

<b>Advisory Committee on Toxic Substances Current Developments</b>		<b>ACTS/06/2007</b>	
<b>Meeting date:</b>	25 May 2007	<b>Open Govt. Status:</b>	Fully Open
<b>Exemptions:</b>	None		

## **HEALTH AND SAFETY COMMISSION**

### **ADVISORY COMMITTEE ON TOXIC SUBSTANCES (ACTS)**

#### **Current Developments**

- 1. IOELV Directives**
- 2. Carcinogens and Mutagens Directive**
- 3. Existing Substances Regulation**
- 4. Prior Informed Consent – export and import of dangerous chemicals**
- 5. Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)**
- 6. 2nd Adaptation to Technical Progress to the Dangerous Preparations Directive (1999/45/EC).**
- 7. 30th and 31st Adaptations to Technical Progress to the Dangerous Substances Directive (67/548/EEC)**
- 8. Disease Reduction Programme (DRP) – Respiratory Disease**

## **IOELV Directives**

1. In March 2007, the Health and Safety Commission approved the list of new and revised Workplace Exposure Limits (WELs) required to implement the 2<sup>nd</sup> Indicative Occupational Exposure Limit Values Directive (2006/15/EC). WELs for six new substances will come into force on 1 October, in line with the Government policy on Common Commencement Dates. At the same time the WELs for a further 13 substances will be amended to take account of the more stringent IOELV, and 3 further substances will attract a "Skin" notation. The Commission also agreed to the removal from the list of WELs of pyrethrins, the withdrawal of the 8-hour time-weighted average WELs for chlorine and nitric acid, and the withdrawal of the short-term exposure limit for nitrobenzene.
2. HSE plans to publish the revised list of WELs on the HSE website in the near future to advise employers and others of the impending changes.
3. Work is progressing within the European Commission (DG Employment and Social Affairs) to develop a 3<sup>rd</sup> IOELV Directive, resembling the 1<sup>st</sup> and 2<sup>nd</sup> IOELV Directives and containing a further list of substances with indicative occupational exposure limit values. Initial negotiations on the content of this Directive are being conducted in the forum of the tripartite Working Part on Chemicals in the Workplace, where an HSE official sits as a Government representative.
4. As of May 2007, 15 substances are being considered for inclusion in the Directive, but this list will grow as the European Commission considers further recommendations from its Scientific Committee on Occupational Exposure Limits (SCOEL). There are potentially a further 10 substances in the pipeline. The Commission's proposals to submit an initial Opinion to the Advisory Committee on Safety and Health in the first half of 2007 have been put on hold.
5. The UK's position on a draft Directive, once published, will be determined with the assistance of the Working Group on European Exposure Limits (WEELS) and once negotiations start in earnest, HSE will need to be informed about issues of reasonable practicability and measurability, to ensure that an eventual Directive can be implemented without undue difficulty.

## **Carcinogens and Mutagens Directive**

6. In April 2007, the European Commission launched the 2<sup>nd</sup> phase of its Social Partner Consultation on proposals to amend the Carcinogens and Mutagens Directive (2004/37/EC). This Directive consolidates the Carcinogens Directive (90/394/EEC) and its subsequent amendments.
7. Social Partner consultation occurs for all workplace health and safety directives, to ensure general agreement to any proposal from both employers and workers. Member States do not formally participate at this stage. The 1<sup>st</sup> phase of Social Partner consultation occurred in 2004 and three years have therefore elapsed while the Commission considered the small number of comments received.
8. The proposals in the 2<sup>nd</sup> phase of consultation differ little from those in the 1<sup>st</sup> phase. These are:

- To extend the scope of the Directive to cover substances classified as Category 1 and Category 2 Toxic to Reproduction;
- To update the binding exposure limit values for the three substances included in Annex III of the Directive (benzene, hardwood dust and vinyl chloride monomer);
- To include binding exposure limit values for more substances in Annex III of the Directive;
- To introduce objective criteria for setting binding occupational exposure limit values for carcinogenic, mutagenic and reprotoxic substances, explaining what these criteria should be, and indicating what should be the process for setting new limit values;
- To introduce training and information requirements (e.g. how existing measures could be implemented more effectively, examples of best practice, ways to improve coordination and sharing of information).

9. Social Partners on ACTS are encouraged to submit their views on these proposals to the European Commission, either through UNICE and ETUC or direct either to Antonis Angelidis ([Antonis.Angelidis@ec.europa.eu](mailto:Antonis.Angelidis@ec.europa.eu)) or to François Ziegler ([Francois.Ziegler@ec.europa.eu](mailto:Francois.Ziegler@ec.europa.eu)).

### **Existing Substances Regulation**

10. HSE is half of the Joint Competent Authority (together with Defra) for the Existing Substances Regulation (ESR) (793/93), and acts as rapporteur for a number of substances on the ESR Priority List. This entails the development of a Risk Assessment for the substance in question, and, in certain cases, a Risk Reduction Strategy. The latter results in proposals to the European Commission for limiting the environmental, workplace health and consumer risks arising from the use of the substance. ESR will be repealed 12 months after the coming-into-force of REACH (June 2008).

11. There are a number of Risk Reduction Strategies still in the pipeline, for which the UK is rapporteur. The European Commission is anxious that as many of these as possible have completed and agreed Strategies before June 2008.

12. At the May meeting of the Risk Reduction Strategy Working Group, HSE/UK presented for a second time the Risk Reduction Strategy for the hexavalent chromium compounds (chromium trioxide, sodium chromate, sodium dichromate, ammonium dichromate and potassium dichromate). At the same meeting, HSE/UK gave an oral update on the ongoing work to prepare a Risk Reduction Strategy for naphthalene. Work has just started on the preparation of a Risk Reduction Strategy for 1-Vinyl-2-pyrrolidone.

### **Prior Informed Consent: A revised Regulation concerning the export and import of dangerous chemicals**

13. HSE is the Designated National Authority for the European Regulation (304/2003/EC) that implements UK obligations under the Rotterdam Convention (PIC). In April, Member States met for the first time to start the negotiations on the European

Commission's proposal revising Regulation 304/2003/EC concerning the export and import of certain dangerous chemicals. HSE led negotiations for the UK.

14. In 304/2003/EC, the European Union went beyond the requirements of the Rotterdam Convention, resulting in additional burdens to industry. The proposal aligns more closely with the Rotterdam Convention in some places, altering a process that has caused industry undue expense and frustration. However, some of the changes are not consistent with the Rotterdam Convention.

15. Member States, at the first meeting, expressed serious concerns about any potential lowering in the standard of protection from the changes that are inconsistent with the Rotterdam Convention. The Commission has invited Member States to submit comments on the draft in writing before negotiations resume in June.

16. Although the new Regulation will act directly on Member States, HSE will still have to prepare new Enforcement Regulations that will allow HSE and HM Revenue and Customs to continue to enforce this Regulation and will re-appoint HSE as the Designated National Authority (the Competent Authority).

### **Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)**

17. At the November 2006 meeting, we explained the recent activity on GHS, including the European Commission's (EC) publication of a draft proposed Regulation to implement GHS in the EU and Government's response (led by HSE) to the public consultation exercise. We attached the UK Government's response to ACTS/27/2006, together with the policy principles that will underpin our negotiating strategy.

18. We have received positive comments on the UK's response both from the European Commission and from a selection of representatives of UK industry. This is welcome and indicates that the UK has, at least for now, some influence on how the GHS Regulation is progressed and suggests that our overall position on GHS is gaining support from industry.

19. Since the EC's public consultation last year, initial timing plans for progressing the GHS Regulation have slipped. Inter-Service consultation was held during November 2006 and EC officials worked very hard to finalise the proposal before 1 January 2007, when the entry into the EU of Romania and Bulgaria would require the translation of the proposed Regulation and its supporting documentation into these countries' languages (as well as Gaelic).

20. However, despite best endeavours, the GHS Regulation became tied-up in internal EC discussions. Although the detail is not always clear, it appears that the Commission Legal Services intervened. Issues appear to include how the GHS Regulation is structured, the detail of how the UN 'purple book' (a non-legal text drafted by committee) is incorporated into a formal legal instrument, and how reference should be made to international standards. The last point is, perhaps, surprising given the various examples of existing Directives which refer to ISO standards, including Directives on the transport of dangerous goods. However, it appears that direct reference to such standards in Community law raises issues of whether Community law can change automatically when

the standard is revised/re-issued and of availability of the standard in all Community languages.

21. While these issues cause difficulties for the EC in finalising its proposals, they do not affect the overall UK negotiating strategy.

22. The latest projected timetable for GHS is:

- **May/early June 2007** – expected formal publication date of proposed GHS Regulation
- **May/June 2007** – HSE to submit EM to Ministers and Parliamentary Scrutiny Committees, 10 days after formal publication
- **June 2007** – formal negotiations begin (under German Presidency)
- **2007/08** – UK consultation on proposed Regulation
- **2008** – adoption of GHS in the EU.

23. HSE officials continue to work closely with colleagues across Whitehall on the development of the UK negotiating strategy. Work also continues on the development of an initial Regulatory Impact Assessment, in consultation with industry and business representatives. HSE officials continue to deliver talks and presentations on GHS both in the UK and in Europe to a range of industry and government audiences. Efforts are being targeted at engaging small businesses to raise awareness of GHS and how classification and labelling with change.

24. We will keep Members up to date with developments.

### **2nd Adaptation to Technical Progress to the Dangerous Preparations Directive (1999/45/EC)**

25. The 2nd ATP to the Dangerous Preparations Directive (DPD) was due to enter into legal effect in EU Member States on 1 March 2007. For technical reasons we have not been able to meet this deadline, but we are seeking to overcome the difficulties and will implement as soon as possible.

26. The delay results from our concerns about an unintended consequence of one of the amendments to Annex III of the Dangerous Preparations Directive (as outlined in the ACTS paper dated 30 November 2006). Annex III relates to preparations that contain substances that are classified as very toxic to the aquatic environment (classified as N) and assigned the Risk phrases R50 or R50-53. Where such substances are listed in Annex I of the Dangerous Substances Directive, specific concentration limits are sometimes applied in order to avoid an underestimation of the hazard present (e.g. the entry for triclosan). However, where no specific concentration limits are listed, or where substances have been self-classified (in accordance with Article 6 of the Dangerous Substances Directive and the supporting Approved Classification and Labelling Guide) and provisionally assigned Risk phrases R50 or R50-53, the default concentration limits apply. The difference between these concentration limits can be significant.

27. The amendment in Annex III, which introduces generic concentration limits, seeks to address this imbalance. In consequence, preparations such as water-based paints and perfumes, containing small quantities of powerful biocides will be classified as “dangerous

to the environment". This may have implications for premises in which such products are manufactured, canned, packaged or stored, as strict application of the existing criteria in the COMAH Regulations would trigger application of these Regulations where the total quantities of substances or preparations classified as dangerous to the environment exceed threshold tonnages for Dangerous to the Environment. But in practice, the major accident potential at such sites seems low.

28. We are currently working with trade associations, DIY retailers, manufacturers and formulators etc to establish the extent of the problem and we aim to find a solution that will allow the UK to implement the Directive, while ensuring appropriate and proportionate regulation is applied. Discussions are ongoing. An October 2007 implementation date is being considered but no firm decision has yet been made. When implemented, the 2nd ATP would be given legal effect through an amendment to the CHIP Regulations following public consultation.

### **30th and 31st Adaptations to Technical Progress to the Dangerous Substances Directive (67/548/EEC)**

29. The 30th ATP to the Dangerous Substances Directive was finally adopted by Member States on 16 February 2007. Publication of the final ATP is expected shortly in the Official Journal.

30. The timescale for implementation of the 30th ATP is 1 June 2009 - deliberately longer than is usual. The same implementation date will be used for the 31st ATP due to be held later this year.

31. The longer implementation date reflects the intention that the proposed EC Regulation to adopt the GHS in the EU will be agreed before this date. This Regulation will take the existing Annex 1 of Dangerous Substances Directive, together with all the adaptations to technical progress (including the 30th and 31st ATPs), convert the entries to GHS classifications and labels, and insert them in a new Annex that will act directly at EU level.

32. The practical consequence is that the UK and other Member States will not need to implement the 30th and 31st ATPs into national legislation (in our case CHIP).

### **Disease Reduction Programme (DRP) – Respiratory Disease**

33. Following on from our update on the skin and cancer strands of the DRP in the last Current Developments paper, here are the 07/08 planned activities for the DRP's respiratory project.

#### **Occupational Asthma**

34. In 2001 HSC agreed a plan of work to deliver a Revitalising Health and Safety target of a 30% reduction in new cases of OA by 2010. This focused on the top 10 causes of OA. Effective communications activities are vital to maintain awareness of the risks and the appropriate control measures. DRP is targeting our activities at those industries with the highest incidence of occupational asthma.

35. Our top priority group for 07/08 are vehicle paint sprayers (VPS) as they are exposed to isocyanates - the top cause of occupational asthma according to THOR statistics. We are targeting the two industry groups with the highest incidence of asthma; VPS in the motor vehicle repair (MVR) sector and VPS in the sector involved in the motor manufacture, semi trailers and caravans etc. This is building on the work HSE has been doing in this industry over the last few years. We have run a series of Safety and Health Awareness Days (SHADS) for employers and employees in the MVR sector and a proportion of those who were invited but did not attend were inspected. However, to achieve our aim of reaching all those working in this sector we have developed a focused communication initiative, which includes HSAO-lead interventions and direct marketing to reach all those who have not already received the key messages. On May 1<sup>st</sup> 'World Asthma Day' we sent out 8500 letters to MVR premises on 'Time to clear the Air' to raise awareness that paints containing isocyanates cause asthma. The letter outlined the need to know the clearance time of the booth as well as explaining how easily this can be done.

36. We are continuing to tackle occupational asthma caused by flour dust by working with LACORS and supermarkets to develop a benchmark enforcement standard and LA colleagues are continuing to inspect small bakeries.

#### Longer latency respiratory diseases particularly Chronic Obstructive Pulmonary Disease (COPD)

37. COPD is a lung condition that encompasses chronic bronchitis and emphysema. Symptoms include cough, excess sputum production, wheeze and breathlessness. The disease is characterised by impaired flow of air from the lungs and is not fully reversible. There are approximately 30,000 deaths each year from COPD in the UK (NICE 2004). Smoking is the main cause, but evidence suggests that the combination of smoking and occupational exposures, to fumes, chemicals and dusts, accounts for 15% of the burden of COPD (that is approximately 4000 deaths annually in the UK).

38. Current HSE interventions are tackling exposures in construction (eg kerb cutting initiative), stonemasonry, brickmaking, welding and agriculture (poultry). There are, however, a very wide and diverse range of industries where exposure to high levels of dust, gases and fumes may cause COPD. We know that there is generally poor awareness of COPD and particularly the work-related aspects of the disease, so we are developing a crosscutting initiative, capable of reaching many industries, encouraging improvements in engineering controls.

39. The communications element of this work involves publishing two simple leaflets (or something similar) to give advice on buying local exhaust ventilation control systems for employers and how to maintain them for users of the equipment. These will complement a detailed technical guidance publication for designers of the systems. We are currently looking at developing an engineering controls web site as part of this work stream.