

Advisory Committee on Toxic Substances Current Developments		ACTS/04/2008	
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HEALTH AND SAFETY COMMISSION

ADVISORY COMMITTEE ON TOXIC SUBSTANCES (ACTS)

Current Developments

1. European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (Globally Harmonised System for the Classification and Labelling of Chemicals - GHS)
2. European Marketing and Use Directive (76/769/EEC) – proposal to restrict Dichloromethane
3. Indicative Occupational Exposure Limit Values (IOELVs)
4. 2nd Adaptation to Technical Progress to the Dangerous Preparations Directive (1999/45/EC)
5. 30th and 31st Adaptations to Technical Progress to the Dangerous Substances Directive (67/548/EEC)
6. Regulation of the European Parliament and of the Council concerning the Export and Import of Dangerous Substances
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1. European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (Globally Harmonised System for the Classification and Labelling of Chemicals - GHS)

At the November 2007 meeting, we explained the recent activity on GHS, including the publication of the European Commission's formal proposed Regulation to adopt the GHS criteria in EU Member States in June 2007, and the beginning of negotiations between the Council and the European Parliament (EP). The last few months has seen considerable activity both in negotiations and also in ensuring the appropriate domestic Government and Parliamentary clearance was secured for the UK's negotiating strategy, and for the Regulatory Impact Assessment (RIA).

Council Working Party meetings have been held every month since September 2007. HSE officials have attended all meetings.

The UK, represented by HSE, has been, and continues to be, very active in the Council negotiations, and is following closely developments in the EP. Every effort is being made to achieve a first reading deal with the EP in either June or July 2008, in order to meet the internationally agreed implementation deadline of GHS of 2008. The change in Presidency, from Slovenia to France at the beginning of July, will see no loss in momentum in achieving a first reading deal. As such, negotiations are now moving rapidly and may be concluded by the time of this ACTS meeting.

The main issues expected to be raised in negotiations were outlined in paper ACTS/21/2007. Subject to any unexpected developments in the final stages of the negotiations, the UK has worked proactively with like-minded member States to secure the following positive outcomes:

- Better definition of the duties of the different 'actors' in the supply chain, and in particular clarification that *distributors* do not have responsibility to classify substances and mixtures, though they do have responsibilities for labelling and packaging. This was an issues raised early on by the UK and many in UK based industry.
- Derogations for labelling of small and awkwardly shaped packages similar to those we have written into the CHIP Regulations now, under discretionary powers available to Member States.
- The removal of the derogation for research an development based on the highest possible level of control applied universally (ie CMR Cat 1A or 1B). The derogation removes from the scope of the Regulation, substances and mixtures used in scientific research and development, which are not placed on the market, provided they are used under controlled conditions in accordance with Community workplace and environment legislation.
- Improved provisions for companies to keep the chemical name of a substance confidential (without loss of safety) by using a generic or alternative name.
- Flexible arrangements for combined transport and supply labelling.
- Numerous clarifications and improvements throughout the text of the Articles and Annexes.

The UK has also been at the forefront of resisting changes that would have increased the cost of adopting the GHS system. These include:

- Preventing the adoption of acute toxicity category 5, as pressed for by Sweden, Denmark, France and Poland. If adopted this would have meant that essentially all substances and mixtures would be classified for acute toxicity.
- Preventing the introduction of new classifications for substances and mixtures that are persistent, bioaccumulative and toxic (PBT) and very persistent and very toxic (vPvBs) - in essence a combination of existing classifications.
- Preventing the substantial extension of the classification and labelling of flammable liquids to include liquids with a flash point from 60 to 93°C that would have resulted in the GHS category Flammable Liquids category 4 being adopted, as advocated by certain Member States.
- Maintaining the existing requirements for provision of child resisting fastenings and tactile warnings of danger on containers of certain hazardous substances and mixtures, thereby avoiding very substantial costs (estimated as at least £37m by the cleaning products sector).

HSC/E Consultation

The timing of the (formerly) HSC Consultative Document No 213, was determined by the publication on 27 June 2007 of the EC's formal proposed Regulation on the Classification, Labelling and Packaging of Substances and Mixtures, and the immediate start thereafter of Member State negotiations and consideration in the European Parliament. The HSC consultation ran from 14 August – 2 November 2007. A copy of the CD and RIA can be found at:

<http://www.hse.gov.uk/aboutus/hsc/meetings/2007/170707/c58.pdf>

Approximately 30,000 consultees were contacted. These were made up from those that subscribe to HSE's web site; subscribers that have indicated a particular interest in chemical matters; separately targeted industry, business, trades unions, academic and other contacts who have previously been consulted on amendments to the CHIP Regulations; and the Standing Committee of ACTS, specialising in classification and labelling matters (SCHIP).

Overall, the proposed Regulation was supported, and relatively few consultees commented in any detail. In some cases respondents offered alternative costs for the RIA and these have been included, where they were supported by evidence, experience of re-classifications, or how the new Regulation would incur costs in addition to those already assigned to existing classification, labelling and packaging processes. However, the assumptions originally made have largely held. A report on the results of the formal consultation, together with the final Regulatory Impact Assessment can be found at Annex A to this paper.

Consultation with Government colleagues and industry/business representatives continues, at both UK and European level. HSE hosted a second, well-supported and successful Stakeholder Workshop on 19 February 2008.

Cost of implementing the CLP Regulation in the UK

The implementation of the GHS criteria through the new CLP Regulation will be staged over a 7 ½ year period. The total, quantified costs of implementation in the UK have been estimated as between **£95,680,000** and **£215,680,000**, as against the estimated £57.2 billion annual UK chemical industry turnover. These are largely one-off costs, which reflect the migration from the existing to the new system.

Downstream legislation

As part of its Public Stakeholder Consultation in August 2006, the European Commission included a study which identified 22 pieces of downstream European legislation that would be affected by the introduction of GHS. This downstream legislation refers to the classification and labelling of chemicals as a trigger for additional control measures. The legislation needs to be amended to reflect the proposed Regulation.

The EC confirmed that its policy is to keep the scope of downstream legislation the same under the present classification system, so far as possible. To do this, the EC has proposed two strands of action:

- a draft proposed Regulation and six proposed Decisions to amend certain Community legislation to align with GHS terminology, but to maintain the existing scope essentially unchanged;
- to review the remaining existing downstream legislation and to bring forward proposals for amendment over a longer timescale (around 3 – 4 years), consistent with the transitional periods in the new Regulation.

The choice between strands 1) and 2) appears to have been made by the relevant Commission Services responsible for the affected downstream legislation. For example, under strand 1), the EC has proposed the following:

- A Commission (EC) Regulation to amend the Detergents Regulation (648/2004) to change “preparations” to “mixtures” and to update references to existing legislation, such as the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (99/45/EC) to reflect the new Classification, Labelling and Packaging Regulation.
- A Commission (EC) Decision to amend the following Council Directives: Cosmetics (76/768), Toys (88/378), Volatile Organic Compounds (99/13), End-of-Life Vehicles (2000/96), Waste Electrical and Electronic Equipment (2002/96), and the Commission Directive on paints and varnishes (2004/42). The amendments will again replace “preparations” with “mixtures” and will make reference again to the new Regulation rather than current Directives.

While these proposals deal with some of the affected legislation, under strand 2) above, EC intends to review in more detail the other Directives that deal more directly with certain chemicals controls, including: the Plant Protection Products Directive (91/414), the Biocides Directive (98/8), the Seveso II Directive (96/82), the Aerosols Directive (75/324) and the Chemicals Agents Directive (98/24), together with other occupational health and safety provisions such as the Carcinogens, and Mutagens Directive (04/37) and the Pregnant Workers Directive (92/85).

In the case of the Seveso II Directive, the review has already started. HSE leads for the UK and is playing a major role in this review, including engaging relevant stakeholders.

Timing

Negotiations are still on track for a first reading deal between the European Parliament and the Council in July 2008. Once adopted, the Regulation is expected to be published in the EU's Official Journal in Nov/Dec 2008, entering into legal effect 16 days later.

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2. European Marketing and Use Directive – proposal to restrict Dichloromethane

The European Commission has made a proposal for a Decision of the European Parliament and of the Council to amend the Marketing and Use Directive (76/769/EEC) to restrict the sale and use of paint strippers containing dichloromethane (DCM).

Such paint strippers are the most commonly-used chemical paint strippers in the UK and concerns have been expressed by a number of EU Member States concerning the number of fatal accidents and other incidents caused by the use and misuse of these substances.

The European Commission is therefore proposing to prohibit the supply of DCM-based paint strippers to the general public and to professional users. Member States would individually be allowed to permit the continued use of these paint strippers by professionals, subject to them obtaining a licence following training in their safe use. The use of DCM-based paint strippers would be permitted in industrial installations provided that certain safety conditions are met (e.g. effective exhaust ventilation and appropriate protective clothing).

Discussions are about to start (June 2008) in the forum of the Council Working Group on Technical Harmonisation (Dangerous Substances). The HSE, as the lead Government Department for this proposal, is currently developing its negotiating position and preparing its impact assessment. Our initial view is that the restriction is disproportionate in view of the relatively small number of deaths (18 deaths across the EU since 1989, none of whom were the general public). The cost to UK manufacturing industry, were the restriction to pass into law, is estimated to be excessive. We nevertheless support the proposed tightening of workplace standards for the use of DCM-based paint strippers in industrial premises.

Because the Marketing and Use Directive is due to be repealed on 1 June 2009 under the terms of REACH, the proposed Decision would, if agreed by the Council and by the Parliament, become a directly acting regulation as part of Annex XVII of REACH. Member States would not be required to implement it into domestic legislation.

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3. Indicative Occupational Exposure Limit Values (IOELVs) – 3rd List

Work is progressing within the European Commission on the development of a 3rd list of Indicative Occupational Exposure Limit Values (IOELVs) under the Chemical Agents Directive. The 2nd such list (Directive 2006/15/EC) was adopted in February 2006 and was implemented in Great Britain in October last year.

The proposed 3rd list contains 20 substances with IOELVs. These are: Bisphenol A (inhalable dust), Carbon disulphide, N,N-Dimethylformamide, 1,4-Dioxane, 2-Ethoxyethanol, 2-Ethoxyethyl acetate, Ethylacrylate, Formaldehyde, Hydrogen sulphide, Mercury and divalent inorganic compounds, 2-Methoxyethanol, 2-Methoxyethyl acetate, Methyl acrylate, Methylisocyanate, Methyl methacrylate, n-Methyl-2-pyrrolidone, Phenol, Sulphuric acid (mist), Tertiary-butyl-methyl ether and Vinyl acetate.

An Annex to this paper gives details of the proposed IOELVs with, where relevant, the existing British WEL. In order to implement the Directive, were it to be adopted in its present form, HSE would need to introduce new WELs for six substances for which no WEL currently exists, a new short-term limit for phenol, and reduce the value of the existing WELs for a further ten substances. For the remaining 3 substances in the 3rd list, the current WEL is the same as, or lower than, the IOELV and no change to EH40 would be required.

The draft Directive containing the 3rd list of IOELVs has recently been subject to a vote by members of the tripartite Advisory Committee on Safety and Health. HSE expects that it will be adopted by the European Commission early in 2009, with a likely implementation date of 18 months later.

Once the Directive is adopted, HSE will consult on its implementation plans for including new and revised WELs in "EH40 Workplace Exposure Limits". ACTS will be asked to agree the Consultation Document prior to its submission to the HSE Board.

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4. 2nd Adaptation to Technical Progress to the Dangerous Preparations Directive (1999/45/EC)

On 14 April 2008 HSE published a public consultative document (CD) which sought comments on proposed amendments to the Chemicals (Hazard Information and Packaging for Supply Regulations 2002 (CHIP). The amendments implement into national legislation EC Directive 2006/8/EC, commonly known as the 2nd Adaptation to Technical Progress of the Dangerous Preparations Directive (the 2nd ATP). The consultation period ended on 4th July 2008.

The 2nd ATP makes changes to three of the annexes in the Dangerous Preparations Directive (DPD) which are technical in nature. The changes do not affect the main legal duties but do adjust:

- the rules and procedures for classifying and labelling a chemical preparation containing carcinogens, mutagens or substances toxic for reproduction;
- the generic concentration limits to be used for the evaluation of the hazards for the aquatic environment; and
- the classification and labelling requirements for preparations containing ozone depleting substances;

Prior to publishing the proposals HSE worked with trade associations, DIY retailers, manufacturers and formulators etc to identify the extent of any unintended consequences related to the re-classification of products that are dangerous for the environment. Discussions with affected parties highlighted that reclassification of certain products was unlikely to invoke the provisions of the COMAH Regulations for the majority of premises as originally thought.

We are currently analyzing responses to the consultation and the new CHIP amending regulations will come into force on 1 October 2008.

In addition to the changes to CHIP needed as a result of the 2nd ATP, the consultative document also outlined several minor editorial changes to clarify existing requirements and correct errors which do not alter the existing requirements. The CD also sought views on whether HSE should continue to update and republish paper copies of the HSE's Approved Supply List (ASL) given that the EC now has easily searchable and up-to-date electronic databases available on the Internet. A report summarising the responses to the CD will be published on HSE's website in the near future.

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5. 30th and 31st Adaptations to Technical Progress to the Dangerous Substances Directive (67/548/EEC)

The 30th ATP to the Dangerous Substances Directive was adopted by Member States on 16 February 2007. Various objections and comments from third party countries have been heard at the World Trade Organisation concerning the 30th ATP which has caused delays in publication in the Official Journal. However, these issues have been addressed by the European Commission and they are now moving towards the final stages of adoption. Publication of the 30th ATP in the Official Journal is expected shortly.

A date for the vote on the 31st ATP has yet to be announced by the Commission, but the timescale for implementation of the 30th and 31st ATP remains the 1 June 2009. The practical consequence is that both ATPs will be implemented as the first ATP to the new directly acting European Classification Labelling and Packaging Regulation and, as a result, it will not be necessary to transpose these ATPs into the Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP). CHIP will be need to be changed thought to reflect the transitional measures in the new EC Regulation and to provide for the eventual full repeal of CHIP in 2015.

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6. Regulation of the European Parliament and of the Council concerning the Export and Import of Dangerous Substances

This EC Regulation implements the provisions of the UN Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Rotterdam Convention) within the European Community. HSE has been the Designated National Authority for this Regulation since 2003.

The current EC Regulation (304/2003) was annulled by the Court of Justice of the European Communities in its judgment in Case C-178/03 (*Commission v Parliament and Council*) of 10 January 2006. In annulling Regulation 304/2003/EC, the Court ruled that the Regulation should have both Articles 133 (external trade) and 175 (1) (environment), as its joint legal base.

Like the current Regulation (304/2003/EC), the new Regulation goes beyond the requirements of the Rotterdam Convention. The proposal not only relates to chemicals listed in the Rotterdam Convention (called part 3 of Annex I) but also creates restrictions and obligations for the international trade of chemicals restricted in the EU (called part 2 of Annex I).

The UK and other Member States share this ambition for the EU to be a world leader in the responsible trade of dangerous chemicals. HSE worked closely over the latter half of 2007 with other member states, particularly Germany, to ensure that the new Regulation improved on the flexibility of Regulation 304/2003 while providing adequate protection of human health and the environment. This was done to our satisfaction and the new Regulation is likely to be agreed by co-decision on 5 June and come into force at the end of July.

HSE is currently developing a new set of Enforcing Regulations and is working with Northern Ireland to ensure enforcement arrangements extend to the whole of the UK. HSE Board has cleared HSE (28 May) to write to other government departments about the new EC Regulation.

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7. Flour Dust

An overview of the current developments and the progress of work under HSE's Disease Reduction Programme to tackle occupational asthma caused by flour dust.

Implementation and Embedding of new Benchmark

The control of dust from flour and flour improvers in in-store supermarket bakeries benchmark framework was finalised in March 08. It has been introduced to improve good practice in supermarket bakeries and ensure that appropriate control measures are in place. The new benchmark provides a framework to be used by Environmental Health Officers. The benchmark framework has been added to HSE's FIT3 street webpages. It will shortly be uploaded to the HELA Extranet, included in the Local Authority Unit's monthly newsletter and issued as a Local Authority Circular (LAC).

E-Learning Course

HSL is developing an e-learning course covering 'The Health Effects of Bakeries' which is targeted at Local Authority Environmental Health Officers (EHOs). The course will be split into four distinct modules covering health effects, controls, legal issues and enforcement. The package will include text, images, videos, quizzes and an interactive element. It is scheduled to be completed later in 2008.

Sector Information Minutes (SIM)

The Sector Information Minute (01/2008/02) from HSE's Agriculture & Food Sector was updated in January 08. This highlighted to all HSE and LA visiting staff the importance of re-enforcing the need to reduce exposure to flour and dust in bakeries. [SIM 01/2007/09 also provided guidance to inspectors on the significance of the WEL when enforcing measures to achieve adequate control for exposure to flour dust in bakeries]

Industry Stakeholders

Representatives from HSE continue to liaise with the main industry stakeholders including the Federation of Bakers, the National Association of Master Bakers, the Bakers, Food and Allied Workers Union and Unite (TGWU) through both formal and informal contacts. Recent activities include a review of the HSBLC 'Guidance on Dust Control and Health Surveillance in Bakeries' and a visit to a bakery to assess the effectiveness of the company's extensive dust control programme.

Dustiness & Simulation Project

Research is being carried out by HSL and The Association of Bakery Ingredients Manufacturers (ABIM) to investigate the potential for reducing respiratory hazards by modifying the properties of enzyme containing baking ingredients to reduce their dustiness.

Bakers Flour Dust Workshop

A Bakeries Flour Dust Workshop is planned for January 09. The aim of this initiative is to reduce the risk of respiratory disease to workers exposed to flour dust by raising awareness of the health risks, explaining the requirements of COSHH and introducing the new guidance on LEV as well as offering practical advice and guidance. This is a joint venture between HSE and IOSH.

8. Current and Future Disease Reduction Programme Activities

1. The Disease Reduction Programme (DRP) is focusing on three priority areas: **occupational cancer (including asbestos), respiratory disease and skin disease**. In each of these areas, DRP is delivering a variety of initiatives to raise awareness of the risks from exposure to chemicals and change the behaviour in target industries. To ensure that these initiatives are effective DRP is working with a range of stakeholders to take forward a mixture of regulatory, enforcement, communications and supply chain interventions.

2. Outlined below are the main areas of work the DRP will be taking forward over the next few months and into the next financial year:

Asbestos

- Continuation of Duty to Manage inspection and enforcement activity by both FOD and LA inspectors
- Development and roll out of new online facility (e-tool) intended for SME duty holders. E-tool to assist understanding and compliance with Building owners'/managers responsibilities under 'Duty to Manage' (reg 4 of CAR 2006)
- Following successful regional pilot in NW England. HSE is to launch a national asbestos campaign – 'Asbestos – The Hidden Killer'. A campaign to target building maintenance and repair workers who are still at risk from exposure to asbestos.
- Publicity campaign to be reinforced with work with key stakeholders inc. Trade Unions, Trade associations, supply chain and hire outlets, Victim support groups.
- 'Step Change' training events for CEOs of large licensed asbestos removal companies. At these events CEOs will be trained on the management of asbestos-related risks, and required to produce a management plan.

Cancer

- Last June HSE hosted a workshop to discuss priorities for tackling occupational cancer. An emerging theme from this was the need to widen the focus to consider improving control of dusts, gases and fumes to reduce the risks of developing a range of occupational diseases. A second workshop will be held in London on 4 June 2008 so that HSE and key stakeholders can start formulating ideas and laying the basis for initiatives to do this.
- Broad assessment and inspection initiative based on LEV and engineering controls, intended to make stakeholders and duty holders aware of new guidance, defining and improving good practice, contributing to both DRP Cancer and Respiratory Disease Projects.

Skin Disease

- New and follow-up visits by LAs to salons to maintain awareness of the 'Bad Hand Day?' campaign messages, check on adoption of good practice controls and to take enforcement action where appropriate.
- Working with HBSA and glove suppliers to continue raising awareness about suitable gloves (i.e. longer length nitrile or vinyl) and to improve supply through hairdressing wholesalers.
- Working with the Learning and Skills Council (LSC) and Habia to help deliver H&S messages in hairdressing training colleges.
- Working with City & Guilds to develop a short-course qualification for dermatitis that can be incorporated into NVQs for vocational training courses such as hairdressing and catering.
- Awareness raising by EHOs, as part of food safety visits.

- Promotion of 'Dermatitis in Catering' toolbox talk, for dissemination within medium to large businesses. Copies of the talk will be distributed free of charge to a range of businesses, and will also be available in power point as a free download from the web.
- Intervention by FOD and LAs to raise dermatitis where appropriate as part of visits for Slips & Trips initiative.
- Launch of a more audience focussed 'Skin at work' website and revision of guidance on dermal exposure management, simplifying and amalgamating current publications into one, due to be launched this summer.

Respiratory Disease

- The new technical guidance on local exhaust ventilation (LEV) was published on 20th May with free leaflets for employers and employees, supported by new webpages. HSE is now working with professional stakeholder groups to develop activities to help publicise and embed the key messages.
- A direct marketing initiative (focusing on LEV) was sent to 20,000 woodworking premises on World Asthma Day (6th May) and linked to the updated website with video clips of a woodworker who has occupational asthma.
- We are working with UKLA (United Kingdom Lubricants Association) and UNITE to disseminate guidance on the risks of metal working fluids, including contributing to UKLA training DVD.
- HSE continues to raise awareness of, and check compliance with, the lower respirable crystalline silica (RCS) Workplace Exposure Limit with an enforcement intervention in quarries later this year.
 - The kerb, block and paving cutting initiative has gained widespread support from many stakeholders in the construction industry. A suite of solutions was announced at a ministerial launch event on World Asthma Day.
 - The need to clarify what health surveillance is appropriate for employees exposed to RCS emerged as a result of the previous interventions. HSE has hosted a workshop to discuss this issue with a range of stakeholders and a working group has now been formed to develop industry guidelines.
- HSE is participating in the Department of Health's initiative to develop a National Service Framework (NSF) for COPD. We expect this to be published at the end of 2008 and would now looking to develop partnerships with stakeholders to raise awareness of work related COPD to coincide with this.