

| | | | |
|----------------|-------------|--------------------|---------|
| Meeting date: | May 2011 | Open Govt. Status: | Open |
| Type of paper: | Information | File Ref: | 2011/1/ |
| Exemptions: | None | | |

ADVISORY COMMITTEE ON TOXIC SUBSTANCES

Revision of the Carcinogen and Mutagens Directive (2004/37/EC) – a discussion paper seeking the views of the Committee

Background

1. The Carcinogens Directive (90/394/EEC) was one of the so-called "Six-Pack" of Directives made under the terms of the overarching Directive 89/391/EEC "on the introduction of measures to encourage improvements in the health and safety of workers". It has been amended twice; once to add the words "and mutagens" and once to revise the binding limit for benzene. It was then consolidated in 2004 to give the Carcinogens and Mutagens Directive (CMD) 2004/37/EC.
2. The original directive was introduced at a time when it was generally considered by the scientific community that 'no-effect threshold levels' could not be reliably established for carcinogens or mutagens. The control regime presented in CMD is, therefore, based on the principles of occupational exposure occurring only when there is no alternative substance/system available and with the greatest possible reduction in exposure. The binding limits in Annex III of CMD (for benzene, vinyl chloride monomer and hardwood dust) sit alongside the binding limit values in Annex I of the Chemical Agents Directive (CAD) (inorganic lead and its compounds).
3. The European Commission (DG Employment, Social Affairs and Equal Opportunities) is considering amending Directive 2004/37/EC noting in 'Adapting to change in work and society: a new Community strategy on health and safety at work 2002–2006' (COM(2002) 118 final) that:

"...The Commission, with the assistance of the Advisory Committee, will produce reports on the practical application of the various "health and safety" directives, with a view to identifying any practical problems and improving certain of the provisions to make them more readily comprehensible, more consistent, and to fill the gaps in the existing framework. It will also propose extending the scope of the "carcinogenic agents" directive."
4. The first stage of Social Partner consultation occurred in 2004 and the second stage in spring 2007. The main proposals as set out in the second stage of Social Partner consultation are:
 - The scope of the Directive to be extended to cover substances classified as Category One and Category Two Toxic to Reproduction (categories 1A and 1B under the Globally Harmonised System now adopted in Europe by the EU Classification, Labelling and Packaging Regulation, 1272/2008);
 - The exposure limits for the three substances listed in Annex III of the Directive to be reviewed (para 2 above); and
 - Additional exposure limits for carcinogenic, mutagenic and toxic to reproduction substances to be placed in Annex III.

5. Thereafter the European Commission put to tender the 'SHEcan project'¹ - a collaborative research study undertaken by consultants to investigate the potential socioeconomic, health and environmental impact of amendments to the Carcinogens and Mutagens Directive. A synopsis of the work streams and potential chemical carcinogens for inclusion in a revised directive are presented in Annexes 1 and 2 of this paper respectively. The first reports and Impact Assessments (IAs) from this project were made available in March 2011, with further reports anticipated through 2011.
6. In addition, a separate research study is being undertaken to investigate the potential socioeconomic, health and environmental impact of the possible inclusion of category 1 and 2 reproductive toxins within the scope of a revised directive. This work is due to produce a final report February 2012.

Discussion

7. HSE invites the views of ACTS on the work-streams within the SHEcan project and on what the Committee considers the outcomes of this project should be. These views will inform the HSE approach that will be developed, initially with a view to influencing the European Commission, primarily via the Working Party on Chemicals, a sub-group of the Advisory Committee on Safety and Health.
8. In particular, ACTS is invited to give its views on:
 1. How exposure limits should be set for carcinogenic and other substances for which it is not possible to establish a no-effect threshold dose and so it is not possible to establish a health-based limit? In particular, does ACTS have any comments on the approaches using:
 - a. Quantitative risk criteria using dose-response data usually available only at relatively high doses and extrapolating to low doses (SHEcan WP 2, 3 & 6);
 - b. Socio-economic assessment (SHEcan WP 4);
 - c. Environmental impact (SHEcan WP 5);
 2.
 - a. The prospect of new binding limits for
 - i. Diesel exhaust fumes (SHEcan WP 8);
 - ii. Respirable crystalline silica (SHEcan WP 8);
 - iii. Rubber process fume and dust (SHEcan WP 8);
 - iv. Mineral oil (SHEcan WP 8);
 - b. Revised binding limits for:
 - i. Hardwood dusts (SHEcan WP 9);
 - ii. Vinyl chloride monomer (SHEcan WP 9);
 - iii. Benzene (not within the SHEcan project as relatively recently revised (para 1), but we assume open for comment);
 - c. The prospect of binding limit values for some or all of the 20 other substances listed in Annex 2 (SHEcan WP 10);
 3. Whether ACTS (or WATCH) wish to see the individual outputs from the SHEcan project when they become available?
 4. The strengths and weaknesses of the requirements in Article 5 (Prevention and reduction of exposure) of the CMD (SHEcan WP 7)?

¹ <http://www.occupationalcancer.eu/Home/tabid/56/Default.aspx>

Furthermore, what changes do ACTS consider should be proposed in the future?

5. What should be the scope of a future CMD? In particular:
 - a. Should reprotoxic Cat 1 or 2 substances be included (e.g. borates and ethanol)?
 - b. Should all carcinogens be incorporated, including those where a health based threshold can be established (e.g. formaldehyde)?
 - c. Should other substances for which a health based threshold limit cannot be established be included?

6. Does ACTS have any other comments on the CMD and its relation to the Chemical Agents Directive (CAD) 98/24/EC? In particular:
 - a. Would it be appropriate to have one Directive that includes specific requirements for substances where it is not possible to establish a health-based threshold no-effect?
 - b. What would be the advantages and disadvantages of combining the two Directives?

7. Are there any other issues regarding the SHEcan project or CMD that ACTS would like to raise?

Contact

Tim Fry COSHH and Chemical Carcinogens Unit

Email: Tim.Fry@hse.gsi.gov.uk

Tel: 0151 951 3017

Annex 1 – EU Impact Assessment project (SHEcan): Aims and Objectives

| | |
|------------|---|
| WP1 | <i>Estimation of the number of people exposed to the 25 agents identified in the tender request</i> – by industry, country and gender; taking account of the uncertainties involved. |
| WP2 | <i>Estimation of exposure level by industry and country</i> , taking account of the uncertainties involved. |
| WP3 | <i>Assess the risk associated with exposures</i> , for specific cancers taking account of the uncertainties. |
| WP4 | <i>Socioeconomic assessment</i> , to analyse the social and economic impacts of implementation and non-implementation of the proposed policy options. This will consider the costs and benefits of the impacts on the health of workers potentially exposed to the substances, the economic impacts on businesses implementing changes to the directive and the costs of implementation for regulatory authorities and agencies (following the EU administrative costs model). The analyses will take into consideration the current situations in different member states of the EU (as the directive sets out minimum provisions and member states may already go beyond these) as well as consider foreseeable changes in the uses of substances as a result of market changes, changes in technology and other legislation (especially REACH), as this may affect the assessment of the non-implementation scenarios. |
| WP5 | <i>Environmental impact</i> , to assess the potential environmental impact of the policy options on the ecosystem (it may also be important to ensure consideration of the exposure and impacts on man via the environment i.e. non-workers that are potentially exposed via use of products, air or consumption of drinking water and food). As the proposed policy options are directed at improving the protection of human health they may have unintended impacts on the environment. This will of course depend on what measures are used to implement the suggested changes, for example the consequence of compliance with an OEL may increase emissions of the substance to the environment or increase the amount of hazardous waste. As number of the substances have been subject to risk assessment (for example under the Existing Substances Regulation), this information will be helpful for this analysis. |
| WP6 | <i>Review the advantages/disadvantages of introducing a system for setting OELs based on quantitative risk criteria</i> , and the possible impact at the EU level should this type of approach be introduced. |
| WP7 | <i>Review the requirements in the Carcinogens Directive for prevention and reduction of exposure</i> , with the aim of evaluating the strengths and weaknesses of the requirements in Article 5 to minimise the exposure of workers. This evaluation will consider the suitability, comprehensiveness and effectiveness of the requirements in the Directive. |

Annex 1 – EU Impact Assessment project (SHEcan): Aims and Objectives

| | |
|-------------|--|
| WP8 | <i>Assess the impact of introducing four additional substances onto the list contained in Annex I of the Directive: namely diesel engine exhaust, respirable crystalline silica, rubber process fume and dust, and mineral oil. The assessment will include the technical feasibility of introducing these substances to the Directive, an overview of the occupational exposures in Europe, the number of workers exposed, typical adverse effects from exposure, the benefits from introducing the substances into the scope of the Directive, possible changes in the extent of exposure and risk, issues affecting particular demographic groups, the effect on the environment and the economic impacts of the proposed changes.</i> |
| WP9 | <i>Assess the impact of reducing the OELs for hardwood dust and vinyl chloride monomer, which are currently listed in Annex III of the Directive. In these assessments we will provide an overview of the occupational exposures in Europe, the number of workers exposed, typical adverse effects from exposure, the benefits from reducing the OEL, possible changes in the extent of exposure and risk as a consequence, issues affecting particular demographic groups, the effect on the environment and the economic impacts of the proposed changes. For hardwood dust we will also outline the benefits and drawbacks of basing the OEL on the inhalable dust fraction.</i> |
| WP10 | <i>Assess the impact of introducing OELs for 20 substances listed in Appendix 1 of the SHEcan tender document into Annex III of the Directive. For 1, 3 butadiene, chrome VI and respirable crystalline silica we will also assess the impact of three possible OEL values. We will provide an overview of the occupational exposures in Europe, the number of workers exposed, typical adverse effects from exposure, the benefits from reducing the OEL, possible changes in the extent of exposure and risk as a consequence of the proposed modifications to the Directive, issues affecting particular demographic groups, the effect on the environment and the economic impacts of the proposed changes.</i> |
| WP11 | <i>Consult with key stakeholders in European industry, national health and safety regulatory authorities and the European trade unions, and provide Project Management. Where appropriate we will seek to obtain relevant information from these stakeholders to help improve the reliability of our work. We will carefully consider all comments and use this information in formulating our conclusions, although none of the stakeholders consulted will have any direct influence on the outcome of the project.</i> <i>IOM and the WP Leaders to ensure that the output is delivered on time and within budget will provide project management.</i> |

Annex 2 - EU CMD Revision candidate chemicals - Industry, worker numbers, classification, UK cancer burden

| | Substance or mixture | Process Generated or Supplied Substance | CAREX (No of EU Workers Exposed) | ¹ HSE estimate of UK Workers Exposed | Typical Exposure circumstances | Human carcinogenicity/ Cancer Burden (RR800); UK Numbers (deaths 2005/registered cases 2004) | IARC | EH 40 WEL (8h TWA) & carc / COSHH Schedule 1 (legally binding in the UK) | Other hazards | Work Package |
|---|-----------------------------------|---|----------------------------------|---|--|---|------|--|---|------------------|
| 1 | Diesel engine exhaust emissions | Process Generated | 3,000,000 | >100,000 | Vehicles, railways, ferry's, warehouses, vehicle maintenance | Not established but considerable evidence for lung cancer. Risks appear low, and confounding by other factors not adequately been investigated. 652/801 | 2A | No entry In schedule 1 COSHH i.e. defined as carcinogen for COSHH purposes | No entry in Annex 1 of Dangerous Subs Directive as this is not a chemical for supply. However DEEE's known to be irritating to respiratory tract. | 6 |
| 2 | Respirable crystalline silica | Process Generated/ Supplied Substance | 3,200,000 | >1,000,000 | Construction, glass and ceramics, foundry industry | Lung cancer 789/907 | 1 | There are ongoing discussions about reducing the WEL for Silica from 0.1mg/m ³ to 0.05/mg ³ No carc. classification | RCS persists in the lungs, culminating in the development of chronic silicosis, emphysema, obstructive airway disease, and lymph node fibrosis | 6 and 8.1 |
| 3 | Rubber process fume and dust * | Process Generated | - | >10,000 | Rubber manufacture and processing | Epidemiological evidence for increased Lung, bladder, stomach and laryngeal. Concerns re. lymphatic and haematopoietic, particularly lymphatic leukaemia among some workers Rubber Industry – 5/4 | 1 | Rubber fumes 0.6 mg/m ³ Rubber process dust 6mg/m ³ Carc. COSHH schedule 1 | No information available | 6 |
| 4 | Mineral oils **(waste management) | | - | No data available | Engine maintenance, hydraulics, metal working, | 566/1730 | 1 | No entry Used engine oils in COSHH schedule 1 | | 6 |
| 5 | Hard wood dust | Process Generated | 2,600,000 | >300,000 | Wood working | Nasal cavity or sinuses 19/54 (as wood dust) | 1 | 5mg/m ³ Carc. COSHH schedule 1 | Wood dust not listed in Annex 1 of the Dangerous Subs Directive | 7 |
| 6 | Vinyl chloride monomer | Supplied Substance | 40,000 | <1,000 | Plastics manufacture, mainly PVC | Established for Angiosarcoma of liver. Some evidence for hepatocellular carcinoma and soft tissue sarcoma. 3/3 | 1 | 3ppm Carc R45 Cat 1 | Flammability | 7 |
| 7 | 1, 3 Butadiene | | 32,000 | No data – probably limited use only | Rubber manufacture, chemical intermediate, fungicide manufacture | Leukemia in workers in styrene-butadiene rubber industry. 1/1 | 2A | 22mg/m ³ or 10ppm Carc. R45 cat 1, 46 cat 2 | Flammability, mutagenicity | 8.1 |
| 8 | Chrome VI | Supplied Substance | 800,000 | >10,000 | Corrosion inhibitors, pigments, in metal finishing and chrome plating, stainless-steel production and in leather tanning | Established for Lung cancer in chrome electroplaters and chromate and chromate pigment production workers 65/73 | 1 | 50µg/m ³ Carc. BMGV | Acute and repeated dose toxicity, corrosivity, skin and respiratory sensitization, reproductive toxicity | 8.1 |

Annex 2 - EU CMD Revision candidate chemicals - Industry, worker numbers, classification, UK cancer burden

| | Substance or mixture | Process Generated or Supplied Substance | CAREX (No of EU Workers Exposed) | ¹ HSE estimate of UK Workers Exposed | Typical Exposure circumstances | Human carcinogenicity/ Cancer Burden (RR800); UK Numbers (deaths 2005/registered cases 2004) | IARC | EH 40 WEL (8h TWA) & carc / COSHH Schedule 1 (legally binding in the UK) | Other hazards | Work Package |
|----|---|---|----------------------------------|---|--|--|------|--|---|--------------|
| 9 | 1, 2 Dichloroethane | | - | No data – probably limited use only | Chemical production | Not established: because of confounding exposures, not possible to draw definitive conclusions about possible links between increased risks of lymphatic, haematopoietic and stomach cancers and occupational exposure to ethylene dichloride. Not in scope of cancer burden study | 2B | 21mg/m ³ or 5ppm Carc. R45 cat 2 | High flammability, acute toxicity (oral), irritancy to skin, eyes and respiratory tract | 8.2 |
| 10 | 1, 2 Dibromoethane | | 1,200,000 | No data – probably limited use only | Chemical production | No adequate data were available to evaluate the potential carcinogenicity in humans (IARC 1977, 1987, 1999). No cancer burden data | 2A | 3.9 mg/m ³ 0.05 ppm Carc R45 cat 2 | Can affect the brain, damage skin, damage sperm in men, and cause death at very high exposures. Breathing EDB can irritate the lungs causing coughing or shortness of breath. Breathing higher levels of EDB can cause a build up of fluids in the lungs (pulmonary oedema). High exposures can cause dizziness, drowsiness, headache, vomiting and unconsciousness | 8.2 |
| 11 | Bromoethylene | | 0 | No data – probably limited use only | Chemical production | Not established – no data No cancer burden data | 2A | No entry | Flammability | 8.2 |
| 12 | Trichloroethylene | Supplied Substance | 280,000 | >1,000 | Solvent | Not established – although concerns raised over potential for renal cancers to occur after high exposure 4/7 | 2A | 550mg/m ³ or 100 ppm Carc R45 cat 2 | Irritancy, mutagenicity and has narcotic potential | 8.2 |
| 13 | 1, 2 Epoxypropane | | - | No data – probably limited use only | Chemical production, fumigant | Not established Not in scope of cancer burden study | 2B | 12mg/m ³ or 5ppm Carc R45, 46 | Flammability, acute toxicity, irritancy (eyes, skin, respiratory tract) mutagenicity | 8.3 |
| 14 | 1-Chloro-2, 3-epoxypropane | | 48,000 | No data – probably limited use only | Chemical production, stabilizer | No cancer burden data | 2A | 1.9 mg/m ³ or 0.5 ppm Carc R 45 | | 8.3 |
| 15 | 2-Nitropropane | | - | No data – probably limited use only | Chemical production, solvent and fuels | Not established Not in scope of cancer burden study | 2B | 19mg/m ³ or 5ppm Carc R 45 | Flammability, acute toxicity | 8.3 |
| 16 | Ethylene oxide (NB: Overall evaluation upgraded from 2A to 1 based on mechanistic and other relevant data) | | 47,000 | No data – probably limited use only | Chemical production, sterilization | Not established. Some studies have alighted to possible increased risks of haematopoietic cancers associated with the use of ethylene oxide as a sterilant. 0/1 | 1 | 9.2mg/m ³ or 5ppm Carc R45 cat 2, 46 cat 2 | Flammability, acute toxicity, irritancy, mutagenicity (germ cells) | 8.3 |
| 17 | 4,4'-Methylene bis 2-chloroaniline (MbOCA) | Supplied Substance | 4,000 | >300 | Polyurethane Manufacturing (Chemical production) | Not established but some evidence of link between workplace exposure to MbOCA at production and increased risk of bladder cancer. No cancer burden data | 2A | 0.005mg/m ³ Carc R45 BMGV | Acute toxicity | 8.4 |

Annex 2 - EU CMD Revision candidate chemicals - Industry, worker numbers, classification, UK cancer burden

| | Substance or mixture | Process Generated or Supplied Substance | CAREX (No of EU Workers Exposed) | ¹ HSE estimate of UK Workers Exposed | Typical Exposure circumstances | Human carcinogenicity/ Cancer Burden (RR800); UK Numbers (deaths 2005/registered cases 2004) | IARC | EH 40 WEL (8h TWA) & carc / COSHH Schedule 1 (legally binding in the UK) | Other hazards | Work Package |
|----|-----------------------------------|---|----------------------------------|---|---|---|------|--|--|--------------|
| 18 | 4, 4' methylenedianiline | Supplied Substance | - | >2,000 | Manufacture of MDI or other chemicals | Not established Not in scope of cancer burden study | 2B | 0.08mg/m3 or 0.01 ppm Carc R45 BMGV | | 8.4 |
| 19 | o-Toluidine | | - | No data – probably limited use only | Dye and pigment manufacture | Not established although links between occupational exp and increased bladder cancer risk report in workers at rubber plant in USA. Not in scope of cancer burden study | 2B | 0.89mg/m3 or 0.2ppm Carc R45 cat 2 | Acute toxicity, eye irritancy | 8.4 |
| 20 | Benzo-a-pyrene | | - | No data – probably limited use only | Component in tars, oils or combustion products | Not established although some evidence for lung cancer in workers exposed to high levels of PAHs. No cancer burden data | 2A | No entry | Skin sensitization, mutagenicity, toxic to reproduction (fertility and development) | 8.5 |
| 21 | Hexachlorobenzene | | - | No data – probably limited use only | Unwanted by-product | Not established Not in scope of cancer burden study | 2B | No entry | Repeated dose toxicity | 8.5 |
| 22 | Hydrazine | | - | No data – probably limited use only | Fuels, boiler water treatments, chemical reactants, medicines | Not established Not in scope of cancer burden study | 2B | 0.03mg/m3 or 0.02 ppm Carc. R45 cat 2 | Flammability, acute toxicity, corrosivity, skin sensitisation | 8.5 |
| 23 | Acrylamide | | 31,000 | | Polymer manufacture | Not established 1/1 | 2A | 0.3mg/m3 Carc R45 cat 2, 46 cat 2 | Acute toxicity, irritancy (skin and eyes), repeat dose toxicity, sensitisation (skin), mutagenicity, toxic to reproduction (fertility) | 8.5 |
| 24 | Beryllium and beryllium compounds | Supplied Substance | 67,000 | <1,000 | beryllium-copper alloys, x-ray applications, nuclear industry | Some evidence for lung tumors in workers at beryllium processing facilities. 6/7 | 1 | 0.002mg/m3 Carc cat 2 | Irritancy (skin, eye, respiratory), repeat dose toxicity, sensitisation (skin) | 8.6 |
| 25 | Refractory ceramic fibres | Supplied Substance | - | >1,000 | High temperature insulation | Not established Not in scope of cancer burden study | 2B | 5mg/m3 and 1 fibre/ml Carc. R49 cat 2 (inhl) | No other hazards listed in Annex 1 of the Dangerous Substances Directive | 8.6 |

¹ Figures taken from Occupational Hygiene Theme Sheet - OH1: June 2007

Annex 3: CMD (2004/37/EC) - Article 5

CMD (2004/37/EC) - Article 5 - Prevention and reduction of exposure

1. *Where the results of the assessment referred to in Article 3(2) reveal a risk to workers' health or safety, workers' exposure must be prevented.*
2. *Where it is not technically possible to replace the carcinogen or mutagen by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen or mutagen is, in so far as is technically possible, manufactured and used in a closed system.*
3. *Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible.*
4. *Exposure shall not exceed the limit value of a carcinogen as set out in Annex III.*
5. *Wherever a carcinogen or mutagen is used, the employer shall apply all the following measures:*
 - (a) limitation of the quantities of a carcinogen or mutagen at the place of work;*
 - (b) keeping as low as possible the number of workers exposed or likely to be exposed;*
 - (c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens or mutagens into the place of work;*
 - (d) evacuation of carcinogens or mutagens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;*
 - (e) use of existing appropriate procedures for the measurement of carcinogens or mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;*
 - (f) application of suitable working procedures and methods;*
 - (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;*
 - (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;*
 - (i) information for workers;*
 - (j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens;*
 - (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;*
 - (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;*
 - (m) means for safe collection, storage and disposal of waste by workers, including the use of sealed and clearly and visibly labelled containers.*

Annex 4: COSHH 2002 (as amended) - Regulation 7

COSHH 2002 (as amended) - Regulation 7 - Prevention or control of exposure to substances hazardous to health

(1) Every employer shall ensure that the exposure of his employees to substances hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled.

(2) In complying with his duty of prevention under paragraph (1), substitution shall by preference be undertaken, whereby the employer shall avoid, so far as is reasonably practicable, the use of a substance hazardous to health at the workplace by replacing it with a substance or process which, under the conditions of its use, either eliminates or reduces the risk to the health of his employees.

(3) Where it is not reasonably practicable to prevent exposure to a substance hazardous to health, the employer shall comply with his duty of control under paragraph (1) by applying protection measures appropriate to the activity and consistent with the risk assessment, including in order of priority –

- (a) the design and use of appropriate work processes, systems and engineering controls and the provision and use of suitable work equipment and materials;*
- (b) the control of exposure at source, including adequate ventilation systems and appropriate organisational measures; and*
- (c) where adequate control of exposure cannot be achieved by other means, the provision of suitable personal protective equipment in addition to the measures required by sub-paragraphs (a) and (b).*

(4) The measures referred to in paragraph (3) shall include –

- (a) arrangements for the safe handling, storage and transport of substances hazardous to health, and of waste containing such substances, at the workplace;*
- (b) the adoption of suitable maintenance procedures;*
- (c) reducing, to the minimum required for the work concerned –
 - (i) the number of employees subject to the exposure,*
 - (ii) the level and duration of exposure, and*
 - (iii) the quantity of substances hazardous to health present at the workplace;**
- (d) the control of the working environment, including appropriate general ventilation; and*
- (e) appropriate hygiene measures including adequate washing facilities.*

(5) Without prejudice to the generality of paragraph (1), where it is not reasonably practicable to prevent exposure to a carcinogen or mutagen, the employer shall apply the following measures in addition to those required by paragraph (3) –

- (a) totally enclosing the process and handling systems, unless this is not reasonably practicable;*
- (b) the prohibition of eating, drinking and smoking in areas that may be contaminated by carcinogens or mutagens;*
- (c) cleaning floors, walls and other surfaces at regular intervals and whenever necessary;*
- (d) designating those areas and installations which may be contaminated by carcinogens or mutagens and using suitable and sufficient warning signs; and*
- (e) storing, handling and disposing of carcinogens or mutagens safely, including using closed and clearly labelled containers.*

(6) Without prejudice to the generality of paragraph (1), where it is not reasonably practicable to prevent exposure to a biological agent, the employer shall apply the following measures in addition to those required by paragraph (3) –

- (a) displaying suitable and sufficient warning signs, including the biohazard signs shown in Part IV of Schedule 3;*
- (b) specifying appropriate decontamination and disinfection procedures;*

- (c) instituting means for the safe collection, storage and disposal of contaminated waste, including the use of secure and identifiable containers, after suitable treatment where appropriate;
- (d) testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of biological agents used at work;
- (e) specifying procedures for working with, and transporting at the workplace, a biological agent or material that may contain such an agent;
- (f) where appropriate, making available effective vaccines for those employees who are not already immune to the biological agent to which they are exposed or are liable to be exposed;
- (g) instituting hygiene measures compatible with the aim of preventing or reducing the accidental transfer or release of a biological agent from the workplace, including
 - (i) the provision of appropriate and adequate washing and toilet facilities, and
 - (ii) where appropriate, the prohibition of eating, drinking, smoking and the application of cosmetics in working areas where there is a risk of contamination by biological agents; and
- (h) where there are human patients or animals which are, or are suspected of being, infected with a Group 3 or 4 biological agent, the employer shall select the most suitable control and containment measures from those listed in Part II of Schedule 3 with a view to controlling adequately the risk of infection.

(7) Without prejudice to the generality of paragraph (1), where there is exposure to a substance hazardous to health, control of that exposure shall only be treated as being adequate if -

- (a) the principles of good practice for the control of exposure to substances hazardous to health set out in Schedule 2A are applied;
- (b) any workplace exposure limit approved for the substance is not exceeded; and
- (c) for a substance –
 - (i) which carries the risk phrase R45, R46 or R49, or for a substance or process which is listed in Schedule 1; or
 - (ii) which carries the risk phrase R42 or R42/43, or which is listed in section C of HSE publication “Asthmagen? Critical assessments of the evidence for agents implicated in occupational asthma” as updated from time to time, or any other substance which the risk assessment has shown to be a potential cause of occupational asthma, exposure is reduced to as low a level as is reasonably practicable.

(9) Personal protective equipment provided by an employer in accordance with this regulation shall be suitable for the purpose and shall –

- (a) comply with any provision in the Personal Protective Equipment Regulations 2002(a) which is applicable to that item of personal protective equipment; or
- (b) in the case of respiratory protective equipment, where no provision referred to in sub-paragraph (a) applies, be of a type approved or shall conform to a standard approved, in either case, by the Executive.

(10) Without prejudice to the provisions of this regulation, Schedule 3 shall have effect in relation to work with biological agents.

(11) In this regulation, “adequate” means adequate having regard only to the nature of the substance and the nature and degree of exposure to substances hazardous to health and “adequately” shall be construed accordingly.