluded that although REACH was an extremely complex process he was sure that participants had gained a good insight from the workshop into the issues involved.