Advisory Committee on Toxic Substances Paper			ACTS/05/2012
Meeting date:	13 November 2012	**Open Govt. Status:**	(open)
Type of paper:	for info	**File Ref:**	2012/345641
Exemptions:	(usually none)		

ADVISORY COMMITTEE ON TOXIC SUBSTANCES

Risk vs. Hazard – HSE's European approach

A paper by Rachel Grant

Introduction

At the 12 May 2012 ACTS meeting, members discussed the different approaches Member States are taking in relation to "risk" and "hazard" and the Framework Directive. An action on HSE was to provide ACTS with an update on how HSE is engaging with the EU on this matter.

HSE Approach

The UK and HSE representatives are currently taking the lead in Europe to press wherever possible for a proportionate approach. An example of this is where HSE officials have succeeded in presenting the view that the Commission should carry out an impact study on whether very small firms undertaking certain low risk activities should be exempted from the requirement to record their risk assessments. An HSE official sits on the Working Party that is helping the Commission to supervise this study; he has been arguing that the benefits from the requirement to record the assessment of low risk activities need to be weighed against the costs it imposes. The study is expected to be completed during 2012.

More widely HSE is working to ensure that implementation of EU directives are evidence and risk based. This approach is in line with recommendations from two recent reviews of UK health and safety legislation: **Common Sense, Common Safety** http://www.hse.gov.uk/aboutus/commonsense/index.htm and **Reclaiming Health and Safety for all: An independent review of health and safety legislation** http://www.dwp.gov.uk/docs/lofstedt-report.pdf

I. Common Sense Common Safety

Lord Young of Graffham undertook a Whitehall-wide review of the operation of health and safety laws and the growth of the compensation culture. His report was published in October 2010.

On Europe Lord Young recommended;

"The UK should take the lead in cooperating with other member states to ensure that the EU health and safety rules for low risk businesses are not overly prescriptive, are proportionate and do not attempt to achieve the elimination of all risk".

II. Reclaiming health and safety for all: An independent review of health and safety regulation

Professor Löfstedt who undertook his review, published November 2011, recommended:

"that the Government works more closely with the Commission and others, particularly during the planned review of EU health and safety legislation in 2013, to ensure that both new and existing EU health and safety legislation is risk-based and evidence-based".

"*To strengthen the focus on risk and get around the inherent differences across member states, it is crucial that the EU regulatory making process is informed by hard scientific evidence*."

"*The UK needs to work with the EU to ensure that risk is used as the basis for regulation. I have already outlined the significant drawbacks with regulating on the basis of hazard and the Artificial Optical Radiation directive provides a case in point*."

A risk based approached has also had high level support from the Government Chief Scientist, Professor Sir John Beddington.

HSE has been taking forward these recommendations in negotiations on European legislative proposals on health and safety and in influencing before proposals are adopted by the Commission. In addition, HSE will contribute to the Commission's review of EU health and safety law by providing the UK's report on the practical implementation of EU law to the Commission by December 2013.

Agreeing a common approach to the interpretation and use of terms such as risk and hazard can be problematic at a European level. This reflects the wide range of philosophies, not just in Europe but globally, about how risks should be managed. Here again HSE is seeking to influence the debate.

The example below demonstrates the approach taken by HSE in EU negotiations.

The EU Biocides Regulation

Negotiations have recently concluded on a new directly acting EU Biocidal Products Regulation (Regulation (EU) No 528/2012 on the making available on the market and use of biocidal products), which will replace the current Biocidal Products Directive (98/8/EC) when it takes effect in Member States on 1 September 2013. The BPD aims to provide a high level of protection for human and animal health and the environment by introducing an EU-wide two-step authorisation regime for biocidal products – chemicals such as disinfectants, wood preservatives, insecticides

and rodenticides intended to control harmful organisms. First, active substances are assessed at EU level for inclusion in a positive EU list. Companies can then apply to individual Member States for authorisation to place products containing Annex I-included substances on the market in their territory. Active substance inclusions and biocidal product authorisations are in both cases granted only after a rigorous assessment of risks and efficacy based on a substantial data package provided by the applicant.

The new Regulation retains the basic two-step structure of the BPD and uses similar risk and efficacy based criteria for authorising biocidal products. However Article 5 of the EU Regulation introduces new criteria by which active substances are excluded from being approved for use in biocidal products on the basis of hazard-based criteria (e.g. when they are carcinogens or persistent, bioaccumulative and toxic), similar to restrictions already in place for plant protection products.

The UK was a strong advocate for the provision of a mechanism to allow continued use of these substances in cases where wider public health and socio-economic harm can result if effective active substances and products are not available. We successfully argued for the inclusion of derogations allowing such substances to be used where it is shown that not authorising the substance would have a disproportionate negative impact on society compared with the risks that arise from its use. The UK resisted strong pressure from the European Parliament in particular to remove these provisions and to move to a more hazard-based system.

These provisions mean that, in general, decisions on product authorisations continue to be strongly risk-based. Even where hazard-based criteria come into play, such as 'exclusion' of active substances with certain hazardous properties (carcinogenic, mutagenic, reprotoxic (cmr), endocrine-disrupters, persistent, bioaccumulative , toxic very persistent, very bioaccumulative (vPvB) persistent, bioaccumulative, toxic (PBT) these can still be overridden on the basis of risk-benefit considerations.

There has been a trend towards hazard based regulation by the EU although this is not being applied entirely consistently. For example the approach to the Biocides Regulation is more flexible than the Plant Protection Product Regulations agreed in 2009.

Conclusion

UK and HSE representatives are currently taking the lead in Europe to press wherever possible for a proportionate approach to legislation and to ensure that the implementation of EU directives are evidence and risk based.