

Environmentews

GENERAL

THE EUROPEAN COMMISSION'S CHEMICAL STRATEGY (REACH)

Government department lead: Department for Environment, Food and Rural Affairs (DEFRA). HSE and other Government departments (OGDs) have an interest.

Background

- The European Commission (EC) adopted its proposal for a new scheme called REACH (Registration, Evaluation Authorisation and Restriction of Chemicals) to manage the manufacture, importation and supply of chemicals in Europe on 29 October 2003. Following adoption, the proposal was forwarded to the European Parliament and EU's Council of Ministers for adoption under the co-decision procedure.
- The scheme requires chemicals manufactured or imported at quantities greater than 1 tonne to be registered, those manufactured or imported at quantities greater than 100 tonnes to be evaluated, and certain substances of high concern, ie carcinogenic, mutagenic and reproductive toxic substances, to be authorised.
- The aim is to register chemicals in three phases according to the tonnage of the substance:
 - >1000 tonnes a year, or substances of highest concern must be registered in the first three years;
 - 100-1000 tonnes a year must be registered in the first six years;
 - 1-100 tonnes a year must be registered in the first 11 years.

Developments

Under the UK Presidency a compromise text took on a number of new principles:

- To decrease animal testing the text proposes mandatory sharing of animal test data and consortia sharing the costs: 'one substance, one registration'.
- To reduce information requirements for low volume substances.
- With the first registration phase, to register substances that are persistent, bio-accumulative and toxic, or very persistent and very bio-accumulative.
- To introduce a scheme whereby when a chemical is likely to be released from an article, either in normal, foreseeable use or destruction, the article would have to be notified to the authorities.

Next steps

- In December 2005, Member States achieved political agreement on REACH. This paves the way for the Council and the European Parliament to adopt the Regulation.

- The EU Commission anticipates that REACH will come into force in 2007, with the European Chemical Agency being up and running in 2008.
- DEFRA will appoint a Competent Authority for the UK to oversee the regulation of REACH. The Competent Authority's responsibilities under the REACH legislation will be to:
 - provide advice to manufacturers, importers, downstream users and other interested parties on their respective responsibilities and obligations under REACH (Competent Authorities' help desks);
 - conduct substance evaluation of prioritised substances and prepare draft decisions;
 - suggest harmonised Classification and Labelling for CMRs¹ (carcinogenic, mutagenic and reprotoxic substances) and respiratory sensitisers;
 - identify substances of very high concern for authorisation;
 - suggest restrictions;
 - nominate candidates to membership of ECA committees on Risk Assessment and Socio-Economic Analysis;
 - appoint members for the Member State Committee to resolve divergences of opinion on decisions following evaluation, consider proposals for harmonised classification and labelling and identify substances for authorisation;
 - appoint a member to the Forum for Information Exchange and meet to discuss enforcement matters;
 - provide adequate scientific and technical resources to the members of the Committees that they have nominated;
 - enforce REACH;
 - work closely with the European Chemical Agency in Helsinki.
- DEFRA is producing a 'Vision' for UK Chemicals management to support its decision over who will undertake the Competent Authority duties. DEFRA has had, to date, one joint bid from HSE and the Environment Agency, and a second bid from the Pesticides Safety Directorate.

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Internet links:

General/N/A

Specific

DEFRA page on REACH

<http://www.defra.gov.uk/environment/chemicals/eufuture.htm>

DG Enterprise website:

<http://europa.eu.int/comm/enterprise/chemicals>

Current proposal text:

<http://register.consilium.eu.int/pdf/en/05/st15/st15921.en05.pdf>

¹ Carcinogenic, mutagenic and reprotoxic substances

EC information on the proposal, including the extended impact assessment:
<http://europa.eu.int/comm/enterprise/reach/eia.htm>

RAIL DIRECTIVES

Under the Railways Act 2005 responsibility for regulation of rail health and safety will be transferred from HSC/E to the Office of Rail Regulation. This transfer is expected to take place on 1 April 2006.

HMRI inspectors will continue to operate, in the newly merged organisation, under the same statutory framework.

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NEW EU OCCUPATIONAL SAFETY AND HEALTH STRATEGY

- The Commission will be bringing forward in 2006 a proposal for a new European occupational safety and health strategy to run from 2007-2012. This will succeed the current strategy *Adapting to change in work and society: a new Community strategy on health and safety at work 2002-2006* COM(2002) 118 final. Please see http://europa.eu.int/comm/employment_social/news/2002/mar/new_strategy_en.pdf.
- As part of the recent UK Presidency of the EU, HSE hosted a major health and safety event on 18-19 October in Liverpool. The event consisted of an open meeting on the first day, during which front line health and safety practitioners from the social partners gave presentations on a number of themes relevant to the new strategy.
- This was followed on the second day by a meeting of European Directors General (DGs) that looked at these themes in more detail. Following the event, representatives of the UK and forthcoming Austrian and Finnish Presidencies wrote to the European Commission indicating that DGs believed that five themes should play an important part in the new strategy:
 - mainstreaming health and safety;
 - better regulation;
 - targeting interventions for maximum results;
 - setting targets to achieve outcomes;
 - building an evidence base.
- The letter to the EC and detailed outcomes paper can be found at:
www.hse.gov.uk/aboutus/europe/presidency/outcomesletter.pdf and
www.hse.gov.uk/aboutus/europe/presidency/outcomes.htm.

LEGISLATIVE DOSSIERS UNDER NEGOTIATION

MACHINERY DIRECTIVE THIRD AMENDMENT

Directive of the European Parliament and of the Council on Machinery, and amending Directive 95/16/EC - 29 December 2005

Update

Legal base: Article 95, to facilitate the free movement of goods or services between Member States by removing technical barriers to trade.

Government department lead: Department of Trade and Industry (DTI) for guidance on policy, HSE for enforcement and the European Court of Justice (ECJ) on matters of legal interpretation.

Background

- The Machinery Directive (89/392/EEC) and subsequent amendments (98/37/EC) were implemented in the UK by the Supply of Machinery (Safety) Regulations 1992 and the Supply of Machinery (Safety) (Amendment) Regulations 1994.
- They set out Essential Health and Safety Requirements (EHSRs) that must be met before machinery may be supplied in the EU or in European Economic Area (EEA) countries, ie Norway, Iceland, Switzerland and Liechtenstein.
- Proposals for a Third Amendment to the Machinery Directive were published in the *Official journal of the EU* on 26 January 2001, and broadly consisted of improvements designed to simplify and clarify the existing Directive.
- On 11 February 2003 in the *Official journal of the EU*, the EC published its response to the European Parliament's (EP's) First Reading amendments to the Directive.
- On 24 September 2004, after further negotiations between Member States, the Competitiveness Council reached a political agreement on the third amendment proposal.
- A minor Statutory Instrument (SI 2005/831) amending the original 1992 Regulations (SI 1992/3083), subsequently amended in 1994 (by SI 1994/2063), came into force on 1 May 2005. The 2005 SI extends the penalties available in the event of breaches of the Directive. It implements the remaining recommendation of the joint DTI/HSE Strategic Review Group into penalties available for breaches of certain New Approach Directives by allowing breaches of, and offences under, certain sets of regulations to be tried by Crown Courts where appropriate, instead of Magistrates Courts, which was the only available option under the Regulations as they stood. This SI is not connected with the proposed third amendment of the Directive.

Main provisions

- The Machinery Directive sets out the procedures by which manufacturers must demonstrate conformity with certain essential requirements. Machinery that conforms to all relevant requirements can then carry the CE mark, showing compliance with all relevant Directives and the EHSRs.

Developments

- The Common Position text was submitted to the EP on 5 September 2006.
- The Amendment will now be subject to Jurists Linguists (JL) action, ie the text will be scrutinised to ensure that the words used in the document mean the same thing in all Members State languages.
- It will then need to be formally ratified by a Council of Ministers (CoM).
- It will then be published in the Official Journal of the European Union (OJEU) with the Directive coming into force 20 days later.

Timetable

- Timeframes are difficult to predict. However, it's expected that the JL action will have been completed by Easter, CoM action by early May; and OJEU action by early June - all 2006.
- If secured the Directive would come into force late June 2006.
- Members States then have two years to transpose the Directive into their domestic legislation. There will be no transition period and the original regulations will be withdrawn on the day when the new legislation comes into force. On this indicative timetable the Directive would come into force either December 2009 or January 2010.

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Internet links:

DTI specific:

General machinery site: www.dti.gov.uk/strd/machiner.html

Machinery specific: www.dti.gov.uk/strd/strdpubs.html#m

European specific:

Text of 11 February 2003 proposals:

http://europa.eu.int/comm/enterprise/mechan_equipment/machinery/index.htm

Text of current Directive:

http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_207/l_20719980723en00010046.pdf

NUCLEAR SAFETY PACKAGE

Proposal for a Directive (Euratom) defining the basic obligations and the general principles in the field of safety of nuclear installations

Proposal for a Directive (Euratom) on the management of spent fuel and nuclear waste

Legal base: Proposes the use of Article 2(b) of the Euratom Treaty and Chapter 3 of Title II of the Treaty: establishing safety standards to protect the health of workers and the general public from the risks of ionising radiation.

Government department lead: Department of Trade and Industry (DTI), with input from HSE and other parts of Government.

Background

- The parts of the proposal relevant to HSE are the proposed articles on the safety of nuclear installations during operation and decommissioning.
- On 6 November 2002, the EC approved the draft nuclear package proposals.
- Towards the end of 2003 Finland, Sweden and the UK put forward to other Member States an alternative non-legally binding proposal that should meet the Council's requirements. This alternative was supported by a number of countries, in particular Germany, but not France and the European Commission.
- In June 2004 it was clear that a significant number of Member States were against the nuclear package. As a result the European Commission issued a revised text. This new text is unlikely to attract a sufficient majority for it to become law.
- Now, Member States are to prepare a report on the state of nuclear safety in the EU to implement the Conclusions of the Council of 28 June 2004 (doc. 10823/04). The report will include information on the use of international standards in Europe when addressing nuclear safety, radioactive waste and spent fuel issues. The UK report will be finalised during 2006 and presented to the Council early in 2007.

Main provisions

- Reports and reviews of nuclear safety regulation for each Member State.
- Common EU nuclear safety principles.
- Establishment of a Regulatory Authorities Committee to review nuclear safety regulatory bodies.
- Establishment of requirements for the safe management of spent fuel and radioactive waste.
- National programme for the disposal of radioactive waste.

Developments

- Member States have decided not to develop the nuclear package at this time.

Timetable

- Not available.

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GeneralN/A

Specific

EC Nuclear Issues website:

http://europa.eu.int/comm/energy/nuclear/index_en.html

PHYSICAL AGENTS (ARTIFICIAL OPTICAL RADIATION) DIRECTIVE

Amended proposal for a Directive of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (artificial optical radiation)

Legal base: Article 137, to implement improvements of the working environment to protect workers' health and safety.

Government department lead: HSE.

Background

- Irish officials introduced their proposed Directive in July 2004 which was taken forward by the Dutch Presidency.
- Negotiations finished in October and political agreement was reached at the Council of Ministers in December 2004. The proposed Directive had its debate and vote on amendment by the European Parliament in early September 2005. The main amendment was to remove the provisions on natural radiation.

Main provisions

- Like the previous Noise, Vibration and Electromagnetic Fields Directives, the new proposal introduces provisions on risk assessment, control of exposure, health surveillance and information, instruction and training. The Directive is based on the limit values incorporated in the guidelines issued by the International Commission on Non-ionising Radiation Protection (ICNIRP).

Developments

- At the Conciliation Committee meeting on 6 December it was agreed that the Directive would only cover optical radiation from artificial sources.

Timetable

- The Directive has now been adopted and will be published in the official journal from which point there will be four years before implementing Regulations have to be in place.

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General

Website for the International Commission on Non-ionising Radiation Protection (ICNIRP):

www.icnirp.de/

Specific N/A

personnel across the community and effectively enhance availability of cross-border services.

Main provisions

- Train drivers would be required to possess a mutually recognised licence to operate services across and within Europe.
- Measures apply to all train drivers and staff with an indirect role in operating trains on the rail network (except for functionally isolated railways, such as London Underground).
- Measures first apply to drivers operating cross-border services, extending to purely domestic services on the basis of a positive cost-benefit analysis.

Developments

- The 'general approach' was agreed at the Transport Council in December 2004.
- The Transport and Tourism Committee voted in amendments in April 2005, and recommended that work should be taken forward in parallel to the other measures in the third rail package (that have no applications for safety).

Timetable

- Implementation expected to be in phases from 2006 through to 2015.

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Background

<http://europa.eu.int/scadplus/leg/en/lvb/l24244.htm>

Progress

http://europa.eu.int/prelex/detail_dossier_real.cfm?CL=en&DoslD-189473

UPDATE ON THE WORKING TIME DIRECTIVE

European Parliament and Council Directive amending Council Directive 93/104/EC concerning certain aspects of the organisation of working time (the Directive was amended by Directive 2000/34/EC to cover sectors and activities previously excluded)

Legal base: Article 137, to implement improvements of the working environment to protect workers' health and safety.

Government department lead: Department of Trade and Industry (DTI). HSE has an interest.

Background

- The Working Time Directive made provision for the Commission to review certain aspects by November 2003.
- The Commission published a Communication (essentially a first-stage consultation) on 5 January 2004, inviting comments on its proposals by 31 March 2004. A second-stage consultation, limited to the social partners, began on 19 May 2004. However, the social partners declined to negotiate, leaving the Commission to publish proposals.

The Commission published proposals to amend the Working Time Directive on 22 September 2004, and revised proposals on 31 May 2005 (following the First Reading from the European Parliament). The proposals must be agreed by Council and Parliament in co-decision.

Main provisions

- The revised proposals include solutions to resolve the issues relating to doctors' on-call time, raised by the SIMAP/Jaeger ECJ rulings. The proposals also extend the weekly working time reference period to 12 months, subject to conditions. They would also remove the opt-out agreement (where an individual worker may agree to work more than 48 hours a week) within three years, unless the Commission granted a request for extension, and impose limits on the individual opt-out in the meantime. The proposals also contain new requirements to promote work-life balance.

Developments

- Member States were not able to agree the Commission's proposals at Council and, as Presidency, the UK tabled a revised proposal at the Employment Council in December 2005. This revised proposal included the continuation of the opt-out, subject to further measures to protect employees.
- Member States came close to reaching agreement at the December meeting, but the issue of whether the limits in the Directive apply per worker or per contract proved too contentious to reach agreement.

Timetable

- We expect negotiations on the Directive to continue under the Austrian Presidency.
- Working Time is not on the agenda for discussion during the March Employment Council, but it is likely that the Austrian Presidency will try to reach agreement during the Employment Council on 2 June 2006.

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Internet links:

General

Working Time homepage:
www.dti.gov.uk/er/work_time_regs/index.htm

Specific

Working Time Consultation:
www.dti.gov.uk/er/work_time_regs/hadconsult.htm
Government Response to Consultation:
www.dti.gov.uk/er/work_time_regs/hadgovresp.pdf

LEGISLATIVE DOSSIERS UNDER IMPLEMENTATION

ASBESTOS WORKER PROTECTION DIRECTIVE

Directive of the European Parliament and the Council amending Council Directive 83/447/EEC on the

protection of workers from the risks related to exposure to asbestos at work

Legal base: Article 137, to implement improvements of the working environment to protect workers' health and safety.

Government department lead: HSE.

Background

- The EC published its formal proposal to amend the Asbestos Worker Protection Directive on 27 July 2001 (COM 2001417 final).
- The intention was to refocus the protective measures currently in force onto those who are now considered more at risk from exposure to asbestos, eg maintenance and asbestos removal workers.
- The Directive was published in the *Official Journal of the EU* on 15 April 2003 (ref L97/48).

Main provisions

- New single control limit of 0.1 fibres per cm³ as an eight-hour time-weighted average (TWA). Therefore all types of asbestos, including chrysotile, will have the same lower control limit.
- A new World Health Organisation asbestos fibre counting method. This allows for a more precise measurement of asbestos fibre levels by discounting non-asbestos fibres that may have previously been counted.
- New risk-based criteria for deciding what work activities will be exempt from certain requirements of the Directive such as notifying the enforcing authority. In most cases this will not change which activities are exempt.
- Requirement for employers to identify presumed asbestos-containing materials before beginning demolition and maintenance. This is in line with the duty to manage in the Control of Asbestos at Work Regulations 2002 (CAW) (regulation 4).
- Prohibition on the extraction of asbestos and the manufacture and processing of asbestos products. This is in line with the Asbestos (Prohibitions) (Amendment) Regulations 1999.
- Requirement to provide appropriate training for all workers who are, or who are likely to be, exposed to asbestos. This is in line with the current requirements in regulations and Approved Codes of Practice.

Additional changes

- The currently existing CAW, Asbestos Licensing Regulations (ASLIC) and Prohibitions Regulations will be combined to form a single set of Regulations. This will simplify and clarify the legislative regime and is in line with the move towards better regulation.
- The removal of asbestos-containing textured materials from the licensing regime.

Developments

- The Consultative Document was published on 3 November 2005, with the consultation period ending on 31 January 2006.

Timetable

- Date of adoption: 18 February 2003.
- Deadline for Directive to come into force: 15 April 2006.

- Target date for Regulations to come into force: October 2006. The European Commission has been informed of the late implementation.

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Internet links:

General

HSE Asbestos Campaign homepage:
www.hse.gov.uk/campaigns/asbestos/index.htm
Consultation Document
www.hse.gov.uk/consult/live.htm

Specific

Text of the EC proposal: http://europa.eu.int/lex/en/com/pdf/2001/en_501PC0417.pdf

INDICATIVE OCCUPATIONAL EXPOSURE LIMIT VALUES (IOELVs): SECOND IOELV DIRECTIVE

Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC

Legal base: Article 137, to implement improvements of the working environment to protect workers' health and safety.

Government department lead: HSE.

Background

- The Directive establishes a second list of 33 substances with agreed indicative occupational exposure limits (IOELVs). Member States are obliged to take account of IOELVs when setting national limits, and must set a national limit for all the substances listed in the Directive.

Developments

- The text of the Directive was formally agreed by Member States on 5 October 2005, and adopted by the European Commission on 7 February 2006. It was published in the Official Journal of the European Union on 9 February.

Timetable

- Member States have 18 months following adoption to transpose the Directive into domestic legislation.
- In Great Britain, this will be achieved by including the new and revised limits in HSE's occupational exposure limits framework. Widespread public consultation on the implementation of the Directive is planned to take place in mid 2006.

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Internet links: N/A

BIOCIDAL PRODUCTS DIRECTIVE (BPD)

Commission Directive 98/98/EC of 15 December 1998 adapting to technical progress for the 25th Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (Text with EEA relevance)

Legal base: Article 95, to facilitate the free movement of goods or services between Member States by removing technical barriers to trade.

Government department lead: HSE.

Background

- The BPD establishes a single market in biocidal products. The Directive is implemented in Great Britain by the Biocidal Products Regulations 2001 (SI 2001/880), April 2001; and in Northern Ireland by the Biocidal Products Regulations 2001 (SR 2001/422) January 2002 (see internet links).
- The Regulations will ultimately require all biocidal products to be authorised before they can be placed on the market.

Main provisions

- The BPD does not apply to biocidal products that come within the scope of other EU Directives already in place when the BPD was implemented in May 2000. These other Directives are listed in Article 1 of the BPD.
- A series of EC Review Regulations will govern the review of active substances already on the market before May 2000.
- The first of these (EC No 1896/2000) required producers and/or formulators of biocidal active substances to inform the EC by 28 March 2002 of their intentions with respect to the review programme.
- The second Review Regulation (EC No 2032/2003) came into force on 14 December 2003. It establishes:
 - lists of active substances identified and notified under 1896/2000;
 - priority lists for the full review of the notified active substances (see internet links);
 - the dates by which dossiers must be submitted and, for the first two priority lists, details of which Member States will deal with which substances; and
 - the timetable for withdrawal from the market of products containing active substances that have been identified, but not notified.
- The third Review Regulation (EC No 1048/2005) came into force on 29 July 2005. It establishes:
 - the allocation of Rapporteur Member States (RMS) for the review of substances on the lists in parts C and D of Annex V of the second Review Regulation;
 - an update to Annexes II and III of the second Review Regulation;
 - a position for extending the 1 September 2006 phase-out deadline for active substances with 'essential uses', making it possible for 'only identified substances' to be added to the review programme.

Developments

- The Commission presented for discussion a draft Directive setting out procedures for the inclusion of active substances in Annex I of the BPD.
- The Commission presented a paper on a 'phase-out period' for active substances on priority list 2. The proposed date of 31 December 2007, by which all products containing non-supported active substances on this list should be off the market, was agreed.
- A meeting of the Standing Committee on Biocidal Products was held on 14 December 2005, at which Member States voted on and agreed a Commission Directive that amends Annexes IVA and IVB of the BPD. This sets out the data requirements for micro-organisms including viruses and fungi.

Timetable

- Deadlines for industry to submit to Rapporteur Member States dossiers on active substances in the review programme (see internet links):
 - Priority List 1: dossiers should have been submitted by 28 March 2004;
 - Priority List 2: between 1 November 2005 and 30 April 2006;
 - Priority List 3: between 1 February 2007 and 31 July 2007;
 - Priority List 4: between 1 May 2008 and 31 October 2008.

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Internet links:

General

HSE Biocides and Pesticides Unit: www.hse.gov.uk/biocides

Specific

Text of the Biocidal Products Directive:

http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_123/l_12319980424en00010063.pdf

GB/NI Biocidal Products Regulations:

www.legislation.hmso.gov.uk/si/si2001/20010880.htm

[www.northernireland-](http://www.northernireland-legislation.hmso.gov.uk/sr/sr2001/20010422.htm)

[legislation.hmso.gov.uk/sr/sr2001/20010422.htm](http://www.legislation.hmso.gov.uk/sr/sr2001/20010422.htm)

European Chemicals Bureau website:

<http://ecb.jrc.it/biocides>

EC Manual of Decisions:

http://europa.eu.int/comm/environment/biocides/main_subjects.htm Manual of Decisions

Background

- The Regulation aims to ensure that the risks to human health and the environment from existing substances are evaluated so that there can be better EU-wide management of those risks.
- The priority given to ESR work in the EC is likely to be considerably affected by the development of the new EU chemicals policy (see update on EC White Paper Strategy in the first article in this issue of Euronews) that has, in part, been triggered by the failure of the ESR programme to deliver to expectation.

Main provisions

- A data-gathering technical assessment of the risks and the development of proposals for risk reduction where appropriate.
- This is a multi-stage process: substances of concern are placed on priority lists for risk assessment and Member States volunteer to act as rapporteur for each one.
- Rapporteurs then assess the risks of that chemical for the environment, workers, consumers and human health indirectly via the environment. The risk assessment is subject to in-depth technical discussions at a European level.
- When the assessment is agreed, and if a risk is identified, the rapporteur for that substance must propose measures to address this risk, and these too are subject to discussion and agreement at EU level.

Developments

- The EC has now reached Member State agreement on a number of recently discussed risk-reduction strategies including 1,3 butadiene and acrylamide for which the UK is the rapporteur.
- The UK hosted the November 2005 ESR Competent Authority meeting in London.

Timetable: N/A

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Internet links:

General

Specific

Existing chemicals: <http://ecb.jrc.it/existing-chemicals/>

EXISTING SUBSTANCES REGULATION (ESR)

Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances

Legal base: Article 95, to facilitate the free movement of goods or services between Member States by removing technical barriers to trade.

Government department lead: HSE and Department for Environment, Food and Rural Affairs (DEFRA) are Joint Competent Authorities.

THE FIRST RAILWAY PACKAGE

Conventional Rail Interoperability Directive

Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the interoperability of the trans-European conventional rail system

Legal base: Articles 154 and 155, the establishment and development of trans-European networks in the areas of transport, telecommunications and energy infrastructures.

Government department lead: Department for Transport.

Background

- The Conventional Rail Interoperability Directive extends the principles of the High Speed Rail Interoperability Directive to specified routes on the conventional Trans-European Network (TEN) to cover both passenger and freight operations on designated routes.

Main provisions

- 'Essential requirements', such as safety and technical compatibility, apply to the sub-systems into which the transport system has been divided and 'interoperability constituents' into which sub-systems are divided. Sub-systems include infrastructure, rolling stock, environment, energy supply, and control/command and signalling systems.
- Requires the use of Notified Bodies to assess conformity of sub-systems and interoperability constituents with the Technical Specifications for Interoperability (TSIs) and to draw up a Technical File.
- Requires contracting entities to request and receive authorisation before placing any sub-system (within the scope of the Directive) into use.

Developments

- Following consultation on regulations to implement the Conventional Rail Interoperability Directive in 2004, the Department for Transport now intends to implement the Interoperability Amendment Directive (part of the second railway package) with the same set of regulations. These regulations would also replace the existing 'high speed regulations', providing a single set of regulations for interoperability.
- This Directive is subject to codification or recasting under EC proposals to simplify European Law.

Timetable

- The Department for Transport is consulting on proposals for revised interoperability Regulations until 15 November 2005, along with draft guidance and a new partial Regulatory Impact Assessment.
- It is anticipated that the new regulations would come into force in early 2006.

THE SECOND RAILWAY PACKAGE

Legal base: Article 71, implementation of common transport policy.

Government department lead: Department for Transport (DfT); HSE was part of the negotiating team and is implementing some sections of the Directives.

1 Railway Safety Directive – 2004/49/EC

Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification

Background

- Provides a common approach to safety, overseen by national safety authorities, including Common Safety Indicators (CSIs), Methods (CSMs) and Targets (CSTs), and the introduction of independent accident investigation bodies in each Member State.

Main provisions

- Provides a common structure for safety management systems and safety certification.
- Establishes the principle of independent accident investigation bodies in each Member State, separate from the industry.

Developments

- HSE issued a Consultative Document (CD 199) on proposals for new safety regulations for railways and other guided transport systems (ROGS) to implement safety aspects of the Directive. The consultation closed in November 2004.
- HSC consulted on Part 5 (safety verification) of the draft regulations as part of DfT's consultation on interoperability until 15 November 2005. More information can be found at www.hse.gov.uk/railways/liveissues/cd199.htm
- This Directive is subject to codification or recasting under EC proposals to simplify European Law.

Timetable

- The Commission agreed the regulations as amended following consultation, and agreed that they should be forwarded to Ministers. However, the Commission noted that the Secretary of State could not be invited to make the regulations until the Department for Transport (DfT) had brought forward and consulted publicly on new regulations to implement European requirements on interoperability. (See above entry on the First railway Package).
- The DfT consultation, including a question on safety verification, ran until 15 November 2005. It is anticipated that both ROGS and the new interoperability regulations will come into force in early 2006.

2 Interoperability Amendment Directive – 2004/50/EC

Directive 2004/50/EC of the European Parliament and of the Council of 29 April 2004 amending Council Directive 96/48/EC on the interoperability of the trans-European high-speed rail system and Directive 2001/16/EC of the European Parliament and of the Council on the interoperability of the trans-European conventional rail system

Background

- The High Speed Rail Interoperability Directive (96/48/EC) was adopted in 1996 and was implemented in the UK in 2002 via the Railways (Interoperability) (High Speed) Regulations 2002.
- The Conventional Rail Interoperability Directive (2001/16/EC) was adopted in 2001 and is currently due to be implemented in the UK in 2006.

Main provisions

- Gradually extends the scope of the High Speed Rail Interoperability Directive and the Conventional Rail Interoperability Directive to the whole of the rail network, except for lines and rolling stock exclusively for local, historical or tourist use and functionally isolated from the rest of the rail system.

Developments

- Following consultation on regulations to implement the Conventional Rail Interoperability Directive (part of the first railway package) in 2004, the Department for Transport now intends to implement the Interoperability Amendment Directive with the same set of regulations. These regulations would also replace the existing 'high speed regulations', providing a single set of regulations for interoperability.
- This Directive is subject to codification or recasting under EC proposals to simplify European Law.

Timetable

- The Department for Transport consulted on proposals for revised interoperability regulations until 15 November 2005, along with draft guidance and a new partial Regulatory Impact Assessment.
- It is anticipated that the new regulations would come into force in early 2006.

3 European Railway Agency Regulation – (EC) No 881/2004

Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European Railway Agency (Agency Regulation)

Background

- Technical Specifications for Interoperability (TSIs) required by the Interoperability Directives have so far been drafted by the AEIF, a European Railway Industry body, under a mandate from the EC.

Main provisions

- The new European Railway Agency (ERA) will provide technical support for work on interoperability and safety.
- ERA will work to produce common safety standards and help develop a system for monitoring safety performance, and will manage the system to establish, register and monitor TSIs.

Developments

- ERA has been established.
- ERA's work programme has now been published and its activity will focus on safety and interoperability (as well as becoming fully operational).
- ERA has established the network of National Safety Authorities, and working groups to develop ERA's work on common safety targets/indicators/methods, Safety Certification and other parts of ERA's work programme.
- This Regulation is subject to codification or recasting under EC proposals to simplify European Law.

Timetable

- ERA is expected to become fully operational by 1 May 2006.

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Rail activity in Europe:

<http://europa.eu.int/scadplus/leg/en/s13002.htm>

DFT Interoperability: http://www.dft.gov.uk/stellent/groups/dft_control/documents/contentservertemplate/dft_index.hcst?n=9508&l=2>&l=2

ERA: <http://europa.eu.int/comm/transport/rail/era/doc/wp2004-2005.pdf>

PHYSICAL AGENTS (NOISE) DIRECTIVE

Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (17th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

Legal base: Article 137(2), the improvement of the working environment to protect workers' health and safety. It is an individual Directive under Article 16(1) of the Health and Safety Framework Directive (89/391/EEC).

Government department lead: HSE.

Background

- In January 2001 the Swedish Presidency introduced a proposal for a Noise Directive. This would repeal the existing 1986 Noise Directive (86/188/EEC), implemented in the UK by the Noise at Work Regulations 1989.
- Following agreement between the EP, Council and EC, the Directive was adopted on 9 December 2002 and came into force on 15 February 2003 when it was published in the *Official journal of the EU*.
- The UK had three years to introduce implementing legislation.
- HSE published a Consultative Document on the proposals in April 2004, setting out draft Regulations backed by substantial guidance. The formal consultation period ended on 25 June 2004.
- In May 2005, HSC endorsed slightly revised Regulations following formal consultation and Ministers laid the Regulations (SI 2005/1643) in Parliament on 28 June 2005.

Main provisions

- Assessment of noise levels where workers are likely to be exposed to risks; the elimination of risks at source or reduction to minimum; and appropriate health surveillance where the risk assessment indicates a risk to health.
- Weekly averaging of exposure in justified circumstances.
- A reduction of 5 dB(A) in the exposure levels at which action has to be taken (from 90 and 85 dB(A) in the previous Directive to 85 and 80 dB(A)).

- A limit on personal noise exposure, taking account of any hearing protection worn, of 87 dB(A) (likewise for peak sound pressure of 140 dB(C)).
- A range of protective measures where noise levels exceed new specified levels.
- Transitional period of two years for the music and entertainment sector.
- Transitional period of five years for application to sea transport.

Developments

- Supporting guidance for the Control of Noise at Work Regulations 2005 (ISBN 0 7176 6164 4), a free employers leaflet (INDG362(rev1)) and a free employee pocket card (INDG363(rev1)) were published on 11 October 2005.
- HSE is working with an industry music and entertainment working group to produce guidance for the music and entertainment industry. The guidance is being piloted between February and June this year; this will allow the guidance to be tested before wider public consultation at the end of 2006.
- The European Noise at Work Summit took place in Bilbao on 12 December 2005.
- The Regulations came into force on 6 April 2006 around which time a trade and direct mail campaign helped to raise awareness.
- HSE plans four more Noise and Vibration roadshows in June 2006 and local workshops/seminars for small firms later in the year. Details will be posted on the HSE website in due course.

Timetable

- June 2005: Regulations made and laid.
- October 2005: Guidance published.
- April 2006: Regulations came into force.

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Internet links:

General

Noise homepage: www.hse.gov.uk/noise

Specific N/A

PHYSICAL AGENTS (VIBRATION) DIRECTIVE

Directive 2002/44/EC of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration) (16th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

Legal base: The Directive is based on Article 137, improvement of the working environment to protect workers' health and safety.

Government department lead: HSE.

Background

- The Directive came into force on 6 July 2002 when it was published in the *Official Journal of the EU*.

- Member States are required to implement the Directive by 6 July 2005.

Main provisions

- Reduce exposure to a minimum.
- Provide information and training.
- Assess exposure levels.
- Carry out a programme of measures to reduce exposure and provide appropriate health surveillance when exposure reaches the exposure action value.
- Keep exposure below the exposure limit value.
- Transitional period for WBV until the end of 2010 which allows the limit value to be exceeded, but only in relation to equipment already in use by 2007 and only if current technology and processes do not permit compliance. The limit values will apply to any new equipment after 2007.
- For agriculture and forestry equipment the transitional period for the limit value is extended to July 2014.

Developments

- In 2005 we worked with interested parties in the mining, construction and quarrying industry to produce whole-body vibration (WBV) data for a range of typical uses of vehicles and mobile machinery in those industries. We published reports on this research last year (RR377 and RR400) which can be downloaded from HSE's website at www.hse.gov.uk/research/rrhtm/index.htm. We are now planning to carry out further research on road vehicles, including vehicles at ports, during 2006.
- To support the Regulations we held a successful series of seminars on Noise and Vibration in partnership with the EEF last autumn. The presentations from these roadshows which covered noise, hand-arm vibration and whole-body vibration, can now be found on our events web page at www.hse.gov.uk/vibration/roadshow.htm.
- HSE has planned four more roadshows in June 06 and local workshops/seminars for small firms later in the year. Details will be posted on the noise and vibration web sites in due course.

Timetable

- April 2005: Regulations made and laid.
- June 2005: guidance leaflets published.
- 6 July 2005: Regulations come into force.
- 27 September 2005: priced hand-arm vibration guidance published.
- November 2005: whole-body vibration guidance to be published.

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General

Vibration homepage: www.hse.gov.uk/vibration/index.htm

Vibration Regulations:

www.legislation.hmso.gov.uk/si/si2005/20051093.htm

Specific N/A

PHYSICAL AGENTS (ELECTROMAGNETIC FIELDS) DIRECTIVE

Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

Legal base: Article 137, to implement improvements of the working environment to protect workers' health and safety.

Government department lead: HSE.

Background

- The Directive came into force on 30 April 2004 when it was published in the *Official journal of the EU*. Member States have four years to implement the Directive and UK Regulations must be introduced by 30 April 2008.

Main provisions

- Like the Noise and Vibration Directives, the new proposal introduces provisions on risk assessment, control of exposure, health surveillance and information, instruction and training.
- The Directive is based on the values incorporated in the occupational exposure guidelines issued by the International Commission on Non-ionising Radiation Protection (ICNIRP), which are broadly in line with those of the National Radiological Protection Board (NRPB).

Timetable

- New Regulations must be introduced by 30 April 2008. HSE is likely to publish a Consultative Document on new Regulations by the middle of 2006.

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General

Website for the International Commission on Non-ionising Radiation Protection (ICNIRP): www.icnirp.de/

Specific N/A

AMENDED SEVESO II DIRECTIVE

Directive 2003/105/EC of the European Parliament and of the Council of 31 December 2003 amending Council Directive 96/82/EC (Seveso II) on the Control of Major Accident Hazards Involving Dangerous Substances

Legal base: Article 175, action on the environment to contribute to the objective of protecting human health and preserving, protecting and improving the quality of the environment.

Government department lead: HSE. Department for Environment, Food and Rural Affairs (DEFRA) and the Department of Trade and Industry (DTI) have an interest. The Office of the Deputy Prime Minister (ODPM), the Scottish

Executive (SE) and the National Assembly for Wales (NAW) lead on planning provisions.

Background

- The Directive, published in the *Official journal of the EU* on 31 December 2003, responds to recent major accidents and the reports of technical working groups on carcinogens and substances dangerous for the environment.
- HSC agreed in February 2004 that implementation should be through amendments to the Control of Major Accident Hazards Regulations 1999.
- HSC consulted on implementation proposals between 12 July and 1 October 2004.
- The Control of Major Accident Hazards (Amendment) Regulations 2005 came into force on 30 June 2005.

Main provisions

- Clarifies the definitions and enlarges the scope of Seveso II with regard to activities involving dangerous substances at mines, quarries, boreholes and land-fill sites.
- Lowers the qualifying quantities of various substances dangerous for the environment.
- Includes additional named carcinogens and raises the threshold limits of all carcinogens.
- Introduces a new category for petroleum products.
- Redefines explosives according to the UN/ADR classification system.
- Redefines ammonium nitrate with new classes and qualifying quantities.
- Adds potassium nitrate to the list of specified substances.
- Modifies the aggregation rule.
- Makes administrative provisions for establishments coming into scope.

Developments

- ODPM is considering comments received in response to consultation on proposed changes to planning law.

Timetable

- Directive requires implementation by 1 July 2005.

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General

HSE's website on chemical manufacture and storage:
www.hse.gov.uk/chemicals/index.htm

Specific

EC chemical accident prevention website:
<http://europa.eu.int/comm/environment/seveso/index.htm>

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