HSC
Health & Safety Commission

Proposals to introduce a new occupational exposure limits (OEL) framework

This consultative document is issued by the Health and Safety Commission in compliance with its duty to consult, under sections 16(2) and 50(3) of the Health and Safety at Work etc. Act 1974, bodies which appear to it to be appropriate before submitting proposals for the making of Regulations and the issue of Approved Codes of Practice.

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to reach him no later than 31 December 2003

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Responses to this consultative document are invited on the basis that anyone submitting them agrees to theirbeing dealt with in this way. Responses, or part of them, will be withheld from the Information Centres only at the express request of the person making them. In such cases, a note will be put in the index to the responses identifying those who have commented and have asked that their views, or part of them, be treated as confidential.

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CONSULTATIVE DOCUMENT

Further single copies of this document may be obtained from HSE Books – see back cover

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Executive Summary

1. Can you imagine any aspect of modern life that does not involve chemicals? Without them we would not have mobile phones, cars, freezers – commodities we all take for granted. They are also found in common household products such as paints, glues and detergents. Society wants the benefits from chemicals, but some, both man made and naturally occurring, may harm human health. It is HSE's responsibility to provide a legal framework and advice so that employers can protect their workers from these harmful effects. Workers may be exposed to chemicals during manufacturing processes or from using products such as resins and paints.

2. Regulations on the use of harmful chemicals in workplaces were introduced in 1989. They are known as the Control of Substances Hazardous to Health (COSHH) Regulations. These require employers to prevent their workers being exposed to chemicals – referred to in the law as hazardous substances – or, if that is not possible, then to take measures to protect their workers from the harmful effects. Other regulations cover fire and explosion risks from chemicals.

3. Chemicals can harm you in many ways, ranging from unpleasant but not life threatening effects such as damage to the skin or eye irritation through to cancer or harm to unborn children. They can get into your body being breathed in, through the skin or by being swallowed. To help employers protect their workers from chemicals, the Health and Safety Commission (HSC) publishes, for some widely used chemicals, limits on the amount of chemical allowed in the workplace air. They are known as Occupational Exposure Limits (OELs).

4. Research shows many employers, particularly in small firms, do not know about OELs and, of those that do, very few understand how to work out whether the chemicals in the air at their workplace are above or below OELs. These results, and other work on the needs of small firms, convinced us that a new approach was necessary.

5. Part of our new approach is to make available on the Internet free practical advice for small firms on the steps they have to take to protect their workers from the chemicals they are using. The advice can be accessed at www.coshh-essentials.org.uk. A sample of the advice is at Annex 5.

6. This consultative document (CD) further develops the new approach and gives proposals for a simplified system of OELs that should be much easier for small firms to understand and use. The aim is to help the wide spectrum of firms using chemicals (now over 1.3 million, many employing fewer than 10 people) to properly protect their workers.

A new Occupational Exposure Limit

7. The present COSHH Regulations use two types of OEL. They impose different requirements on employers. But only a very small percentage of firms understand the differences. The proposal in this CD is to replace them with a single type of OEL, to be called a Workplace Exposure Limit (WEL). This will impose a single duty on employers – the amount of a chemical in their workplace air must not exceed the WEL. Table 1 (page 13) compares the duties associated with existing OELs and the WEL.

8. A WEL aims to protect workers' health by giving the amount of a chemical allowed in the workplace air. Therefore a WEL is set after a careful analysis of the available information on the harmful effects of the chemical. But for very few chemicals is there enough information to be able to state categorically that harm will not occur to anyone exposed at the WEL. This is because there are often uncertainties in the scientific information available on the health effects of chemicals and we cannot predict how all individuals will respond to the same chemical. For many chemicals we can be 99% certain that the vast majority of people will not suffer any harm at the WEL, but at the other end of the spectrum there may be considerable uncertainties.

Adequate Control

9. If we are to have a system that properly protects workers, it must take account of these uncertainties and the different types of harm chemicals can cause. The COSHH Regulations already require employers to properly (referred to as "adequately" in the regulations) control exposure to protect employees. The proposals in this CD bring the main features of adequate control into a list of principles of good practice for controlling chemicals (see box 1, page 12). A key feature of the proposals is to make a link between the principles and compliance with the WEL. Thus the Regulations will require employers to apply the principles and not exceed the WEL. The correct use of the principles should keep amounts of the chemical in the workplace air below the WEL in proportion to the extent of concern about harm from the chemical.

10. There are some special cases. Chemicals that can cause cancer are of particular concern and the law requires that the amounts in the workplace air must be reduced as much as possible – the lawyers call it "as low as is reasonably practicable (ALARP)".

11. The key changes to the COSHH Regulations needed to introduce the WEL and the principles are given in paragraph 35, page 10.

Helping firms control chemicals

12. Do I hear you say this all sounds very complicated. How are managers of small firms going to work out what they have to do? The answer is that in most cases they will not need to worry about understanding the principles of good practice nor about taking air samples to check they are below the WEL. HSE will do all the hard work for employers. For each substance that has a WEL, HSE will produce practical advice that will tell employers what they have to do to control for their use of the chemical. For chemicals that can cause cancer HSE's advice will explain what ALARP means in practice. Thus employers will not simply be left with a number, as in the present OEL system, but will have information on what they have to do to comply with the law.

Free advice on the Internet

13. The practical advice will be available on the Internet. We propose to link together information on WELs, *COSHH Essentials* – which gives practical advice - and more in depth information on individual chemicals and the COSHH Regulations. The aim is that employers who just want practical advice on what they have to do will be able to get it, but specialists who want more technical detail will get it through hypertext links. The list of WELs and associated practical advice will also be available in hard copy.

Existing OELs

14. There are over 500 OELs in the present system, but many of these were set decades ago and are no longer considered reliable. The proposal is that only existing OELs considered to be scientifically robust will be transferred into the new system as WELs. This will leave us with a list of about 150 substances. For substances not carried forward into the new system advice on how to control exposure will be made available – in many cases through *COSHH Essentials*.

Your views

15. Please let us know what you think of these proposals. A reply form is at annex 11; there is no need to feel obliged to answer all the questions.

Introduction

Revitalising Health and Safety

16. The review of the Occupational Exposure Limit (OEL) system is in line with the Revitalising Health and Safety Strategy initiative, which recognises the need for new energy and a new strategic direction to improve occupational health and safety over the early part of the 21st century. This Consultative Document (CD) explains how the proposed new OEL system can contribute to the delivery of the Revitalising Health and Safety targets, particularly the occupational health target of reducing the incidence rate of work-related ill-health by **20% by 2010.**

Invitation to comment

17. CDs are issued to explore and develop various policy options and to draw in new ideas. The Health and Safety Commission (HSC) believes that this enables an open and transparent approach to decision-making which is essential if policies and decisions are to have widespread ownership and reflect the needs and aspirations of the people they will affect. The results are used to decide how best to take the issue forward based on interpretation and analysis of the results of the exercise.

18. Please consider the analysis of the current system and proposals for a new OEL framework presented in this CD and let us have your views. We would like all replies to arrive no later than **31 December 2003**. The Health and Safety Executive (HSE) will acknowledge all responses but it will not be possible to give detailed replies to them all. We may also contact you again if, for example, we have a query.

19. The OEL Working Group of HSC's Advisory Committee on Toxic Substances will give full consideration to the substance of arguments in the responses to this document. Subject to approval by HSC, any changes to the Control of Substances Hazardous to Health Regulations (COSHH) would not occur until mid 2004 at the earliest.

20. Specific questions are listed in bold text throughout the document and in the tear-out reply form at the back of the document (Annex 11). We have included the reply form for your convenience, but we are happy to receive comments in any form. Please do not feel constrained by these questions - you are welcome to comment on any other issue you wish relating to the OEL framework.

21. This CD may be freely copied and is also available on the HSE website at www.hse.gov.uk/condocs/. Alternatively you may request further copies from HSE Books from the address on the back cover.

22. The HSC tries to make its consultation process as thorough and as open as possible. You are reminded that, unless you request otherwise, your responses to this CD will be lodged in HSE's Information Centres after the close of the consultation period. Members of the public will be able to inspect the responses or obtain copies on payment of the appropriate fee to cover the costs. If you ask for your response to be kept confidential, a note will be put in the index to the responses identifying that you have commented but asked that your views, or part of them, be treated as confidential.

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24. The HSE Information Centres are located at:

London Information Centre
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2 Southwark Bridge
London SE1 9HS

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25. If you reply to this CD in a personal capacity, rather than as a post holder of an organization, you should be aware that the information that you provide may constitute "personal information" in terms of the Data Protection Act 1998. For the purposes of this Act, HSE is the "data controller" and will process the data for health, safety and environmental purposes. HSE may disclose this data to any person or organization for the purposes for which it was collected, or where the Act allows disclosure. You have the right to ask for a copy of the data and to ask for inaccurate data to be corrected.

26. If you are not satisfied with the way in which this consultation exercise has been conducted, we want to know and to put things right. Please write to Dr Michael Topping, Health and Safety Executive, Rose Court, 2 Southwark Bridge, London SE1 9HS. He will investigate your complaint and tell you what he is going to do about it. We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome of your complaint, you can raise the matter with the Director-General of HSE - Timothy Walker, at the same address. You can also write to ask your MP to take up the case with us. Your MP may refer the matter to the Parliamentary Commissioner for Administration (the Ombudsman) who will investigate your complaint.

Background

27. The COSHH Regulations are a useful tool of good management setting out the measures that employers must take to protect both employees and others who may be exposed. (For a summary see: *COSHH: a brief guide to the regulations* www.hse.gov.uk/pubns/indg136.pdf). At the heart of the Regulations is the requirement on employers to prevent their employees being exposed to hazardous substances or, where this is not reasonably practicable, ensure exposure is adequately controlled. Two types of Occupational Exposure Limits (OELs) define adequate control by inhalation: the Occupational Exposure Standard (OES) and the Maximum Exposure Limit (MEL).

28. In recent years a number of difficulties have arisen with the present system of OESs and MELs. In summary, the concerns are:

- Research shows that OESs and MELs are not understood by much of industry, particularly small firms, with many employers not knowing how to determine whether exposure levels in their workplaces comply with the limits;

- The OES purports to be a "safe" limit at which no ill-health will occur, but the concept of a "safe" limit is not secure. In reality, it may not be possible to give an absolute guarantee of complete health protection for all individuals because of uncertainties, for example in the extent of human variability, and gaps in knowledge about the effects of chemicals;

- There are some incompatibilities with the European Commission's (EC) system for OELs. There is a need to develop a limit system under COSHH which will readily incorporate Indicative Occupational Exposure Limit Values (IOELVs); and

- Experience has shown that the criteria used to set OESs and MELs are not wide enough in their scope; some substances of concern meet neither the OES nor MEL criteria, and so it has not been possible to establish an OEL for those substances under the current system.

29. As a result of these concerns, HSE and stakeholders consider OELs have not realised their full potential as important tools to help employers control exposure. As a first step to developing a new approach, the HSC published last spring a discussion document (*Discussion Document on the Occupational Exposure Limit (OEL) framework* (DDE19)) setting out the concerns with the current system of occupational exposure limits and proposing options for a new system. Although comments on this document had to be with HSE by 31 July 2002, it is still available for reference on the HSE website (www.hse.gov.uk/consult/disdocs/dde19.htm). The options proposed for a new system were:

1 maintain the present system with minor modifications;

2 good practice control advice supported by a single type of limit;

2A. good practice control advice supported by a two tier system which flags carcinogens.

The majority of the 56 consultees who responded agreed with the concerns about the present system and only 2 did not support either proposal 2 or 2A. The analysis of the responses can be found at http://www.hse.gov.uk/aboutus/hsc/iacs/acts/211102/paper43.pdf.

30. In addition, HSE spent considerable time giving lectures on the proposals to key interest groups. There was overwhelming support from attendees at seminars to moving towards a single limit system coupled to good practice advice on controlling chemicals.

31. Building on this consensus, this CD makes formal proposals for a new OEL framework. The document:

- describes the proposed new system;
- makes proposals for amendments to the COSHH Regulations 2002 and the COSHH Approved Code of Practice (ACoP);
- makes proposals for incorporating the existing OELs into the new system; and
- presents a Regulatory Impact Assessment (RIA) for the new system.

The proposed new system

Objectives for the new system

32. In 2002 the HSC agreed a strategy for HSE's work on chemicals, which places more emphasis on activities which will have a direct impact in the workplace. The aim of the proposals in this CD is to ensure OELs contribute to this strategy. To achieve this the proposed new system needs to:

- be simple and easy for duty holders to understand;
- provide a tool which will help dutyholders improve standards of control;
- address the difficulties associated with the OES; and
- improve the efficiency of the process for setting limits in the light of the EC system.

Fundamentals of the new system

33. A proposal to meet these aims has been developed by a Working Group of the HSC's Advisory Committee on Toxic Substances and endorsed by the HSC. The proposal is to:

- introduce a new approach to adequate control;
- shift the emphasis from the OES/MEL system to good practice advice on how to control exposure underpinned by a single type of OEL;
- set out the principles of good practice for the control of exposure to substances hazardous to health in a new Schedule to the COSHH Regulations; and
- provide advice to support the principles of good practice for the control of substances hazardous to health and make it readily available free of charge.

A new approach in the COSHH Regulations to adequate control

34. In the current COSHH Regulations 2002, regulation 7 (7) and (8), define adequate control of exposure to a substance hazardous to health by inhalation by reference to MELs and OESs. For substances without an OEL, the COSHH ACoP, paragraph 126 states "…employers should control exposure to a level to which nearly all the working population could be exposed, day after day at work, without adverse effects on health."

35. The proposal is to broaden the definition of adequate control, to include the duty to apply the principles of good practice for the control of exposure to substances hazardous to health, as well as complying with any relevant OEL. The aim is to bring into the scope of adequate control the duties already set out in COSHH regulations 7 (2), (3) and (4). Thus adequate control would include dermal exposure and ingestion in addition to inhalation exposure. To achieve this broader approach to adequate control it is proposed to replace COSHH regulation 7 (7) and (8) by a new 7(7) as follows:

- Reg 7(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 that substance is not exceeded; and
  (c) for a substance which carries the risk phrase R45, R46 or R49[1] or for a substance or process which is listed in Schedule 1, the level of exposure is reduced so far as is reasonably practicable.

36. Employers will be required to apply the principles of good practice for the control of exposure to substances hazardous to health as well as not exceed any relevant OEL. Regulation 7(7)(c) is included to make clear that exposure to carcinogens is subject to the Carcinogens Directive and must be reduced so far as is reasonably practicable. In the current COSHH Regulations this duty is only stated explicitly for carcinogens assigned a MEL, although in practice application of regulation 7(5) – additional control measures that apply to carcinogens and to mutagens (substances that cause heritable damage) - will achieve the same result.

37. This approach to adequate control is unchanged from that currently set out in COSHH regulation 7(11). This states "adequate" means adequate having regard only to the nature of the substance and the nature and degree of exposure to substances hazardous to health.

Do you agree with the proposed new approach to adequate control?

[1] R45 Substances that may cause cancer;
R46 substances that may cause heritable genetic damage;
R49 substances that may cause cancer by inhalation.

A system of good practice advice on how to control exposure underpinned by a single type of OEL

38. The aim is to set OELs in the context of the duty on employers to protect employees by preventing or, if this is not reasonably practicable, adequately controlling, exposure. The intention is that if the principles of good practice are followed correctly, exposure will be below any relevant OEL. The OEL can be considered a backstop that should not be exceeded. The following paragraphs explain the proposals for the principles of good practice and proposals for a single type of OEL.

A new Schedule to the COSHH Regulations setting out the principles of good practice for the control of exposure to substances hazardous to health

39. It is already implicit within the existing COSHH Regulations that there is a need to follow the principles of good occupational hygiene practice. However, for improved ease of understanding, these principles will be clearly listed in a new schedule to the COSHH Regulations. The idea is that the wording of the principles will be brief, consisting of eight simple statements, but HSE will also provide additional guidance on how to apply the principles.

40. The proposed new Schedule sets out the principles employers have to follow if their risk assessment under COSHH Regulation 6 shows that prevention of exposure, including substitution, is not reasonably practicable. The Schedule does not change or lessen employers' duties under COSHH regulation 7(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.'

41. The actions needed to adequately control exposure are set out in the COSHH regulations 7(2), 7(3) and 7(4), although, as discussed in paragraph 34, adequate control is only described in terms of complying with OESs and MELs. Since the proposal is that the COSHH Regulations define "adequate" as complying with these principles, HSC consider they should be set out in a new schedule to the COSHH Regulations, in a similar way to the General Principles of Good Microbiological Practice in the Genetically Modified Organisms (Contained Use) Regulations.

42. The proposed principles are in Box 1. They set out eight statements on which current duties under the COSHH Regulations are based, but they do not extend the duties under the Regulations. HSE will produce guidance on the application of these principles to help employers. The guidance will form a bridge between the principles and the control advice discussed in paras 57 – 61.

Box 1 - Principles of good practice for the control of exposure to substances hazardous to health

a) Control exposure by measures that are proportionate to the health risk.

b) Design and operate processes and activities to minimise emission, release and spread of substances hazardous to health.

c) Take into account all relevant routes of exposure – inhalation, skin absorption and ingestion – when developing control measures.

d) Choose the most effective and reliable control options which minimise the escape and spread of substances hazardous to health.

e) Where adequate control of exposure cannot be achieved by other means, provide, in combination with other control measures, suitable personal protective equipment.

f) Check and review regularly all elements of control measures for their continuing effectiveness.

g) Inform and train all employees on the hazards and risks from the substances with which they work and the use of control measures developed to minimise the risks.

h) Ensure that the introduction of control measures does not increase the overall risk to health and safety.

43. The first principle "control exposure by means that are proportionate to the health risk" will be explained in the COSHH ACoP. For substances that are not carcinogens or causes of asthma, the proposed ACoP on Regulation 7 states "The employer's aim should be to apply the principles of good practice and to select the most appropriate controls that are proportionate to the risks arising from the work. So if the risks to employees' health are serious or uncertain, stringent control of exposure by all routes will be required." (see paragraph 96, page 30 of this CD). Guidance will explain what this means in practice.

44. For carcinogens subject to the Carcinogens Directive and those listed in Schedule 1 to the COSHH Regulations, - *other substances and processes to which the definition of "carcinogen" relates* - the proposed regulation 7(7)(c), requires that the level of exposure is reduced so far as is reasonably practicable. For substances which cause asthma, it is proposed to add to Appendix 3 of the COSHH ACoP a statement to the effect that limited scientific knowledge on levels below which substances will not cause asthma means that it will normally be necessary to reduce exposure so far as is reasonably practicable (see paragraph 12, page 49 of this CD).

Do you agree with the proposed principles of good practice for the control of substances hazardous to health as listed in Box 1?

Changes to the COSHH Regulations

45. Annex 1 contains the proposed COSHH (Amendment) Regulations 2004 that will replace COSHH regulations 7(7) and 7(8) with a new Regulation 7(7); OESs and MELs with a single type of limit, a Workplace Exposure Limit (WEL), and introduce a new Schedule 2A on the principles of good practice for the control of exposure to substances hazardous to health.

Do you agree with the proposed changes to the COSHH Regulations?

Changes to the COSHH ACoP

46. Annex 2 contains the proposed revised text of the COSHH ACoP resulting from the amendments to the COSHH Regulations. It contains the revised text of the ACoP on regulation 7; the text of paragraph 202 from regulation 10 on monitoring exposure; and the text of paragraph 12 of Appendix 3 to the ACoP - *CONTROL OF SUBSTANCES THAT CAUSE OCCUPATIONAL ASTHMA*, and a list of changes consequent to replacing OES and MEL by the WEL.

Do you agree with the proposed changes to the COSHH ACoP?

A single type of Occupational Exposure Limit - The Workplace Exposure Limit (WEL)

47. The proposal is to replace both the OES and MEL with a single type of limit, referred to as the Workplace Exposure Limit (WEL). The duties in the COSHH Regulations associated with OESs and MELs and the proposed duty for the WEL are summarised in Table 1. A single duty is attached to the WEL - it is a value which should not be exceeded. An explanation of what this will mean in practice is set out in paragraphs 62 - 66.

Table 1 - Duties associated with OESs, MELs and Workplace Exposure Limit

Occupational Exposure Standard	**Maximum Exposure Limit**	**Workplace Exposure Limit**
Standard must be met	Limit must be met	Limit[2] must not be exceeded
No requirement to further reduce exposure	Exposure must be reduced below the limit so far as is reasonably practicable	
If the standard is exceeded steps must be taken to meet it as soon as is reasonably practicable	Limit must not be exceeded	

48. The proposal is to define the WEL as the concentration of hazardous substances in the air that people breathe, averaged over a specified reference period referred to as time weighted average (TWA). Two time periods are used: long-term (8 hours) and short-term (15 minutes). This definition is the same as that used for the current OESs and MELs. Similarly there will be no change to the calculation method, as set out in the HSC approved schedule *Calculation of exposure with regard to the specified reference periods*, in the HSE publication *EH40 Occupational Exposure Limits.*

49. The present system will be maintained, whereby OELs are published in a list approved by the HSC and thereby become subject to the COSHH Regulations. Proposals for publicising WEL values are given in paragraphs 71 - 76.

[2] An explanation of what this will mean in practice is set out in paragraphs 62 - 66.

Do you agree with the definition of a WEL?

Do you agree with the proposed duties associated with the WEL?

Criteria for setting WELs and what they represent in terms of health protection

50. The present criteria for setting OESs and MELs will be replaced by a single set of criteria that will:

- allow WELs to be set for any substance of concern; and

- enable Indicative Occupational Exposure Limit Values (IOELVs) and Binding Occupational Exposure Limit Values (BOELVs) to be implemented as WELs without lengthy debate as to whether they should be implemented as OESs or MELs.

51. As with the present criteria for setting OESs and MELs, the criteria for setting WELs will not form part of the COSHH Regulations or ACoP. Nevertheless they are included as Annex 3 in this CD for comment.

52. Under the present system OESs are perceived as "safe" limits since there is no requirement to reduce exposure below the limit. With the proposed new system, although the primary objective is to control risks to health, it will be made clear that the WEL does not represent a complete guarantee of health protection for all workers. This acknowledges the fact that for many substances there are:

- gaps in knowledge;
- uncertainties about potential health hazards; and
- uncertainties about the potential for differences in human responsiveness.

53. The degree of uncertainty surrounding occupational health risks will vary from substance to substance depending on the amount of safety testing and the nature of the information available. In some cases there is likely to be considerable confidence that the WEL will protect health fully, while in other cases some residual uncertainties are likely to remain.

54. Also, the WEL needs to cover substances such as genotoxic carcinogens for which current scientific thinking suggests it is not possible to identify a threshold level of exposure below which there would be no risk. A system in which there is a single type of OEL, that has to apply to all types of substance, means that the WEL cannot be portrayed as representing a complete guarantee of health protection for all workers.

55. This approach is consistent with the advice in the Scientific Committee on Occupational Exposure Limits' (SCOEL) key document on *Methodology for the Derivation of Occupational Exposure Limits*, which states that "It should however be emphasised, that it is always prudent to reduce exposure as far below OELs as can be reasonably achieved, in order to provide the greatest degree of health protection. This is particularly true for OELs which are not 'health-based'".

56. Research commissioned by HSE found that the problems of understanding and use of OELs in the UK identified in the HSC's Discussion Document are borne out by experience in other EU countries. The study concluded that the continental European experiences analysed

seem to indicate that Options 2 and 2A, represent the best way forward: i.e. good practice either supported by a single limit or a two tier system combining good practice with special arrangements for carcinogens.

Do you agree with the proposed criteria for setting WELs in Annex 3?

Good practice advice

57. The good practice advice will give practical guidance on controls needed for specific tasks and chemicals. It will:

- take account of the risk to employees' health; this will involve consideration of:
    - the nature and severity of the hazard posed by the chemical
    - the potential for exposure
- take account of the work process in which it is being used or generated; and
- be designed to keep exposures below any relevant WEL.

58. Good practice advice will be available from HSE for many substances including those assigned a WEL (see paragraphs 47 - 49). This will be either substance specific advice, or generic advice, i.e. advice related to particular hazard/risk combinations rather than a specific substance. Following good practice advice published by HSE, or advice prepared by others (e.g. trade unions, industry, suppliers and consultants) and endorsed by HSE as representing good practice, will not be compulsory. Employers will be free to follow guidance from any source, providing it is equally effective in ensuring compliance with the legal duty (see paragraph 35).

59. The good practice advice produced or endorsed by HSE will be designed to keep exposures below any relevant WEL and will be subject to peer review and consultation with stakeholders. It will, in the vast majority of cases, bring exposure below the WEL. However while it is impossible to guarantee that generic advice will be suitable for every substance/task combination, it is expected that in the vast majority of circumstances it will result in adequate control. If an employer has concerns they should seek specialist advice. Thus the generic advice will make clear that it is to help employers comply with the requirements of the COSHH Regulations 2002.

60. The advice will cover all the points in the principles of good practice for the control of exposure to substances hazardous to health and take account of risks from skin contact and ingestion as well as inhalation. So it will include information on design, degree of containment, maintenance, training, supervision and housekeeping.

61. Good practice advice will remind readers of the need to consider other COSHH duties and the need to comply with legislation relating to safety risks (e.g. fire and explosion) and environmental legislation. While not attempting to provide advice on these regulations, the aim will be to give advice which does not conflict with duties under them.

Do you agree with the proposals for good practice advice?

Practical application of the new approach in the workplace

62. Research on the current system of OESs and MELs has shown that they are not understood by much of industry, particularly small firms, with many employers not knowing how to determine whether exposure levels in their workplaces comply with the limits. Even when employers understand them, they are of limited use in assessing compliance. One reason is the difficulty of demonstrating whether an air sample suggesting exposure in excess of the OES is a "one-off" occurrence or is generally representative of the exposures in that workplace.

63. To help overcome this difficulty the emphasis in these proposals is placed on the need to follow good practice, consistent with the control advice that will be available. This will make it easier for employers to comply with the duty and it will be easier, for the purposes of enforcement, to demonstrate that good working practices have, or have not, been followed. This is not to say that exposure information would not be taken into account when evaluating compliance with an OEL.

64. If an employer finds that the measures used to control exposures are failing, then immediate steps will need to be taken to protect employees by using appropriate Personal Protective Equipment (PPE) and remedial measures implemented. The first response to a measurement above the WEL, will be to check that it is representative of conditions in the workplace, and is not an isolated incident. The response to confirmed exposures above the WEL will need to be proportionate to the health risks posed by the substance. Particular care will be needed where serious health effects may occur from short-term exposures. If over exposures are confirmed, employers should investigate immediately and take appropriate action to reduce exposure.

65. HSE will use the "Enforcement Management Model" (EMM)[3] to guide action when the principles have not been applied properly or when there is evidence of exposures above the WEL. The EMM is a robust framework to help inspectors make enforcement decisions in line with the HSC Enforcement Policy Statement. The model aims to promote:

- enforcement consistency;
- proportionality and targeting by confirming the risk based criteria against which decisions are made; and
- transparency and accountability in the decision making process.

66. HSE will take enforcement action in relation to any of the three elements of the proposed new reg 7(7). However, failure to comply with two or more would not result in two or more separate offences. Annex 4 explains how, in cases where the principles have not been applied adequately or where the WEL has been exceeded, the EMM will direct inspectors to appropriate, proportionate enforcement action, taking account of local factors.

Will the new system make it easier for you to comply with the COSHH Regulations?

[3] The HSC Enforcement Policy Statement can be found on the web site (http://www.hse.gov.uk/pubns/hsc15.pdf). There is also a hard copy leaflet HSC15.

Need for monitoring

67. The circumstances when monitoring is required are set out in the COSHH Regulations 2002 and accompanying ACoP. These proposals would not change this aspect of the Regulations. If the employer is following good practice advice and ensures that the controls are functioning correctly by, for example, monitoring the airflow into local exhaust ventilation, he may not need to monitor for the hazardous substance. Continuing to follow good practice should keep concentrations of the chemical below the WEL.

Delivering good practice advice

68. The proposal is to provide generic good practice advice by linking, where appropriate, WELs into the *COSHH Essentials* system to provide advice that can help employers apply the principles of good practice. The *COSHH Essentials* system was originally designed to provide control advice on substances without an OEL but it has been found equally useful in providing control advice to support OELs. It simply asks users to input readily available information about the chemicals they use and the way that they use them. The system then automatically identifies a range of control approaches and produces easy-to-follow instructions on how to put the guidance into practice and carry out other duties required by COSHH. A brief explanation of how *COSHH Essentials* works is given in Box 2. It is available either as a priced HSE publication or free on the Internet at www.coshh-essentials.org.uk. Annex 5 contains an example of a *COSHH Essentials* guidance sheet (www.coshh-essentials.org.uk/assets/G217.pdf). The detailed rationale for linking WELs into the *COSHH Essentials* risk assessment is set out in Annex 6.

69. The *COSHH Essentials* generic risk assessment applies to supplied chemicals and preparations, i.e. those covered by the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP). For the more hazardous substances, i.e. those causing asthma and some carcinogens, it defaults to directing the user to seek specialist advice. *COSHH Essentials* does not cover gases, some naturally occurring substances, (e.g. grain dust) and process generated dusts and fumes.

70. HSE is expanding the range of *COSHH Essentials* control guidance sheets to provide advice for substances with WELs in those categories not currently covered. Work is currently underway to develop *COSHH Essentials* control guidance sheets for the main causes of occupational asthma and process generated dusts and fumes. It is proposed to break this guidance down into specific activities and draft *COSHH Essentials*-style guidance sheets for each of the main unit activities within that industry. For example, for ferrous foundry particulate, there will be control guidance sheets giving good practice advice for casting, knockout and fettling of small castings and fettling of large castings. The first batch will be incorporated into the Internet version of *COSHH Essentials* in autumn 2003.

Do you agree with the proposal to use the COSHH Essentials system to provide the primary route to good practice advice?

Box 2

COSHH Essentials – A summary

COSHH Essentials was developed to help firms, particularly small businesses, control health risks from the use of chemicals in the workplace. The guidance pack *COSHH Essentials: easy steps to control chemicals* provides:

- a simple checklist-based risk assessment that leads users to a control approach suitable for their chemicals and tasks: There are 4 control approaches: 1 - general ventilation; 2 - engineering control; 3 – containment; or 4 - users are directed to seek specialist advice for the most hazardous chemicals and riskiest tasks.
- practical advice on using the control approaches and advice on getting specialist help.
- 60 illustrated control guidance sheets giving good practice control advice for common tasks such as mixing, weighing, sieving and additional sheets on avoiding skin and eye contact with chemicals and protective equipment.
- a reminder about other duties under the COSHH Regulations and pointers to helpful publications.

To get the advice for their chemicals and tasks the user enters onto a checklist:

- the hazard group - one of A-E, with E being the most hazardous and group S for substances which can cause harm as a result of skin contact – these are based on the risk phrases for the chemical, which are given in section 15 of the safety data sheet;
- how much they are using: small (grams or millilitres), medium (kilograms or litres) or large (tonnes or cubic metres);
- for solids - how dusty: low, medium or high, based on simple descriptors; or
- for liquids - how volatile: low, medium or high, based on boiling point and the temperature at which the chemical is used.

A table then directs users to the right control approach. An index gives a list, for each control approach, of control guidance sheets for common tasks.

An Internet version is freely available at www.coshh-essentials.org.uk. The user enters the same information and the system, using the same risk assessment approach, selects the right control approach and control guidance sheets, which can be printed out. The user can also print out an assessment form giving the information entered and a reminder of the need to implement the controls, consider other COSHH duties and other legislative requirements.

COSHH Essentials covers chemicals and chemical preparations supplied for use at work. It does not cover process generated dusts and fumes, gases, lead and asbestos. Work is in hand to expand the range of control guidance sheets.

Making information on WELs and good practice advice readily available.

71. The list of WELs will be published in a successor to *EH40 Occupational Exposure Limits (EH40)*. The document will also be available free of charge in electronic format either in HSEdirect or HSE's web site.

72. *EH40* is aimed at the expert user. The accompanying text assumes considerable background knowledge and gives a reference to technical manuals on measurement methods. HSE believes that there is a need for a publication that is simpler and more useful to employers in small businesses and safety representatives. HSE therefore proposes to publish two documents:

- a one-off priced document containing technical information for expert users;
- a free more user-friendly web site based document that will contain the table of limits which will be updated as required.

73. Table 2 sets out how the second publication would look. It aims to make information on chemicals much more accessible. The first column of table 2 contains the name of the substance, including any commonly used names. The second column will list the HSC approved Workplace Exposure Limits in $mg.m^{-3}$ and/or ppm, as appropriate.

74. In the third column of table 2 there will be a simple statement explaining how the chemical might affect health. Column 4 will direct users to the correct Hazard Group as set out in *COSHH Essentials*, where appropriate. Text in the second publication will explain how *COSHH Essentials* can be used to provide good practice advice and alternative sources in circumstances when advice is not available from *COSHH Essentials*. The Hazard Group column will also contain the Sk and Sen notations currently in EH40, and a Carc notation for substances subject to COSHH reg 7(7)(c).

75. Columns 5 and 6 in Table 2 provide the linkage to the good practice advice. The column marked "Control Approach" is the appropriate *COSHH Essentials* control approach assuming the substance is used at room temperature. If the substance is used at any other temperature the user will need to work through the *COSHH Essentials* system to identify the appropriate control approach. By clicking on Column 6 of table 2, users will be directed to relevant guidance through a hypertext link.

76. Column 7 (not in Table 2) will enable the user to access through a hyper text link information on the basis of the limit, known as *EH64 Summary of Criteria for Occupational Exposure Limits (EH64). EH64* documents will explain the basis for the WEL.

Table 2. Proposed layout of list of WELs giving examples of hazard banding and good practice advice

Substance	Workplace Exposure Limit		How it might affect your health	Hazard Group & flags	Control Approach for use at Room Temperature			Helpful guidance
	8 hr TWA	15 min ref. Period			Small* Scale Use	Medium Scale Use	Large scale Use	
4-methylpentan-2-one	50 ppm	100 ppm	Iirritation of eyes, nose and throat	B & S	1	2	2	
Acetone	500 ppm	1500 ppm	Vapours may cause drowsiness, dizziness and eye irritation.	A & S	1	2	2	
Barium Sulphate	10 mg/m^3		Lung damage from breathing the dust	A	1	2	2	
Ferrous Foundry Particulate	10 mg/m^3		May cause cancer, lung disease and asthma	N/A				Knockout Fettling Casting
Glutaraldehyde	0.05 ppm	0.05ppm	May cause asthma and irritation of eyes, nose and throat	N/A Sen**				Sterilisation of medical equipment
Toluene	50 ppm	150 ppm	Vapours may cause dizziness, drowsiness and eye irritation	B & S	1	2	2	
Triethylamine	2 ppm	4ppm	Vapour causes visual disturbance (blue haze) and eye irritation.	C & S	2	3	4	
Xylenes	50 ppm	100 ppm	May cause dizziness and headache	B & S	1	2	2	

*** as defined in *COSHH Essentials* – *COSHH Essentials* is obtainable from HSE books or at www.coshh-essentials.org.uk and provides advice on control (see box 2)**

**** a cause of asthma – COSHH ACoP, Appendix 3 applies**

Do you agree with the proposed method for publishing WELs?

Electronic linkage between the WEL publication, *COSHH Essentials* and EH64

77. Respondents to the Discussion Document (see paragraphs 28 - 30) felt it would be helpful to duty holders to have an electronic package linking together OELs, *COSHH Essentials* and *EH64*. The proposal is that if a user of the electronic version of *COSHH Essentials* (*eCOSHH Essentials*) enters the name of a chemical that has been assigned a WEL, the system will automatically select the appropriate hazard group and the user will not be asked to input the risk phrases. This will not apply if the user selects the *eCOSHH Essentials* option "using a mixture made by yourself before starting this task", when the risk phrases are needed for the dilution rules which calculate the hazard group for the mixture. If the user selects to view the list of WELs, hypertext links will become available to *COSHH Essentials* and EH64.

Do you agree with the proposals to link WELs, COSHH Essentials and EH64?

78. The design of the electronic list of WELs and interactions with EH64 and *eCOSHH Essentials* will involve market testing to find out in more detail what users want and piloting with users, including small firms and safety representatives, to ensure the final system is user friendly. Boxes 3 and 4 give examples of how the system may operate.

Is the link between the principles of good practice and good practice guidance, such as COSHH Essentials clear?

Box 3

How the new system will operate – electronic format

Example 1. Jane Green, works manager at Wonderglues Ltd, wants to dispense 4-methylpentan-2-one from drums into 250ml bottles. She has not used the chemical before, so she searches HSE website for information. The COSHH web pages tell her information on specific chemicals can be obtained free of charge from either a list of WELs or from *eCOSHH Essentials*.

a. Jane Green opens the list of WELs and scrolls down the alphabetic list to 4-methylpentan-2-one. The screen displays:

- the WEL values - 50ppm 8 hour time weighted average (TWA) and 100ppm short term limit;
- the skin notation, which warns Jane that the chemical can cause harm as a result of being absorbed into the body through the skin;
- the main health effects – irritation of eyes, nose and throat; and
- a hypertext link to *eCOSHH Essentials* and *COSHH: a brief guide to the Regulations.*

b. Jane opens *eCOSHH essentials*, either from the web address or the hypertext link from list of WELs, and starts a new assessment. At the prompt to enter the chemical's name, she enters 4-methylpentan-2-one. Based on the 8 hour TWA of 50ppm, *eCOSHH Essentials* allocates 4-methylpentan-2-one to hazard groups B and S. *eCOSHH Essentials* displays the hazard group allocation and tells Jane it is based on the WEL. The system then proceeds to ask Jane to input usage information. She is not shown the screen asking her to input risk phrases from the safety data sheet. At the end of the assessment *eCOSHH Essentials* tells her she needs engineering control and provides links to files giving general advice on engineering control, a task specific sheet on use of engineering controls in drum emptying and advice on skin protection.

Example 2. John White, a safety representative at Brunels Foundries, is concerned about the levels of fume during casting at the traditional foundry. He obtains a copy of the WEL publication from a union official and is disturbed to find the fume can cause cancer, lung disease and asthma. He notes that the publication tells him that control advice is available in *eCOSHH Essentials*. He accesses *eCOSHH Essentials* from the free portion of hsedirect. On the task screen he selects the option – dusts or fumes produced by a work process. From the drop down list he selects ferrous foundry fume, which leads to another list of activities including casting. By clicking on this he gets a file giving good practice control advice, information on health effects and the WEL for ferrous foundry fume.

Box 4 - Examples of how the new system will operate – paper format

Jane Green, works manager at Wonderglues Ltd, wants to dispense 4-methylpentan-2-one from drums into 250ml bottles. She has not used the chemical before so she purchases the list of WELs from HSE Books.

She looks up 4-methylpentan-2-one and finds:

- it has WEL values of 50ppm 8 hour time weighted average (TWA) and 100ppm short term limit;
- it has a skin notation, with an explanation which warns Jane that the chemical can cause harm as a result of being absorbed into the body through the skin;
- the main health effects are irritation of eyes, nose and throat;
- it has been assigned *COSHH Essentials* hazard groups B and S – (the publication explains *COSHH Essentials* and tells her it can be purchased from HSE Books); and
- for quantities of less than 1 litre general ventilation will provide adequate control, but for larger quantities engineering control will be required.

Jane decides *COSHH Essentials* will help her and orders it from HSE Books. Using the checklist and the hazard grouping given in the list of WELs, she selects control guidance sheets on general advice on engineering control, use of engineering controls in drum emptying and skin protection.

Integration of existing OELs into the new framework

79. There are currently about 500 limits (72 MELs and 430 OESs) listed in EH40. Around 80 of the OESs are based on a thorough scientific evaluation by the Working Group on the Assessment of Toxic Chemicals (WATCH) but the rest were derived historically from the 1980 list of Threshold Limit Values set by the American Conference of Governmental and Industrial Hygienists. Many of the values date back to the 1960s. To facilitate decision making as to which of the existing limits in EH40 could be taken forward into the new systems as WELs, ACTS endorsed an analysis by HSE of the MELs and OESs published in EH40. This assessed the quality and quantity of data on which the limits are based and the extent of industrial usage. The analysis informed proposals for which limits should be transferred to the new system as WELs. The aim is to establish a robust list of limits supported by documentation setting out the basis for the limit.

80. Annex 7 divides the current lists of OESs and MELs into 3 tables. Table 1 lists the OESs that ACTS propose should be transferred in to the new system as WELs. Table 2 lists all the MELs currently approved by HSC and the two MEL proposals currently under consultation, subtilisins and Refractory Ceramic Fibres (RCFs). The proposal is to transfer these into the new system as WELs. Table 3 lists the OESs that ACTS propose should not be transferred to the new system. The Annex gives the rationale for the proposals and sets out the advice HSE intends to make available for substances ACTS propose should no longer have an OEL assigned by HSC.

Consultees' views are sought on the allocation of individual substances to tables 1 - 3 in Annex 7, (Specific questions are listed in Annex 11).
Views are also sought on the proposed WEL values in tables 1 and 2.

Regulatory Impact Assessment (RIA)

81. Annex 8 contains an RIA. Total compliance costs are estimated to lie in the range of £16.2 to £69.0 million (policy costs of £1.9 to £38.6 million and implementation costs of £14.2 to £30.4 million). A large number of firms will have to spend a small amount of time familiarising themselves with the new requirements (implementation costs). However, the cost per firm for the majority of firms will be negligible, as a relatively small number of firms will have to take significant action to meet the new requirements (policy costs).

82. It is expected that there will be health benefits from improved risk control of this proposal, but it has not been possible to estimate them due to uncertainty over which substances (and corresponding industries) may be affected by the new framework. There will also be benefits to HSE from easier enforcement.

HSE would welcome views on the Regulatory Impact Assessment (RIA). (Specific questions are listed in Annex 11).

Conclusion

83. The weakness of the present system is that many employers, particularly in small businesses, do not know what OELs mean in practical terms, how to assess whether they are complying with them or what control measures they need. A major survey of the perception and use of OELs by small firms concluded; "OELs play little part in the decisions these firms make on the management of risks from chemicals". Research also shows that small businesses want clear guidance on what they have to do to control the chemicals they are using in their workplace. This is what the proposals in this CD aim to do. The benefits of the proposals set out in this CD compared with the existing system of MELs and OESs are listed in Table 3.

Table 3: The benefits of proposals in the CD compared to the existing system

Benefit	Current System	Proposed system
"position" of OELs in the COSHH Regulations	Stand alone – little practical advice on steps needed to comply with the OEL	OELs clearly linked to guidance on controls needed to keep exposure below the limit
OEL system	OES and MEL system not understood by many employers. Concept of the OES as a "safe" limit is not sustainable	A single type of limit applicable to all substances is the simplest system possible.
OEL compliance & enforcement	OESs difficult to comply with and enforce in practice	Requirement to follow good practice easier for employers to comply with and HSE to enforce. Single requirement to not exceed the limit and a clear explanation of what that means.
System for setting OELs	Slow, cumbersome and resource intensive, not fully compatible with new EC system	Simplified criteria for a single limit - will make limit setting easier, compatible with EC system
Role of OELs	Legal limits	Legal limits also apply under the new system, which tells people how to apply. OELs are set in context of other COSHH duties, by being linked to good practice
Electronic use/availability	Not user friendly. The current list of limits is published in priced hard copy format only in EH40	The new list of limits will be available free of charge on the web and will link to the *COSHH Essentials* good practice advice.
Substances covered by system	Over 30,000 high volume production chemicals are used in the UK. Of these, only 500 have Occupational Exposure Limits, some of which are no longer scientifically well-founded.	There will be limits for approx. 150 substances, all of which will be scientifically well-founded. Employers will be able to apply the principles of good practice to these and all other substances.
Innovative approach	OESs and MELs stem from the work on Threshold Values the American Conference of Governmental Industrial Hygienists began in 1948. They are outdated and poorly understood.	The system of good practice control advice to accompany the limit would be the first of this kind in the world.

S T A T U T O R Y I N S T R U M E N T S

2004 No.

HEALTH AND SAFETY

The Control of Substances Hazardous to Health (Amendment) Regulations 2004

Made - - - -	*Day Month 2004*
Laid before Parliament	*Day Month 2004*
Coming into force - -	*Day Month 2004*

The Secretary of State, being the Minister designated ([4]) for the purpose of section 2(2) of the European Communities Act 1972([5]) in relation to the abolition of restrictions on the import or export of goods, in the exercise of the powers conferred on him by the said section 2(2) and sections 15(1), (2), (4), and (6)(b) and 82(3)(a) of, and paragraphs 1(1), 8, 9, 10, 11, 13(1), 14, 15 and 16 of Schedule 3 to the Health and Safety at Work etc. Act 1974([6]) hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Control of Substances Hazardous to Health (Amendment) Regulations 2004 and shall come into force on Day Month 2004.

Amendment of the Control of Substances Hazardous to Health Regulations 2002

2. In the Control of Substances Hazardous to Health Regulations 2002([7])-

(a) in regulation 2(1)-

(i) delete the definition of "maximum exposure limit";

(ii) delete the definition of "occupational exposure standard";

(iii) after the definition of "the risk assessment" add the following definition-

""risk phrase" has the meaning assigned to it in regulation 2(1) of the CHIP Regulations;";

([4]) S.I. 1992/2661

([5]) 1972 c.68; the definition of the Treaties referred to in section 2(2) of the European Communities Act 1972 was extended by section 1 of the European Economic Area Act 1993 (c.51).

([6]) 1974 c.37; sections 11(2), 15(1) and 50(3) were amended by the Employment Protection Act 1975 (c.71), Schedule 15, paragraphs 4, 6 and 16(3) respectively.

([7]) S.I. 2002/2677, as amended by S.I. 2003/978.

(iv) in the definition of "substance hazardous to health" in sub-paragraph (b), for the words "a maximum exposure limit or an occupational exposure standard" substitute the words "a workplace exposure limit";

v) after the definition of "workplace" add the following definition-

"workplace exposure limit" for a substance hazardous to health means the exposure limit approved by the Health and Safety Commission for that substance in relation to the specified reference period when calculated by a method approved by the Health and Safety Commission.";

(b) in regulation 6(2) sub-paragraph (f), for the words "occupational exposure standard, maximum exposure limit" substitute the words "workplace exposure limit";

(c) in regulation 7-

(i) for paragraph (7), substitute the following paragraph-

"(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 that substance is not exceeded; and

(c) for a substance which carries the risk phrase R45, R46 or R49, or for a substance or process which is listed in Schedule 1, the level of exposure is reduced so far as is reasonably practicable.";

(ii) delete paragraph (8);

(d) in regulation 12(2)-

(i) in sub-paragraph (a)(ii) for the words "occupational exposure standard, maximum exposure limit" substitute the words "workplace exposure limit";

(ii) in sub-paragraph (d) for the words "maximum exposure limit", in each place where they occur, substitute the words "workplace exposure limit"; and

(k) at the end of Schedule 2 insert the Schedule to these Regulations.

Signed by the authority of the Secretary of State for Work and Pensions.

D. Browne
Minister of State,
Department for Work and Pensions

Day Month 2004

SCHEDULE Regulation 2

"SCHEDULE 2A

Regulation 7(7)

PRINCIPLES OF GOOD PRACTICE FOR THE CONTROL OF EXPOSURE TO SUBSTANCES HAZARDOUS TO HEALTH

(a) Control exposure by measures that are proportionate to the health risk.

(b) Design and operate processes and activities to minimise emission, release and spread of substances hazardous to health.

(c) Take into account all relevant routes of exposure – inhalation, skin absorption and ingestion – when developing control measures.

(d) Choose the most effective and reliable control options which minimise the escape and spread of substances hazardous to health.

(e) Where adequate control of exposure cannot be achieved by other means, provide, in combination with other control measures, suitable personal protective equipment.

(f) Check and review regularly all elements of control measures for their continuing effectiveness.

(g) Inform and train all employees on the hazards and risks from the substances with which they work and the use of control measures developed to minimise the risks.

(h) Ensure that the introduction of control measures does not increase the overall risk to health and safety.".

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations amend the Control of Substances Hazardous to Health Regulations 2002 (S.I. 2002/2677) by-

(a) introducing a new requirement to observe principles of good practice for the control of exposure to substances hazardous to health;

(b) introducing a single new workplace exposure limit for substances hazardous to health which replaces occupational exposure standards and maximum exposure limits;

(c) deleting regulation 7(8) concerning occupational exposure standards; and

(d) introducing a list of principles of good practice for the control of exposure to substances hazardous to health as Schedule 2A.

2. A copy of the regulatory impact assessment prepared in respect of these Regulations can be obtained from the Health and Safety Executive, Economic Advisers Unit, Rose Court, 2 Southwark Bridge, London, SE1 9HS.

THE CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH (AMENDMENT) REGULATIONS 2004

PROPOSED REVISED ACOP TEXT SUPPORTING REGULATION 7

Prevention of exposure

89 An employer's overriding duty and first priority is to consider how to prevent employees being exposed to substances hazardous to health (regulations 7(1) and (2)). Employers who do not first consider this are failing to comply with a fundamental requirement of the Regulations. The duty to prevent exposure should be achieved by measures other than the use of personal protective equipment. Employers can best comply with this requirement by eliminating completely the use or production of substances hazardous to health in the workplace. This might be achieved by:

(a) changing the method of work so that the operation giving rise to the exposure is no longer necessary; or

(b) modifying a process to eliminate the production of a hazardous by-product or waste product; or

(c) substituting wherever reasonably practicable, a non-hazardous substance which presents no risk to health where a hazardous substance is used intentionally.

90 In many workplaces, it will not be possible or practicable to eliminate exposure to substances hazardous to health completely. Therefore, where it is necessary to use a hazardous substance, an employer should consider whether it is possible to significantly reduce exposure by:

(a) using an alternative less hazardous substance; or

(b) different form of the same substance; or

(c) different process,

which, in the circumstances of the work, presents less risk to the health of employees. This might be achieved by changing the form of the substance concerned so that exposure is negligible, e.g. using a substance in pellet rather than powder form.

91 The employer will need to take many factors into account when considering whether to use an alternative substance, including all the harmful properties of any proposed replacement. The harmful properties of many potential replacement substances may not all be known, and employers should be aware of this in considering alternatives. The ultimate decision should be based on a balance of any new risks they might present against the potential benefits. For example, in seeking a less toxic substitute chemical for a process, the employer's choice of one with lower toxicity but higher flammability might increase the overall risk if the process has an intrinsic fire risk. Therefore, in considering potential substitutes, employers should be aware of the responsibilities they have under the Dangerous Substances and Explosives Atmospheres Regulations 2002.

92 More guidance on substitution is provided by HSE's publication *Seven steps to successful substitution of hazardous substances*.

Adequate control of exposure by all routes

93 Where prevention of exposure to substances hazardous to health is not reasonably practicable, employers must comply with the secondary duty in regulation 7(1) to adequately control exposure. Employers can achieve adequate control of exposure from all routes of exposure by complying with the provisions of regulation 7(7). These require employers to take the following measures:

(a) apply the principles of good practice for the control of exposure to substances hazardous to health as set out in Schedule 2A [regulation 7(7)(a)]; and

(b) ensure that any workplace exposure limit (WEL) approved for a substance hazardous to health is not exceeded [regulation 7(7)(b)]; and where appropriate

(c) reduce exposure so far as is reasonably practicable for:

(i) substances assigned the risk phrase R45 "May cause cancer"; or R46 "May cause heritable genetic damage"; or R49 "May cause cancer by inhalation" (carcinogens and mutagens, regulation 7(7)(c)); and

(ii) substances or processes listed in Schedule 1 *Other substances and processes to which the*

definition of "carcinogen" relates **(regulation 7(7)(c)).**

94 Where appropriate, employers should be able to comply with the requirements of sub-paragraphs (b) and (c) by applying the principles of good practice for the control of exposure to substances hazardous to health as required by sub-paragraph (a). Guidance on applying those principles is provided by HSE's publication *[title]*.

95 In complying with regulation 7(7) to achieve adequate control of exposure, employers must also comply with the provisions of regulation 7(3) supported by those in regulation 7(4). Regulation 7(3) requires that employers apply protection measures appropriate to the activity and consistent with the risk assessment in an order of priority.

96 At the same time as considering how to apply the protection measures set out in regulation 7(3) and (4), employers must also consider how to implement the general principles of good practice for the control of exposure to substances hazardous to health required by regulation 7(7) and Schedule 2A. Some aspects of the requirements in regulation 7(3) duplicate or overlap the list of principles in the Schedule. Therefore, this reinforces the need for employers to consider the separate requirements concurrently in order to achieve adequate control of exposure by all routes. The employer's aim should be to apply the principles of good practice and to select the most appropriate controls that are proportionate to the risks arising from the work. So if the risks to employees' health are serious or uncertain, stringent control of exposure by all routes will be required.

97 The order of priority in applying protection measures required by regulation 7(3) means that employers must first consider the application of the measures set out in regulation 7(3)(a) in so far as they are appropriate for the circumstances of the work, before considering those in 7(3)(b) and finally those in 7(3)(c).

98 Where employers cannot achieve adequate control of exposure by a combination of the measures in regulation 7(3), (4), (7) and Schedule 2A, then they may supplement them by the use of suitable personal protective equipment (PPE). Wherever possible, however, PPE should only be used as a last resort and then in addition to other control measures. For example, in certain circumstances, e.g. maintenance and cleaning operations where there is

the potential for a high level of exposure that may be particularly difficult to adequately control, employers may also need to provide personal protective equipment, including respiratory protective equipment.

99 The employer should apply the principles of good practice in all circumstances, but it will not always be necessary to apply all the controls described in regulations 7(3) and (4). However, it will often be necessary to use a combination of them which in practice will work best to protect the health of employees. The employer should give priority to those controls that contain or minimise the release of contaminants and the spread of hazardous substances into the workplace. Administrative and procedural options for controlling exposure are also important elements that the employer should consider, e.g. the arrangements for the safe handling, storage and transport of hazardous substances, of waste containing such substances, and suitable maintenance procedures etc. Many examples of how to adequately control exposure are provided in *COSHH Essentials: Easy steps to control hazardous substances*.

100 The specific standards that are needed to achieve adequate control of exposure by all routes of exposure, i.e. inhalation, absorption through the skin and ingestion, are described in paragraphs 124-147.

Specific control measures

101 Regulation 7(4) supports regulation 7(3) by providing a list of typical control measures that employers should consider when applying the control measures set out in regulation 7(3).

102 The requirement at regulation 7(4)(c)(iii) - "reducing to the minimum required for the work concerned .... the quantity of substances hazardous to health present at the workplace" - is not intended to prevent employers buying hazardous substances in bulk in order to reduce their costs, but to reduce the overall risk by minimising the amount potentially released into the working area.

103 The control measures that employers may have to use could be any combination of the following:

(a) totally enclosed process and handling systems;

(b) plant or processes or systems of work which:

(i) keep the production or generation of the hazardous dust, fume, vapour, biological agent etc. to a minimum, e.g. by modifying a process or changing its conditions such as temperature or pressure to reduce emissions; or

(ii) contain it within the plant;

(iii) reduce or eliminate the need for maintenance staff to go into hazardous areas; and

(iv) limit the area contaminated if spills and leaks occur;

(c) ventilation -

(i) partial enclosure, with local exhaust ventilation;

(ii) local exhaust ventilation; and/or

(iii) sufficient general ventilation;

(d) reducing to the minimum required for the work:

(i) the number of employees exposed and excluding non-essential employees, e.g. by using "refuges";

(ii) the level and duration of exposure; and

(iii) the quantities of hazardous substances used or produced;

(e) regular cleaning of contamination from walls, surfaces etc. or their disinfection;

(f) providing safe handling, storage, transport and disposal of substances hazardous to health and waste containing such substances;

(g) hygiene measures:

(i) adequate facilities for washing, changing and storage of clothing and PPE (see paragraph 185);

(ii) including arrangements for laundering contaminated clothing;

(iii) separate accommodation for clothing worn at work which may become contaminated by work clothing; and

(iv) where appropriate, prohibiting employees from eating, drinking and smoking in contaminated areas which may result in the ingestion of hazardous substances.

104 Employers should ensure by appropriate supervision that employees follow good practice and defined methods of work at all times. This can play a significant role in helping to secure and maintain adequate control of exposure to hazardous substances.

105 Employers must also ensure that whoever provides advice on the prevention or control of exposure is competent to do so in accordance with regulation 12(4). The people who carry out this work should have adequate knowledge, training and expertise, e.g. in the design of processes, ventilation and personal protective equipment, the human and technical reasons why these control measures can fail, and the importance of following the principles of good practice.

Control of exposure to hazardous substances <u>not</u> classified as carcinogens or mutagens

106 For these hazardous substances, the employer should make every effort to achieve adequate control of exposure by applying the principles of good practice in Schedule 2A and the protection measures in regulation 7(3) other than personal protective equipment (PPE). However, PPE must be used where it is not reasonably practicable to achieve adequate control of exposure by other control measures alone, and then only in addition to them (regulation 7(3)(c)).

COSHH Essentials: Easy steps to control chemicals

107 Employers may use the step-by-step process described in *COSHH Essentials* for identifying the appropriate controls for a wide range of hazardous substances/task combinations. Employers correctly using the *COSHH Essentials'* risk assessment scheme and following the control advice will be applying good practice and complying, in the vast majority of circumstances, with the control requirements of regulation 7(3). However, it remains the responsibility of employers to ensure that they:

(a) have made a suitable and sufficient assessment in accordance with regulation 6;

(b) are adequately controlling exposure to substances hazardous to health in accordance with regulation 7(7) and, where appropriate, complying with any relevant workplace or in-house exposure limits; and

(c) are protecting employees' health.

108 They should seek specialist advice if they are in doubt about the suitability of control advice recommended by *COSHH Essentials*.

109 Employers who use the *COSHH Essentials* approach may use the completed checklist from the publication, or the printout from the web-based *COSHH Essentials*, as part of the significant findings of the assessment that the employer may need to record in accordance with regulation 6(4).

Control of exposure to carcinogens and mutagens

110 If it is not reasonably practicable to prevent exposure to a carcinogen or mutagen, the employer must put into place the appropriate controls set out in regulation 7(3) and all the measures in regulation 7(5). This means that whether or not it is reasonably practicable to enclose totally the process and handling systems in accordance with regulation 7(5)(a), all the other measures in 7(5)(b)-(e) are still required.

111 For carcinogens and mutagens assigned one of the risk phrases R45, R46 or R49 (see paragraph 93(c)), or listed in Schedule 1, the employer's overriding aim must be to reduce exposure so far as is reasonably practicable.

112 Further guidance on the control of exposure to hazardous substances defined as carcinogens or mutagens for the purposes of COSHH is set out in Appendix 1.

Control of exposure to substances that cause occupational asthma

113 Further ACoP duties on the control of substances that cause occupational asthma are set out in Appendix 3. A list of the substances that can cause occupational asthma is available on the HSE website at www.hse.gov.uk/asthma/causes.htm.

Further general guidance

114 The HSE publication *[title]:*

(a) provides a list of those hazardous substances for which HSC has approved a WEL;

(b) gives details of the limit(s) concerned;

(c) provides a brief description of how exposure to the substance may affect health;

(d) lists the appropriate *COSHH Essentials* hazard group;

(e) identifies substances with WELs which, for the purposes of COSHH, are also defined as carcinogens or mutagens, substances that may cause occupational asthma, and substances assigned a skin notation (see paragraph 143);

(f) lists the appropriate control approach under *COSHH Essentials*, and

(g) provides further helpful guidance, e.g. work activities which may result in exposure to the substance concerned.

The publication is available on the HSE website at www…..

Control of exposure to biological agents

115 If employers cannot prevent exposure to a biological agent they should take steps to ensure that it is adequately controlled and consider all the requirements set out in regulation 7(3), (4), (6) and (7). They should apply the principles of good practice and use each requirement where, and to the extent that:

(a) it is applicable; and

(b) the assessment carried out under regulation 6 shows that it will lead to a reduction in risk.

116 The selection of control measures for biological agents should take into account the fact that there are no exposure limits for them. Their ability to replicate and to infect at very small doses means that exposure may have to be reduced to levels that are at the limit of detection.

117 Not all the listed measures will be required in every case. The assessment may indicate for example that:

(a) a specific method of transmission and route of infection is required;

(b) a susceptible host is needed;

(c) there is a low prevalence of the infection in that particular activity; and

(d) illness is easily treatable leading to rapid and complete recovery.

118 In these cases, the risk would be relatively low and the control measures required less stringent.

119 Another factor that will determine which controls are to be applied may be the extent to which exposure to a biological agent is incidental to the main purpose of the work (see also paragraphs 48-49), or involves intentional work with a biological agent. The duties under COSHH apply in both circumstances. Schedule 3 applies for all work with biological agents that involves research, development, teaching or diagnosis.

120 Where human patients or animals infected with a biological agent in Group 2 are accommodated, e.g. patients on a hospital ward, the choice of controls and containment, as in other cases, should be on the basis of risk assessment and in particular the nature of infection and the facility for mode of transmission of the agent. The controls selected should reflect the principles in regulation 7(3), (4), (6) and (7). For patients and animals infected with a Group 3 or 4 biological agent the control and containment measures should reflect the above principles with appropriate measures selected from Part II of Schedule 3. The level of risk should be the employer's main consideration, and even where the exposure is incidental to the activity, if the risk is sufficiently high and some of the listed measures can reduce it, then the employer should apply those measures.

121 There are effective vaccines against some biological agents. In addition to other measures designed to prevent or control the risk of exposure to such agents under regulation 7(3), (4), (6) and (7), employers should make arrangements for vaccination, free of charge to employees who are considered vulnerable to the biological agents to which they are exposed or likely to be exposed at work. It is also recommended that employers keep a vaccination record.

122 In addition, employers and employees have responsibilities to protect others who might be put at risk from a work activity, e.g. patients, visitors and members of the public. Vaccination of employees can help prevent the spread of infection to such individuals.

123 Employees should be informed of the benefits and drawbacks of both vaccination and non-vaccination. Protection against serious illness is the most obvious benefit; protection against spread of infection to patients and other members of the public is also important. Drawbacks include the possibility of reactions to the vaccine, and any potential effects on health should be explained to the individual. Having considered the risks and benefits, employers should recommend vaccination to their employees.

Adequate control of exposure by inhalation

Workplace exposure limits (WELs)

124 The HSC has established WELs for a number of substances hazardous to health. These are intended to prevent excessive exposure to specified hazardous substances by containing exposure at or below a set limit. If employers correctly apply the principles of good practice for the control of substances hazardous to health, exposure should be below any relevant WEL. The principles require the degree to which exposure is reduced below the WEL to be proportionate to the health risk.

125 A WEL is the maximum concentration of an airborne substance averaged over a reference period, to which employees may be exposed by inhalation under any circumstances. Substances which have been assigned a WEL fall into two broad groups, i.e.:

(a) those defined as a carcinogen or mutagen for the purposes of COSHH; including those assigned one of the risk phrases R45, R46 or R49 (see paragraph 93(c)), or included in the list of substances and processes in Schedule 1;

(b) all other hazardous substances assigned a WEL.

126 For those substances included in (a) above, employers must ensure that the control measures in place

reduce exposure so far as is reasonably practicable below the WEL (see paragraphs 110 to 112). For all other hazardous substances assigned WELs (paragraph (b) above), adequate control of exposure by inhalation will be achieved by applying the principles of good practice that are proportionate to the health risk and also by ensuring that the WEL is not exceeded (see paragraphs 106 to 109).

127 Regulation 7(4)(c)(ii) requires employers to reduce to the minimum for the work concerned the level and duration of exposure. For substances that have been assigned a WEL or in-house exposure limit that should not be exceeded (regulation 7(7)(b)), employers can comply with this requirement by ensuring that they apply the principles of good practice required by regulation 7(7)(c) and as set out in Schedule 2A. In so doing, they will ensure that exposure is adequately controlled and complies with any relevant exposure limit for the substance concerned.

128 WELs apply only to people at work and to conditions where the atmospheric pressure is normal, i.e. between 900 and 1100 millibars.

129 WELs refer to concentrations of hazardous substances in the air that people breathe, averaged over a specified period of time referred to as time weighted average (TWA). Two time periods are used: long term (8 hours); and short term (15 minutes). These limits cannot be readily adapted to evaluate or control non-occupational exposure.

130 HSE's publication *[title]* includes the list of substances assigned WELs (see paragraph 114). HSE's publication *[title]* includes the approved methods for averaging over the specified reference periods, an explanation of the terms 'respirable' and 'inhalable', and related material.

Substances defined as carcinogens or mutagens and assigned a workplace exposure limit (WEL)

131 To comply with the requirements in regulation 7(7)(c) to reduce exposure so far as is reasonably practicable, for substances with an 8-hour long-term reference period, employers may have to carry out a programme of air monitoring in accordance with regulation 10. This will generally be necessary unless the risk assessment made under regulation 6 shows that the level of exposure is most unlikely ever to exceed the WEL. The extent to which employers can reduce exposure below the

WEL will depend on the type of risk presented by the substance, weighed against the cost and the effort involved in taking measures to reduce the risk (see paragraph 34 on reasonable practicability).

Other substances assigned a workplace exposure limit

132 For a single substance assigned a WEL that is not classified under COSHH as a carcinogen or mutagen, adequate control of exposure will be achieved by applying the principles of good practice to the work involving exposure to the substance concerned. In these circumstances, and particularly if *COSHH Essentials* is used to identify and apply the appropriate control measures, the employer is unlikely to need a programme of air monitoring to check whether exposure is being maintained at or below the WEL.

Short-term exposure limits

133 Some substances for which WELs have been approved have been assigned short-term exposure limits (STELs) (15-minute reference period). These substances can cause acute health effects and the purpose of the short-term limit is to prevent the adverse health effect occurring from brief exposures to the substance. For this reason, and in keeping with the principles of good practice for the control of substances hazardous to health, short-term WELs should **not** be exceeded.

Inhaled substances not assigned WELs

134 The absence of a substance from the lists of WELs does not mean that it is safe. For these substances, employers should apply the principles of good practice for the control of substances hazardous to health and control exposure to a level to which nearly all the working population could be exposed, day after day at work, without adverse effects on health. As set out in paragraphs 107–109, employers may be able to use *COSHH Essentials* to help decide on suitable control measures. In addition, HSE has published good practice advice for a number of substances not covered by *COSHH Essentials*, e.g. gases and process dusts and fumes. HSE has also produced Chemical Hazard Alert Notices (CHANs) for a number of substances and a list of those currently available can be viewed on the HSE website at www.hse.gov.uk/pubns/chindex.htm . In addition, employers can obtain information about the substance concerned from a number of other sources, including:

(a) manufacturers and suppliers of the substance;

(b) industry association publications; and

(c) occupational medicine and hygiene journals.

135 Employers may also have to set their own in-house exposure limit in situations where a substance they are using has an approved WEL, but it is not appropriate to apply it, e.g. it is being used in circumstances above normal atmospheric pressure.

Action if a workplace exposure limit or in-house standard is exceeded

136 The employer's first step should be to consider if there is a visible, obvious reason for the result(s) which exceed the limit, e.g. the person to whom the result(s) relates may be subject to higher than normally expected exposure in a job that only that person carries out. If it is an isolated result, or one or two results which marginally exceed an 8-hour time-weighted average limit, the employer should consider whether they have real significance and indicate a failure to maintain adequate control, or whether they reflect an error in the measurement method. However, a single result above a 15 minute short term exposure limit (STEL) may be cause for concern and require the employer to take immediate remedial action: e.g. where the substance concerned has been assigned a WEL and also an accompanying STEL, and particularly where the substance is a carcinogen, mutagen or can cause occupational asthma. Employers who are unsure of the implications of results that exceed a WEL or in-house standard, may want to consult appropriate expert advice, e.g. an occupational hygienist or the laboratory which carried out the air monitoring.

137 If the employer concludes that the air monitoring results do not indicate adequate control of exposure, the further steps to take should include:

(a) checking control measures to ensure that they are working as they should, and for exhaust ventilation etc., that it is performing to design specification;

(b) liaising with managers, safety representatives and employees to check that all the principles of good practice are being correctly applied, and to establish possible reasons for the rise in the airborne concentration of the substance concerned;

(c) considering whether it is necessary to provide the employees who may be exposed to the substance concerned with suitable RPE. This should be a temporary measure only until the situation is returned to normal and adequate control of exposure is re-established;

(d) devising and implementing a programme of immediate action to reinforce the control measures where a WEL is exceeded and particularly so where the substance concerned is a carcinogen or mutagen; and

(e) taking further air samples to confirm the concentration of the substance in the air in order to check that any remedial action to tighten control has been effective.

138 If the further air monitoring raises doubts as to whether adequate control is being achieved, the employer should review the assessment to decide whether additional and more stringent controls are needed.

139 For detailed advice on the sampling strategies suitable for measuring exposure and practical guidance on interpreting the results in relation to occupational exposure limits see HSE's publication: *Monitoring strategies for toxic substances.*

Adequate control of exposure by routes other than inhalation

140 COSHH requires that employers prevent or adequately control exposure by all routes, not just the inhalation route and deals with substances which can be hazardous to health by:

(a) absorption through the skin or mucous membranes; or

(b) contact with the skin or mucous membranes, e.g. dermatitis; chemical burns and microbial infection; or

(c) ingestion.

141 Some information about substances, that can be absorbed into the body, is contained in HSE's publication *[*EH 40 *Occupational Exposure Limits]*. HSE's publication *[title]* (see paragraph 114) lists those substances that have been assigned a WEL and which can be absorbed through the skin and identifies them with a skin (Sk) notation. Safety data sheets and hazard warning labels are other useful sources of information about substances

that have the potential to affect and be absorbed through the skin.

142 Exposure to any substance hazardous to health that can be absorbed by any of the routes listed in paragraph 140 should be controlled to a standard where nearly all the population could be exposed repeatedly without adverse health effect. Employers will achieve adequate control when they apply the principles of good practice in Schedule 2A and exposure by these other routes does not result in adverse health effects. The following paragraphs provide some guidance on how employers can achieve adequate control of exposure by these other routes.

Absorption through the skin

143 In handling any substance which has been assigned an "Sk" notation, the employers' application of good practice controls, work methods and other precautionary measures should prevent the substance coming into contact with the employee's skin. Employers should also prepare a contingency plan to deal with incidents where a substance makes contact with an employees' skin. The plan should draw on any information and advice provided by the supplier on the particular characteristics and properties of the substance and how to deal with spillages etc.

Contact with the skin and eyes

144 Irritant and corrosive substances such as acids and alkalis can seriously damage the skin and eyes. Therefore, where employers have to use these substances, they should design their systems of work and select their control equipment to minimise the possibility of skin and eyes being exposed. If this is not possible for a particular job, employers may have to provide suitable personal protective equipment and, in these circumstances, pay special attention to how employees wear and use it and how it is maintained.

145 Some hazardous substances, e.g. solvents, remove the natural oils from the skin so that frequent or prolonged contact may cause dermatitis or more serious skin disorders. When such skin contact is likely to occur, employers should provide employees with suitable gloves and dispose of them when they become contaminated, i.e. before the solvent is likely to "break through" the glove material. HSE's publication *Health risk management. A guide to working with solvents* provides further guidance on selecting suitable glove materials for work with a

number of the most commonly used solvents. Employers should also ensure that employees follow good personal hygiene practice, such as thoroughly washing their hands in warm (not hot) water whenever necessary, encouraging them to use moisturising creams after work, and introducing a regular programme of skin inspection.

Ingestion

146 If employees do not follow a high standard of personal hygiene, or do not handle substances with care, solid materials or powder may get trapped under fingernails or transferred from overalls and clothing onto food. Where substances which are potentially hazardous by ingestion are used, employers should ensure that employees remove any contaminated clothing in the area set aside for this activity, and thoroughly wash their hands and face (see paragraph 145), and scrub their fingernails before eating, drinking or smoking. Employers should stress the importance of employees following good personal hygiene practices and of not eating food in the work area.

147 Employers should ensure that the information, instruction and training given to employees in accordance with regulation 12 covers all aspects of achieving and maintaining adequate control of exposure by all routes. In particular, employers should stress the importance of how the combination of good practice under regulation 7(7) and the protection measures the employer applies under regulation 7(3) are designed to protect employees' health from exposure to hazardous substances.

Biological monitoring

148 Biological monitoring can also make a valuable contribution to measuring levels of exposure in those situations where air sampling alone may not give a reliable indication of exposure, e.g. when personal protective equipment is used or where there is liable to be significant dermal exposure to a substance that can permeate the skin. HSE's publication *Biological monitoring in the workplace: A guide to its practical application to chemical exposure* provides further guidance.

When personal protective equipment might be necessary

149 Regulation 7(3)(c) requires the employer to provide employees with suitable personal protective equipment,

e.g. RPE, protective clothing, protective gloves, footwear; and equipment to protect the eyes, *in addition to* all other control measures if the combination of all control measures fails to achieve adequate control of exposure.

150 The situations where PPE will normally be necessary include:

(a) where adequate control of exposure cannot be achieved solely by good practice and the application of operational or engineering measures, appropriate to the activity and consistent with the risk assessment then, in addition, suitable PPE should be used to secure adequate control;

(b) where a new or revised assessment shows that PPE is necessary until adequate control is achieved by other measures;

(c) where there is temporary failure to achieve adequate control of the process, e.g. because of plant failure, and the only practicable solution to reimpose adequate control in the time available may be the provision and use of suitable PPE; and

(d) where maintenance operations have to be carried out. The risk of exposure during these operations should be assessed and appropriate control, such as prior decontamination of equipment and areas, should be identified and carried out. Although exposure may occur regularly during such work, the infrequency and small number of people involved and the difficulties of applying process and engineering controls often makes the use of PPE necessary.

151 In assessing whether the use of PPE is the appropriate option, employers should consider:

(a) the limitations of PPE;

(b) the costs;

(c) the practical difficulties of ensuring its continued correct use;

(d) its effectiveness in the actual work situation; and

(e) the type and level of exposure to the hazardous substance concerned.

Suitable personal protective equipment

152 PPE should adequately control exposure to the hazardous substances to which the wearer is exposed, or is liable to be exposed, throughout the time it is used. When selecting PPE, it is important for employers to take into account:

(a) the circumstances in which it will be used, e.g. the substances to which it will be exposed and for how long;

(b) whether it can resist penetration and permeation by the substance concerned indefinitely or for a specified or recommended period;

(c) whether the design is adequate and suitable, i.e. the equipment does not dislodge, deform, melt or otherwise fail to perform in the conditions in which it is used;

(d) the environment in which it will be worn; and

(e) in dusty environments, whether the materials selected reduce the tendency for dust to collect on the PPE and be re-released.

153 Manufacturers of PPE must ensure that their products comply with the Personal Protective Equipment Regulations 2002.

Suitable respiratory protective equipment (RPE)

154 For each work activity for which it is foreseen that employees will need to wear respiratory protective equipment (RPE), the employer should specify the suitable equipment to be worn to make sure that employees are given adequate protection. To be suitable, RPE must be capable of adequately controlling the inhalation exposure using as a guide the equipment's assigned protection factor as listed in HSE publication *The selection, use and maintenance of respiratory protective equipment: A practical guide.* The selection and provision of suitable RPE should be based on a range of considerations:

(a) the level of protection claimed by manufacturers for different types of RPE, and identification of those types that will provide a greater degree of protection than that required for likely or known exposure;

(b) the type of work to be done; the physical effort required to do it; the length of time the equipment will have to be worn; the requirements for visibility, comfort and the need for employees to communicate with each other;

(c) the different facial characteristics of the RPE wearers, to ensure that the equipment fits correctly, and is matched to the wearer. In addition the equipment must be matched to the job and the environment in which it is to be used. The selection of suitable equipment should be undertaken in full consultation with the wearers. This will help to ensure that the wearers have the most comfortable equipment best suited for them and which, as a consequence, is likely to be the most effective in use;

(d) it must be "CE" marked if it was manufactured on or after 1 July 1995 to show that it is manufactured to meet minimum legal requirements. However, where RPE was manufactured before 1 July 1995 then it must either be "CE" marked or HSE approved;

(f) employees should be properly trained in its use and supervised;

(g) it should be regularly cleaned and checked to ensure that it remains effective.

Fit testing of facepieces

155 The performance of RPE with a tight-fitting facepiece (filtering facepieces, half and full-face masks) depends on a good contact between the wearer's skin and the face seal of the mask. A good face seal can only be achieved if the wearer is clean shaven in the region of the seal and the facepiece is of the correct size and shape to fit the wearer's face. If spectacles with side arms and other PPE are also worn, they should not interfere with the correct fitting of the facepiece or the face seal. The performance of RPE with a loose fitting facepiece, e.g. visors, helmets, hoods, etc. is less dependent on a tight fit on the face, but nevertheless requires the correct size to ensure the wearer achieves an adequate fit and protection.

156 Employers should ensure that the selected facepiece (tight and loose fitting types) is of the right size and can correctly fit each wearer. For a tight-fitting facepiece (filtering facepieces usually known as

disposable masks, half and full face masks) the initial selection should include fit testing to ensure the wearer has the correct device. The test will assess the fit by determining the degree of face-seal leakage of a test agent while the RPE user is wearing the facepiece under test. For full-face masks, a suitable quantitative fit test should be used and the pass level fit factor is 2000. For devices such as filtering facepieces and half masks, the pass level fit factor is 100. For these lower performance facepieces, a suitable and validated qualitative method (often called a semi-quantitative test) can be carried out instead. Employers must ensure that whoever carries out the fit testing is competent to do so in accordance with regulations 12(4).

157 Repeat fit testing will be needed when changing to a different model of RPE or a different sized facepiece or if there have been significant changes to the facial characteristics of the individual wearer, e.g. as a result of significant weight gain or weight loss or due to dentistry. Repeat fit testing will not be required following a change of employer, provided that the same model of RPE continues to be used by the employee.

158 The quantitative fit testing may be carried out using:

(a) a test chamber which uses a salt aerosol or sulphur hexafluoride gas to assess the face-seal leakage; or

(b) a portable device at the workplace which measures particulates in air to assess the face-seal leakage; or

(c) a portable device at the workplace which measures pressure variations inside the facepiece to assess face seal-leakage.

159 Qualitative test methods use bitter or sweet-tasting aerosols. When the tests are carried out the facepiece wearer will perform simple exercises as indicated by the competent person carrying out the test. More information on the selection, including information on assigned protection factors, use and fit testing of RPE is contained in the HSE publications - *The selection, use and maintenance of respiratory protective equipment: A practical guide*, and *Fit testing of respiratory protective equipment facepieces*.

Facilities for washing, changing, eating and drinking

160 Employers should provide certain facilities to:

(a) ensure that employees meet and maintain a standard of personal hygiene that is consistent with adequate control of exposure;

(b) avoid the spread of substances hazardous to health; and

(c) reduce the risk of ingestion of substances hazardous to health.

161 The facilities include:

(a) ***adequate washing facilities*. These should be sited in a convenient position but situated so that they do not themselves become contaminated. The facilities provided should relate to the type and level of exposure;**

(b) **c*hanging facilities. These* should be provided when PPE is used or where outdoor clothing could be contaminated by substances hazardous to health. They should be located and designed to prevent the spread of contamination from protective clothing to personal clothing and from one facility to another;**

(c) ***facilities for eating, drinking etc*. Employees should not eat, chew, drink or smoke in places that are contaminated by substances hazardous to health. This will help reduce the risk of employees ingesting hazardous substances. If employers have to prohibit eating, drinking etc. in certain areas, they should set aside an uncontaminated area or areas where these activities can be carried out. The eating and/or smoking area should be conveniently accessible to the working area and to washing facilities.**

162 Employers should ensure that not only are the hygiene measures provided but also that employees are made aware, through information, instruction and training of why, how and when they must be used. Employers should also ensure through appropriate supervision, that employees use the facilities in accordance with agreed procedures.

163 Employers may also have duties under the Workplace (Health, Safety and Welfare) Regulations 1992 to provide the facilities described above.

PROPOSED REVISED ACOP TEXT SUPPORTING REGULATION 10

Another method of evaluation

201 In many workplace situations, employers are likely to have to rely on a body of evidence rather than a single measure in making a judgement that adequate control of exposure is being achieved. For that evidence, employers will need to include measures drawn from the list in the ACoP on regulation 7 (paragraph 103). In particular:

(a) ensuring all routes of exposure, including skin contact and ingestion, have been considered in the regulation 6 assessment;

(b) using totally enclosed processing and handling systems which are demonstrably working efficiently without leaking a hazardous substance into the work area;

(b) ensuring engineering controls and ventilation systems, including LEV, are demonstrably working to specification;

(d) ensuring the work system is well-defined, predictable, properly supervised and consistent at all times with the assessment.

202 By demonstrating the effective implementation of these and other pertinent measures such as good practice and, where appropriate, *COSHH Essentials*, an employer can show sufficient evidence that he does not require specific exposure monitoring to demonstrate adequate control of exposure.

PROPOSED REVISED TEXT FOR APPENDIX 3 – CONTROL OF SUBSTANCES THAT CAUSE OCCUPATIONAL ASTHMA

Prevention or control of exposure to substances hazardous to health (regulation 7)

12 Exposure to substances with the potential to cause occupational asthma should be prevented. If that is not reasonably practicable, the objective should be to control exposure so as to prevent employees and others who may be exposed from developing occupational asthma as a result of exposure to those substances. Limited scientific knowledge on levels below which substances will not cause asthma means that it will normally be necessary to reduce exposure so far as is reasonably practicable. This will involve considering the potential for short-term peaks of exposure as well as longer-term time-weighted averages.

ANNEX 3: Proposed criteria for setting the WEL

Introduction

1. The ACTS Working Group agreed on seven key objectives for OELs, the first of which was that *"compliance with OELs should control risks to health"*. With this in mind, the proposed criteria for setting the WEL aim to protect occupational health, taking into account the known and/or predicted toxic effects of the substance, and on what standards of control are reasonably practicable in the circumstances. The requirement for reasonable practicability cannot be overlooked because it relates to another of the Working Group's key objectives i.e. *OELs should be legally enforceable*. Another key objective is that "*OELs should be comprehensive*", which means that the criteria need to be sufficiently flexible to accommodate an almost infinite variety of toxicological and occupational exposure profiles. Although the criteria need to be flexible, this should not detract from the need for clarity. Limit-setters need clear criteria to:

- ensure consistency of decision making;
- aid transparency of the process; and
- provide defensibility if challenged.

2. The requirements for health protection and reasonable practicability mean that OEL-setting must be based on an assessment of the toxicology and information on occupational exposure. These elements provide an understanding of:

- the likely human health hazards;
- risks from occupational exposure; and
- what levels of control can be achieved in practice.

3. Limits are set by the HSC, following public consultation on proposals from ACTS and its scientific subcommittee.

Approach to deriving the Workplace Exposure Limit

4. The first stage in the derivation of the WEL involves an assessment of the toxicology of the substance concerned. The purpose of this assessment is to identify the potential for a substance to produce adverse human health effects and to understand the exposure-response relationships for these effects. In the context of OEL-setting, there are certain key reference points on the exposure-response curve. These are the "No-Observed Adverse Effect Level" (NOAEL*) and the "Lowest-Observed Adverse Effect Level" (LOAEL*). The concept of NOAELs/LOAELs is generally agreed to have practical relevance in the OEL-setting context only for those substances or toxicological mechanisms that have a "threshold" of effect. For example, eye irritation caused by an acid vapour will only occur above a certain threshold exposure concentration, and thus the concept of a NOAEL will apply. In

* The NOAEL is the highest point on the exposure-response curve at which no adverse health effects are observed; the LOAEL is the lowest point on the exposure-response curve at which adverse health effects are observed.

contrast, for substances such as DNA-reactive chemicals that cause cancer by a genotoxic mechanism, although in theory a threshold may exist, (because of biochemical defence and repair mechanisms) currently available techniques do not allow the reliable identification of a clear threshold or NOAEL.

5. If a NOAEL (or LOAEL) can be identified, then this value is taken as a starting point for estimating the highest level of occupational exposure at which no adverse health effects would be expected to occur in workers or their progeny following exposure over a working lifetime. Given that in many cases, NOAELs/LOAELs are obtained from studies in animals, numerical "uncertainty factors" (sometimes referred to as "safety factors") are usually applied in order to arrive at this estimated desired level of exposure. These factors are applied to take account of toxicological uncertainties such as possible species differences in response, and also to take account of human variability in responsiveness. No formal documented rules concerning the application and magnitude of toxicological uncertainty factors have been used in setting OESs under the current system. Decisions have been based on precedent and expert judgement on a case-by-case basis.

6. An across-government initiative is examining the ways in which different government departments and agencies deal with toxicological uncertainty in risk assessment and standard-setting procedures[1]. When this work has reported, ACTS and its scientific subcommittee may develop a more formalised approach on the use of uncertainty factors for setting WELs.

7. Having determined the highest level of occupational exposure at which no adverse health effects would be predicted to occur, the next stage is to determine whether this level of exposure is currently being achieved in the workplace. If not, then consideration would be given to the potential for improving existing standards of control such that this level of exposure could be reasonably achieved. If ACTS consider this level of exposure is reasonably practicable, then the WEL will be proposed at this level.

8. In summary, this route to deriving the WEL will result in a limit set at a level at which no adverse health effects would be expected to occur in workers or their progeny, based on the known and/or predicted effects of the substance, and would also be reasonably practicable for industry to achieve.

9. There are some categories of substance to which this route to deriving an OEL, based on the concept of a NOAEL/LOAEL will not be possible:

(a) Genotoxic carcinogens: for such substances, there are no currently available techniques by which it is generally accepted that a NOAEL can be reliably identified; hence an approach based on a NOAEL cannot be applied.

(b) Substances causing asthma: although the concept of a NOAEL may be valid, the quality of the available data means that it is generally not possible to identify a

[1] The Interdepartmental Group on Health Risks from Chemicals: First report and forward plan to 2002. Institute for Environment and Health. University of Leicester. ISBN 1899110 34 8

threshold level of occupational exposure below which there would be no risk of developing the disease.

(c) Mixtures of variable composition such as metal working fluids (MWFs): the variable compositions mean that MWFs pose a variable hazard, and a defined position on the likely human health effects and the identification of single NOAEL value is not possible.

(d) Any other substance for which the balance of doubt and uncertainty about likely human health effects is such that a NOAEL or threshold for effect cannot be confidently identified or predicted. This is more likely to apply to substances with inadequate toxicity datasets. What is meant by an "adequate data-set", particularly in the context of OEL-setting, is difficult to define, as it varies according to the nature of the substance, and other factors such as the ability to "read-across" to data-sets on similar substances. This issue will not be discussed further in this annex, other than to note that expert judgement on a case-by case basis will be needed to determine whether a particular data-set is adequate to predict health effects confidently.

(e) For some substances, a NOAEL/LOAEL may be identifiable from which it is possible to estimate a level of exposure at which no adverse human health effects would be predicted to occur. However, after due consideration of the costs and efficacy of available control solutions, ACTS may consider that it would not be reasonably practical to control below this desired level of exposure across all industry sectors.

10. For substances belonging in one of the above categories (a)-(e), the WEL would be derived by identifying a level of exposure which would represent a standard of control commensurate with good occupational hygiene practice. In determining this level, the severity of the likely health effects, and the cost and efficacy of control solutions would have to be taken into account. Agreement on what represents a good standard of control will be for ACTS and its scientific subcommittee, informed by:

- knowledge of the standards of control currently being achieved in different industry sectors using the substance;
- the potential for improving standards; and
- the potential health impact of the substance.

For example, a good standard of control for a non-reactive dust such as titanium dioxide would not be considered adequate for a cytotoxic dust such as cyclophosphamide. For substances that have had little or no safety testing, for which the potential health hazards were highly uncertain, good practice would dictate the need for an increased stringency of control as a precautionary measure. The process of deriving the value of the WEL would be an iterative one, involving comparisons of the costs of achieving successively lower proposed WEL values against the estimated health benefits until agreement on an appropriate value is reached. The arguments and rationale for each substance would be set out in Regulatory Impact Assessment documents. In relation to this proposed route to OEL-setting, as far as possible, the WEL would not be set at a level at which there is positive evidence of adverse effects on human health.

11. A diagrammatic summary of the proposed OEL-setting process is presented as Figure 1 (page 54).

Criteria for setting Workplace Exposure Limits

12. Applying the logic set out in the preceding paragraphs, the proposal is that WELs are derived by the following criteria:

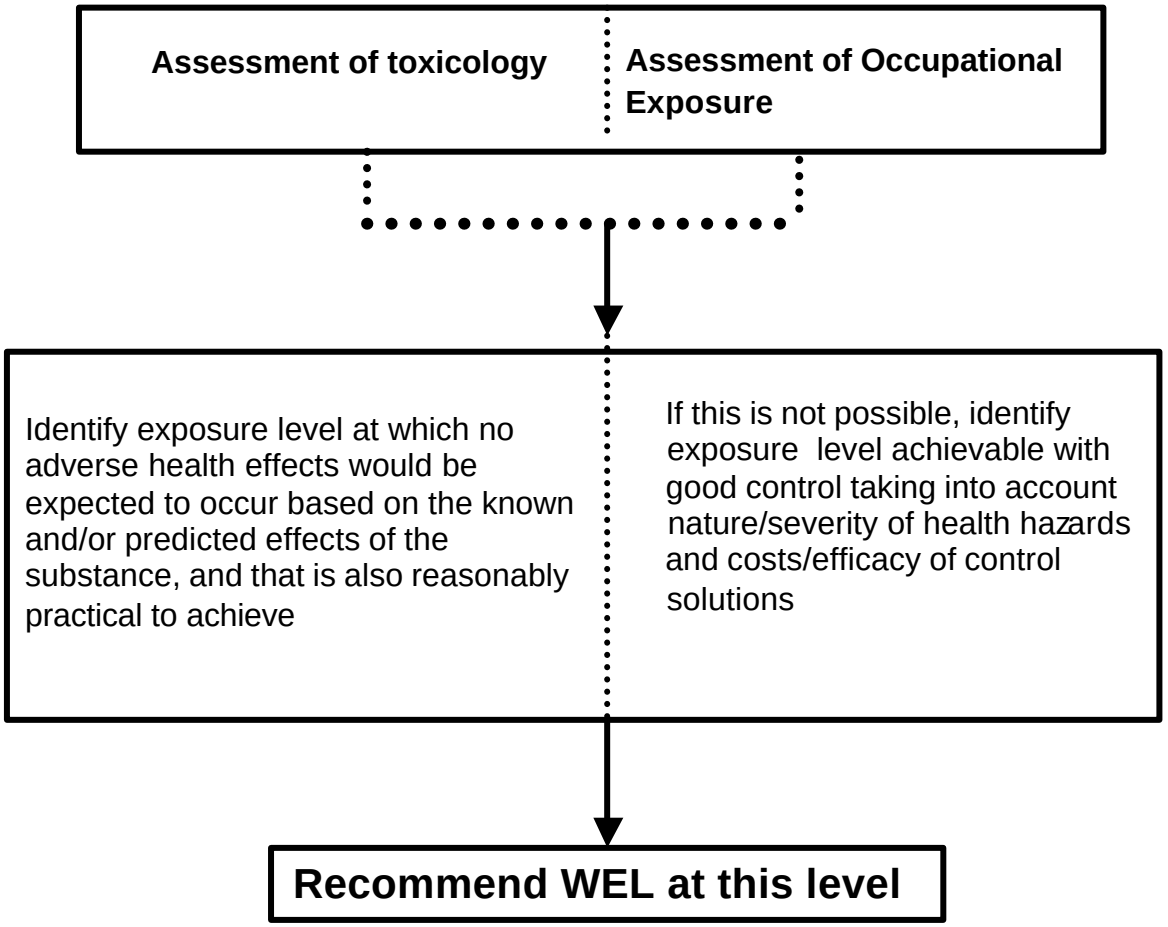
i) The WEL value would be set at a level at which no adverse effects on human health would be expected to occur based on the known and/or predicted effects of the substance. However, if such a level cannot be identified with reasonable confidence (categories (a)-(d)), or if this level is not reasonably achievable (category e) then,

ii) The WEL value would be based at a level corresponding to what is considered to represent good control, taking into account the severity of the likely health hazards and the costs and efficacy of control solutions. Wherever possible, the WEL would not be set at a level at which there is evidence of adverse effects on human health.

13. These criteria show strong similarities to the existing criteria for setting OESs and MELs. However, categories (c) and (d) are not hazard dependent, i.e. the hazard could be high or low or unknown. This is a key departure from the current MEL criteria, and will result in increased flexibility to the proposed system. Under the new limit system, the limit value could match either of the above sets of criteria, but the "user" will merely see one type of limit for all substances, and will have to comply in the same way, thus addressing the confusion caused by the OES/MEL system.

14. The fact that the WEL will not necessarily represent complete health protection is consistent with the advice in the SCOEL key document on *Methodology for the Derivation of Occupational Exposure Limits*, which states that "*It should however be emphasised, that it is always prudent to reduce exposure as far below OELs as can be reasonably achieved, in order to provide the greatest degree of health protection. This is particularly true for OELs which are not 'health-based' ".*

Figure 1. Summary of Proposed WEL-setting process



ANNEX 4: Enforcement of the new OEL framework

HSC's Enforcement Policy Statement

1. The ultimate purpose of enforcing authorities is to ensure that dutyholders manage and control risks effectively, thus preventing harm. The HSC's Enforcement Policy Statement [(1)] sets out the principles inspectors should apply when determining what enforcement action to take in response to breaches of health and safety legislation.

2. The stated purpose of enforcement is to: -

- ensure dutyholders take action immediately to deal with serious risks to health and/or safety;
- promote and secure compliance with the law;
- ensure dutyholders who breach health and safety requirements are held to account where appropriate, including punitive action where appropriate.

Fundamental to this is the principle that all enforcement action should be proportional to the health and safety risks and the seriousness of the breach.

HSE's Enforcement Management Model

3. The Enforcement Management Model (EMM) is a robust framework which helps inspectors make enforcement decisions in line with the HSC Enforcement Policy Statement mentioned above. This model aims to promote:

- enforcement consistency;
- proportionality and targeting by confirming the risk based criteria against which decisions are made;
- transparency and accountability in the decision-making process.

4. Briefly, the EMM works by comparing the actual risk associated with a particular set of circumstances with a relevant benchmark to ascertain the risk gap, i.e. the level of residual risk once the actions required by law and standards are met. In the area of health risks the principles of good practice for the control of substances hazardous to health and any occupational exposure limits are critical in determining the relevant benchmark.

5. This process leads to an initial enforcement expectation that is based solely on the risks and the seriousness of the breach. Specific dutyholder and strategic factors are then built into the model to take account of relevant socio-economic factors. An enforcement conclusion is then reached which in certain circumstances will be documented and reviewed.

[(1)] The HSC Enforcement Policy Statement can be found on the web site (http://www.hse.gov.uk/pubns/hsc15.pdf). There is also a hard copy leaflet HSC 15.

Principles of good practice for the control of substances hazardous to health

6. The nature of health risks and the hierarchical approach of the COSHH Regulations can make it difficult to derive consistent benchmarks. The new OEL framework with the primary emphasis on principles of good practice for the control of substances hazardous to health backed up by WELs for some substances should help provide transparent and proportionate benchmarks for enforcement action. Planned process/substance specific guidance sheets elaborating on the general principles will further aid this. If the guidance is followed and control measures are developed and properly applied, in most cases, the WEL should not be exceeded. If the principles of good practice for the control of substances hazardous to health are not being followed then the risk gap may be substantial and some form of enforcement action will be expected using the EMM.

7. The increased emphasis on these principles of good practice for the control of substances hazardous to health reinforces the message that a judgement on the potential extent of exposure should take into account a variety of elements including: - the condition of any control measures provided; the maintenance of any control measures provided; the provision of adequate instruction, training and supervision and the consequences of limited health surveillance. The judgement is not necessarily dependent on measured exposure against limits.

Workplace Exposure Limits

8. Nevertheless a soundly based numerical limit, which indicates the minimum standard of performance, is a useful tool in managing health risks. An indication of how far limits are exceeded will inform as to the seriousness of the breach and the extent of the actual risk. WELs will be useful in determining benchmarks for certain substances. If WELs are exceeded the risk gap may be substantial by definition and some form of enforcement action will be expected using the EMM.

9. It is important to note that those substances which are carcinogens are flagged up and treated differently in the proposed regulation 7(7)(c) and Appendix 3 of the ACoP. Dutyholders have to go further than not exceeding the relevant WEL. There is a duty to reduce exposure to these substances as far as is reasonably practicable.

Summary

10. If dutyholders are applying the principles of good practice for the control of substances hazardous to health, then they should not exceed any relevant WEL and be achieving adequate control. Where the principles have not been applied adequately or where the WEL has been exceeded, the EMM will direct inspectors to the appropriate, proportionate enforcement action taking account of the local factors.

ANNEX 5: Example of *COSHH Essentials* guidance sheets

See www.coshh-essentials.org.uk/assets/G217.pdf

ANNEX 6: Linking OELs to *eCOSHH Essentials*

1. The proposed new approach to adequate control is to:

   i) apply the principles of good practice for the control of substances hazardous to health; and
   ii) not exceed any relevant WEL.

This makes it imperative for HSE to provide a clear linkage between WELs and sources of good practice advice. *COSHH Essentials* was originally developed as a source of generic good practice advice for substances that did not have an OEL. It is not a comprehensive system, in that for example, it does not apply to gases and process generated dusts and fume. However, it is a useful source of good practice advice for many substances with an OEL, particularly for small to medium-sized companies lacking an in-house source of professional expertise on good occupational hygiene practice. Therefore, it is proposed that where appropriate in the new OEL framework, the WEL will be linked to control advice from the *COSHH Essentials* system. This annex sets out the rationale for the proposed linkage between the *COSHH Essentials* system and WELs.

2. During the development of *COSHH Essentials*, substances with well-validated health-based exposure limit values (OESs) were used to help develop and validate the allocation of R-phrases to one of four hazard groups (A-D), each with an assigned target airborne concentration range. The ranges were considered to represent "acceptable" workplace exposures for substances with R-phrases in these groups.

3. Substances that cannot be assigned health-based limits were allocated to hazard group E. These are predominantly genotoxic carcinogens and substances that cause occupational asthma (i.e. those labelled as such). The resultant allocation of risk phrases to hazard bands is set out in the table below, reproduced from *The Technical Basis for COSHH Essentials: easy steps to control chemicals.*

Table 1: Target airborne concentration ranges for the hazard groups used in COSHH Essentials

Hazard Group	R phrases	Target airborne concentration range	
		Dust mg/m^3	vapour ppm
A	R36, R38 all substances which do not have R phrases in groups B-E	>1 – 10	>50 - 500
B	R 20/21/22; R40/20/21/22	>0.1 – 1	>5 – 50
C	R48/20/21/22; R23/24/25; R34, R35, R36/37, R37/38, R36/37/38, R37, R39/23/24/25, R41, R43	>0.01 - 0.1	>0.5 – 5
D	R48/23/24/25,R26/27/28, R39/26/27/28, Carc Cat 3 R40, R60, R61, R62, R63	> 0.001 – 0.01	> 0.05 – 0.5
E	Muta Cat 3 R40, R42, R42/43, R45, R46, R49	Genotoxic carcinogens and substances which cause asthma	

4. Once a substance has been assigned to a hazard group on the basis of the risk phrases allocated to it, the *COSHH Essentials* system directs the user to controls which are predicted to keep exposures below the minimum of the target exposure range, based on the amount used and the dustiness or volatility of the product (Table 2). The rationale for this is explained in *The Technical Basis for COSHH Essentials: easy steps to control chemicals.*

Table 2 Control approaches

Amount used	**Low dustiness Low volatility**	**Medium volatility**	**Medium dustiness**	**High dustiness High volatility**
Hazard Group A				
Small	**1**	**1**	**1**	**1**
Medium	**1**	**1**	**1**	**2**
Large	**1**	**1**	**2**	**2**
Hazard Group B				
Small	**1**	**1**	**1**	**1**
Medium	**1**	**2**	**2**	**2**
Large	**1**	**2**	**3**	**3**
Hazard Group C				
Small	**1**	**2**	**1**	**2**
Medium	**2**	**3**	**3**	**3**
Large	**2**	**4**	**4**	**4**
Hazard Group D				
Small	**2**	**3**	**2**	**3**
Medium	**3**	**4**	**4**	**4**
Large	**3**	**4**	**4**	**4**
Hazard Group E				
For all hazard group E substances choose control approach 4				

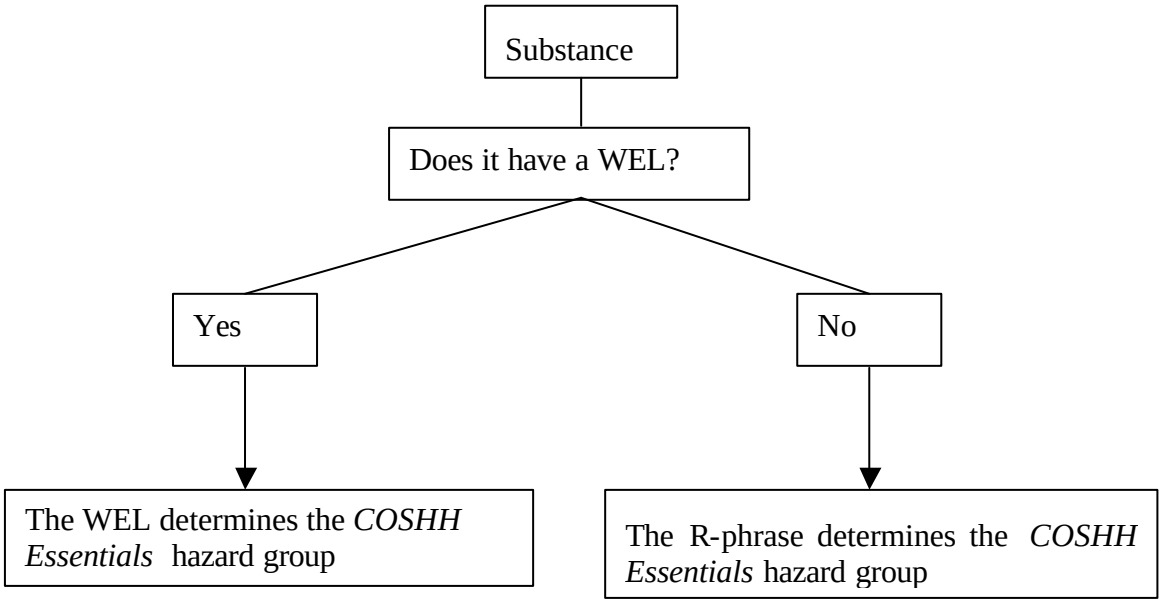
The number in the box represents the control approach:

1 = General ventilation 2 = Engineering control
3 = Containment 4 = Seek expert advice

5. If we are to link a generic system based on R-phrases with WELs, we need to consider the relationship between the two. R-phrases indicate the health hazards of a substance, either based on the dose required to produce a particular health effect (e.g. acute toxicity) or the ability of the substance to cause a health effect based on the strength of evidence, irrespective of dose (e.g. reproductive toxicity). Thus there will be a range of potencies associated with many of the R-phrases. The target airborne concentration range was designed to cater for more potent substances within the spread for that R-phrase. Consequently, it may be over-precautionary for the less potent substances.

6. In contrast WELs are risk management tools set by a specialist expert committee after rigorous examination of the data available on a substance. They are set either at levels at which no adverse health effects would be expected to occur in workers or their progeny or at levels which represent a good standard of control taking account of the health hazard of the substance. Since well-validated WELs are based on substance specific data, they provide a more appropriate means of assigning a substances to a *COSHH Essentials* hazard group than the generic approach using R-phrases.

7. Thus the proposal is that for substances with a WEL and risk phrases that would result in them being assigned to hazard groups A-D, the WEL will be used to determine the hazard group for use in the *COSHH Essentials* risk assessment, rather than the risk phrases. In other words, the WEL takes priority over any R-phrases that may be given for a substance, as it will lead to the most appropriate hazard group. For substances without a WEL, then *COSHH Essentials* can still be used on the basis of the R-phrases.



8. Substances with a WEL and risk phrase that would result in them being assigned to hazard group E will be considered on an individual basis. In the development of *COSHH Essentials*, expert judgment was used to determine the exposures expected from the application of control approaches 1-3 with various combinations of quantity and dustiness for solids or volatility for liquids. The rationale for this is explained in *The Technical Basis for COSHH Essentials: easy steps to control chemicals*. These ranges of exposure will be used to determine whether there is a *COSHH Essentials* control approach consistent with current good practice. If there is a good match, then that match will be the default position. If current good practice involves a different degree of control then a substance-specific good practice advice sheet will be drafted and integrated into the system.

9. WELs may be set for 8-hour Time Weighted Averages (TWAs) and for 15-minute reference periods (Short Term Exposure Limits or STELs). The *COSHH Essentials* control approach will lead to advice which is task specific; consequently it will control exposure below any short term limit as well as the 8-hour time weighted average.

ANNEX 7: Integration of existing OELS into the new framework

Introduction

ACTS endorsed an analysis by HSE of the MELs and OESs published in Tables 1 and 2, respectively, of *EH40 Occupational Exposure Limits*, which assessed the quality and quantity of data on which the limits are based and the extent of industrial usage. This analysis was used as a basis for proposals on which limits should be transferred to the new system as WELs. The aim is to establish a robust list of limits supported by documentation setting out the basis for the limit.

This Annex divides the current lists of OESs and MELs into 3 tables. Table 1 list the OESs that ACTS propose should be transferred in to the new system as WELs. Table 2 lists all the MELs currently approved by HSC and the two MEL proposals currently under consultation, subtilisins and Refractory Ceramic Fibres (RCFs). The proposal is to transfer these into the new system as WELs. Table 3 lists the OESs that ACTS propose should not be transferred to the new system. The following paragraphs give the rationale for the proposals and set out the advice HSE propose to make available for substances ACTS propose should no longer have an OEL assigned by HSC. Consultees' views are sought on the rationale for the 3 tables, and their subdivisions, the allocation of individual substances to the tables and for tables 1 and 2 the WEL values.

Table 1 – OESs proposed for transfer into the new system as WELs

This table contains the OESs set after a thorough review of the available data, in practice all those introduced, or revised, since the COSHH Regulations came into force in 1989. The proposal is to transfer these into the new system as WELs. The numerical value(s) and notation(s) for each substance will be the same as the existing OES values and notations in EH 40.

Notations

Carc	Substances that may cause cancer
	Substances that may cause heritable genetic damage
	Substances that may cause cancer by inhalation
Sen	Substances capable of causing occupational asthma
Sk	Substances that can be absorbed through skin

Substance	Origin of OES	Long-term exposure limit (8-hour TWA reference period)		Short-term exposure limit (15-minute reference period)		Notation
		ppm	mg.m^{-3}	ppm	mg.m^{-3}	
(2-methoxymethylethoxy) propanol	WATCH/19/98	50	308	-	-	Sk
1,1,1,2-Tetrafluoroethane	WATCH/22/94	1000	4240	-	-	
1,1-Dichloroethane	1st IOELV Directive	100	-	-	-	Sk
1,1,1-Trichloroethane	WATCH/31/92	100	555	200	1110	
1,2,4-Trichlorobenzene	WATCH/21/98	1	-	5	-	Sk
1,2-Dichlorobenzene	1st IOELV Directive	25	153	50	306	Sk
1,4-Dichlorobenzene	1st IOELV Directive	25	153	50	306	
1,6-Hexanolactam (caprolactam) Dust only	1st IOELV Directive.	-	1	-	3	
Dust and vapour		-	10	-	20	
1-Methoxypropan-2-ol	1st IOELV Directive	100	375	150	560	Sk
1-Methoxypropylacetate	1st IOELV Directive	50	274	100	548	Sk
1-Methyl-2-pyrrolidone	WATCH/18/97	25	103	75	309	Sk
2-Butoxyethanol	1st IOELV Directive	25	-	50	-	Sk
2-Butoxyethyl acetate	1st IOELV Directive	20	-	50	-	Sk
2-Phenylpropene	1st IOELV Directive	50	246	100	491	
4-Methylpentan-2-one	1st IOELV Directive	50	208	100	416	Sk
5-Methylheptan-3-one	1st IOELV Directive	10	-	20	-	
5-Methylhexan-2-one	1st IOELV Directive	20	95	100	475	Sk
Acetaldehyde	WATCH/32/96	20	37	50	92	
Acetic anhydride	WATCH/27/98	0.5	2.5	2	10	
Acetone	1st IOELV Directive	500	1210	1500	3620	
Allyl alcohol	1st IOELV Directive	2	4.8	4	9.7	Sk

Substance	Origin of OES	Long-term exposure limit (8-hour TWA reference period)		Short-term exposure limit (15-minute reference period)		Notation
		ppm	mg.m^{-3}	ppm	mg.m^{-3}	
Aluminium metal total inhalable dust	WATCH papers 14/90 and 3/91covered aluminium metal and oxides.	-	10	-	-	
respirable dust		-	4	-	-	
Aluminium oxides total inhalable dust	WATCH papers 14/90 and 3/91covered aluminium metal and oxides.	-	10	-	-	
respirable dust		-	4	-	-	
Ammonia, anhydrous	1st IOELV Directive	25	18	35	25	
Barium sulphate respirable dust	WATCH/3/97	-	4	-	-	
total inhalable dust		-	10	-	-	
Butan-2-one (methyl ethyl ketone)	1st IOELV Directive	200	600	300	899	Sk
Carbon monoxide	WATCH/14/97	30	35	200	232	
Carbon tetrachloride	WATCH/11/91	2	13	-	-	Sk
Chlorine dioxide	WATCH/25/98	0.1	0.28	0.3	0.84	
Chlorodifluoromethane	1st IOELV Directive	1000	3590	-	-	
Chloroform	1st IOELV Directive	2	9.9	-	-	Sk
Cumene	1st IOELV Directive	25	125	50	250	Sk

Substance	Origin of OES	Long-term exposure limit (8-hour TWA reference period)		Short-term exposure limit (15-minute reference period)		Notation
		ppm	mg.m^{-3}	ppm	mg.m^{-3}	
Cyclohexane	WATCH/19/90 Included in the 2nd draft IOELV Directive with 8-hr TWA of 200 ppm. Current OESs are 100 ppm and 300 ppm (8-hr TWA and STEL). Propose to retain current OESs as WELs.	100	350	300	1050	
Cyclohexanone	1st IOELV Directive	10	-	20	-	Sk
Diethyl ether	1st IOELV Directive	100	310	200	620	
Dimethyl ether	1st IOELV Directive	400	766	500	958	
Dimethylamine	1st IOELV Directive	2	3.8	6	11	
Dimethylaminoethanol	WATCH/14/96	2	7.4	6	22	
Diphosphorus pentasulphide	WATCH/10/93 and 17/92 Included in draft 2nd IOELV Directive) with similar values to current OESs.	-	1	-	3	
Diphosporus pentoxide		-	-	-	2	
Enflurane	WATCH/17/94	50	383	-	-	
Ethane-1,2-diol	1st IOELV Directive					
particulate		-	10	-	-	Sk
vapour		-	52	-	104	Sk
Ethyl acetate	WATCH/6/98	200	-	400	-	
Ethyl cyanoacrylate	WATCH/3/99	-	-	0.3	1.5	
Ethylamine	1st IOELV Directive	2	3.8	6	11	

Substance	Origin of OES	Long-term exposure limit (8-hour TWA reference period)		Short-term exposure limit (15-minute reference period)		Notation
		ppm	mg.m^{-3}	ppm	mg.m^{-3}	
Ethylbenzene	1st IOELV Directive	100	441	125	552	Sk
Fluoride (inorganic as F)	1st IOELV Directive	-	2.5	-	-	
Fluorine	1st IOELV Directive	1	-	1	-	
Halothane	WATCH/17/94	10	82	-	-	
Heptan-2-one	1st IOELV Directive	50	237	100	475	Sk
Heptan-3-one	1st IOELV Directive	35	166	100	475	Sk
n-Hexane	In proposed 2nd IOELV Directive with same value as existing OES.	20	72	-	-	
Hexan-2-one	WATCH/28/92	5	21	-	-	Sk
Hydrogen bromide	1st IOELV Directive	-	-	3	10	
Hydrogen chloride (gas and aerosol mists)	1st IOELV Directive	1	2	5	8	
Hydrogen fluoride (as F)	1st IOELV Directive	1.8	1.5	3	2.5	
Hydrogen sulphide	WATCH/14/2000, 15/01	5	7	10	14	
Isoflurane	WATCH/17/94	50	383	-	-	
Kaolin, respirable dust	WATCH/23/95	-	2	-	-	
Magnesium oxide (as Mg) total inhalable dust	Reviewed by WATCH in 1989.	-	10	-	-	
fume and respirable dust		-	4	-	10	
Methyl cyanoacrylate	WATCH/28/94	-	-	0.3	1.4	
Methyl methacrylate	Reviewed by WATCH 1994.	50	208	100	416	
Methyl-*tert*-butyl ether	WATCH/33/96.	25	92	75	275	
NN-Dimethylacetamide	1st IOELV Directive	10	36	20	72	Sk
n-Butyl acrylate	1st IOELV Directive	1	5	5	26	

Substance	Origin of OES	Long-term exposure limit (8-hour TWA reference period)		Short-term exposure limit (15-minute reference period)		Notation
		ppm	mg.m^{-3}	ppm	mg.m^{-3}	
n-Heptane	1st IOELV Directive	500	-	-	-	
Nitrous oxide	WATCH/17/94	100	183	-	-	
Orthophosphoric acid	I st IOELV Directive	-	1	-	2	
Ozone	WATCH/13/95	-	-	0.2	0.4	
Paracetamol, total inhalable dust	WATCH/31/93	-	10	-	-	
p-Aramid respirable fibres	WATCH/35/94	0.5 fibres/ml, 8-hour TWA		-	-	
Pentyl acetates (all isomers)	1st IOELV Directive: WATCH/13/96.	50	270	100	541	
Phosgene	1st IOELV Directive; WATCH/04/94.	0.02	0.08	0.06	0.25	
Phosphorus pentachloride	WATCH/15/92. Included in draft 2nd IOELV Directive with proposed 8-hr TWA of 1 mg.m^{-3}. Current OES is the same.	0.1	0.87	-	-	
Phosphorus trichloride	WATCH/18/92	0.2	1.1	0.5	2.9	
Phosphoryl trichloride	WATCH/14/92	0.2	1.3	0.6	3.8	
Portland cement total inhalable dust	WATCH/05/91.	-	10	-	-	
respirable dust		-	4	-	-	
p-Phenylenediamine	WATCH/04/2001	-	0.1	-	-	Sk
Propane-1,2-diol Total (vapour and particulates)	WATCH/07/89	150	474	-	-	
particulates		-	10	-	-	
Propionic acid	1st IOELV Directive	10	31	15	46	

Substance	Origin of OES	Long-term exposure limit (8-hour TWA reference period)		Short-term exposure limit (15-minute reference period)		Notation
		ppm	mg.m^{-3}	ppm	mg.m^{-3}	
Propranolol	WATCH/15/94	-	2	-	6	
Pulverised fuel ash	WATCH/28/91					
total inhalable dust		-	10	-	-	
respirable dust		-	4	-	-	
Silver, metallic	1st IOELV Directive. WATCH/34/96	-	0.1	-	-	
Sodium azide (as NaN_3)	1st IOELV Directive	-	0.1	-	0.3	Sk
Sulfotep (ISO)	1st IOELV Directive	-	0.1	-	-	Sk
Talc, respirable dust	WATCH/2/ 95	-	1	-	-	
Tetrachloroethylene	WATCH/4/ 96, STEL reduced to present value.	50	345	100	689	
Tetrahydrofuran	1st IOELV Directive. WATCH/10/94	50	150	100	300	Sk
Toluene	WATCH Review 1989. Included in draft 2nd IOELV Directive with values of 50 and 100 ppm (8-hr TWA and STEL). Current OESs are 50 and 150 ppm.	50	191	150	574	Sk
Triethylamine	1st IOELV Directive	2	8	4	17	Sk
Trimethylbenzenes, all isomers or mixtures	1st IOELV Directive	25	125	-	-	
Xylene, *o-,m-,-p-* or mixed isomers	WATCH/20/2000	50	220	100	441	Sk

Table 2a - MELs proposed for transfer into the new system as WELs

The proposal is to transfer all the existing MELs, (and the MELs for subtilisins and RCFs, subject to approval by HSC following consultation), into the new system as WELs. The numerical value(s) and notation(s) for each substance will be the same as the existing MEL values and notations in EH 40.

Substances listed in Table 2a have been introduced since the COSHH Regulations came into force and are considered by ACTS to be well founded. This list includes flour dust, this will be marked with an asterisk "ACTS agreed a review would start in March 2004 – this may lead to proposals for a lower value". Table 2b lists MELs that have been unchanged since before the COSHH Regulations were implemented in 1989 and a few for which new hazard data has become available. It is likely that for many of these substances, improvements in control technology mean that it is now reasonably practicable to control to a lower value. These limits will be reviewed. Pending a decision on a new value the existing MEL value will be implemented as a WEL, but marked with an asterisk "under review".

ACTS consider that transferring MELs into the new system as WELs will not result in any overall reductions in standards of control, although the WEL does not contain a duty to reduce exposure as low as reasonably practicable. Maintenance of standards will be achieved by the proposal to broaden the scope of adequate control so that it covers skin exposure and ingestion and by application of the first principle of good practice – control exposure measures that are proportionate to the health risk. Thus the proposed ACoP advises; "if the risks to employees' health are serious or uncertain, stringent control of exposure by all routes will be required."

In addition, 31 of the proposed WELs are covered by the proposed Regulation 7(7)(c) which contains an explicit requirement that exposure to substances assigned the risk phrases R45, R46 or R49 must be reduced as low as is reasonably practicable. For the 13 substances covered by Appendix 3 to the ACoP *Control of Substances that Cause Occupational Asthma* it is proposed to insert in the COSHH ACoP Appendix 3 paragraph 12, a statement to the effect that "Limited scientific knowledge on levels below which substances will not cause asthma means that it will normally be necessary to reduce exposure as low as is reasonably practicable".

Substance	Long-term exposure limit (8-hour TWA reference period)		Short-term exposure limit (15-minute reference period)		Notation
	ppm	$mg.m^{-3}$	ppm	$pg.m^{-3}$	
1,2-Dibromoethane (Ethylene dibromide)	0.5	3.9	-	-	Carc, Sk
1,2-Dichloroethane (Ethylene dichloride)	5	21	-	-	Carc, Sk
1-Chloro-2, 3-epoxypropane (Epichlorohydrin)	0.5	1.9	1.5	5.8	Carc

2,2'-Dichloro-4, 4'-methylene dianiline (MbOCA)	-	0.005	-	-	Carc, Sk
2-Ethoxyethyl acetate	10	55	-	-	Sk
2-Furaldehyde (furfural)	2	8	5	20	Sk
2-Methoxyethanol	5	16	-	-	Sk
2-Methoxyethyl acetate	5	25	-	-	Sk
4,4'-Methylenedianiline	0.01	0.08	-	-	Carc, Sk
2-Nitropropane	5	19	-	-	Carc
Acrylamide	-	0.3	-	-	Carc, Sk
Aniline	1	4	-	-	Sk
Antimony and compounds except stibine (as Sb)	-	0.5	-	-	
Azodicarbonamide	-	1.0	-	3.0	Sen
Benzene (Carcinogens Directive)	1	-	-	-	Carc, Sk
Benzyl chloride	0.5	2.6	1.5	7.9	Carc
Beryllium and beryllium compounds (as Be)	-	0.002	-	-	Carc
Bis(chloromethyl ether)	0.001	0.005	-	-	Carc
Cadmium & cadmium compounds except cadmium oxide fume, cadmium sulphide & cadmium sulphide pigments	-	0.025	-	-	Carc* *cadmiuim chloride, fluroide and sulphate
Cadmium oxide fume (as Cd)	-	0.025	-	0.05	Carc
Cadmium sulphide and cadmium sulphide pigments (respirable dust (as Cd)	-	0.03	-	-	
Chlorobenzene (IOELV)	1	-	3	-	Sk
Chlorethane (IOELV)	50	-	-	-	
Chromium (VI) compounds (as Cr)	-	0.05	-	-	Carc
Cobalt and cobalt compounds (as Co)	-	0.1	-	-	Carc* *cobalt chloride and sulphate
Cotton dust	-	2.5	-	-	
Diethyl sulphate	0.05	0.32	-	-	Carc, Sk
Dihydrogen selenide (as Se) (IOELV)	0.02	-	0.05	-	

Dimethyl sulphate	0.05	0.26	-	-	Carc, Sk
Ethylene oxide	5	9.2	-	-	Carc
Ferrous foundry particulate					Carc
total inhalable dust	-	10	-	-	
respirable dust	-	4	-	-	
Flour Dust	-	10	-	30	Sen
Glutaraldehyde	0.05	0.2	0.05	0.2	Sen
Grain dust	-	10	-	-	Sen
Halogeno-platinum compounds (as Pt)	-	0.002	-	-	Sen
Hydrazine	0.02	0.03	0.1	0.13	Carc, Sk
Hydrogen cyanide	-	-	10	11	Sk
Hydroquinone	-	0.5	-	-	
Iodomethane	2	12	-	-	Sk
Maleic anhydride	-	1	-	3	Sen
Manganese and its inorganic compounds	-	0.5	-	-	
Nickel and its inorganic compounds (except nickel carbonyl):					Sk Carc* *nickel oxides and sulphides
water-soluble nickel compounds	-	0.1	-	-	
nickel and water-insoluble nickel compounds	-	0.5	-	-	
o-Toluidine	0.2	0.89	-	-	Carc, Sk
Phenol (IOELV)	2	-	-	-	Sk
Phthalic anhydride	-	4	-	12	Sen
Piperazine (IOELV)	-	0.1	-	0.3	Sen
Piperazine dihydrochloride	-	0.1	-	0.3	Sen
Polychlorinated biphenyls (PCB)	-	0.1	-	-	Sk
Propylene oxide	5	12	-	-	Carc
Refractory Ceramic Fibres* *(currently under consultation for a new MEL value)*					
Rosin-based solder flux fume	-	0.05	-	0.15	Sen
Rubber fume	-	0.6	-	-	Carc
Subtilisins * *(currently under consultation for a new MEL value)*					
Triglycidyl isocyanurate (TGIC)	-	0.1	-	-	Carc
Trimellitic anhydride	-	0.04	-	0.12	Sen
Vanadium pentoxide	-	0.05	-	-	

Vinyl chloride (Carcinogens Directive)	3	-	-	-	Carc
Vinylidene chloride	10	40	-	-	
Wool process dust	-	10	-	-	

Table 2b

This Table presents a list of current MELs (n=15) which ACTS concluded that, with improvements in control technology , it should be reasonably practicable to control many of these substances to a lower value. Employers should take this into account in considering their duty to reduce exposure so far as is reasonably practicable and in any case below the MEL.

It is proposed that these be taken forward into the new OEL system as WELs but to be flagged as needing review to determine the appropriateness of the limit values.

Substance	**Reason for needing review**	Long-term exposure limit 8-hour TWA reference period		Short-term exposure limit 15-minute reference period		Notation
		ppm	$mg.m^{-3}$	ppm	$mg.m^{-3}$	
Acrylonitrile	The value of the MEL derives from 1979 and given that it is a carcinogen it needs to be established whether a lower OEL value would now be achievable.	2	4.4	-	-	Carc, Sk
Arsenic and arsenic compounds except arsine (as As)	The value of the MEL (0.1 $mg.m^{-3}$) was established in 1989 but there is suggestive evidence for an increased risk of lung cancer at 0.2 $mg.m^{-3}$. As this is close to the MEL value the reliability of this evidence needs to be assessed.	-	0.1	-	-	Carc
Buta-1,3-diene	There is a long established MEL of 10 ppm but since the MEL was established it has been recognised that butadiene is a human carcinogen and there is evidence for lung cancer in animals at 6 ppm.	10	22	-	-	Carc
Carbon disulphide	There is a long established MEL and since the MEL was established evidence has been published suggesting heart problems at exposures below the MEL. The strength of this evidence is uncertain but needs to be assessed. The substance is also under review by SCOEL.	10	32	-	-	Sk

Dichloromethane	New technology to suppress vapour release may allow a lower OEL to be established in the future. If and when this technology becomes established the potential for setting a lower OEL will be explored.	100	350	300	1060	Sk
2-Ethoxyethanol	The MEL was established in 1984 and it needs to be determined whether it would be reasonably practicable for industry to control to a lower value.	10	37	-	-	Sk
Formaldehyde	The MEL is long established and many toxicity studies have since been published. HSE needs to review this evidence to determine whether the current MEL value is appropriate.	2	2.5	2	2.5	
Hardwood dust	Wood dust is the fourth highest cause of occupational asthma and SCOEL have judged that to control against respiratory problems the limit would need to be considerably lower than the current MEL value.	-	5	-	-	Carc, Sen
Isocyanates	The MEL was established prior to 1989 and isocyanates are the leading cause of occupational asthma in the UK. It needs to be established whether a reduced limit would be achievable.	-	0.02	-	0.07	Sen
MMMFs	HSE is now establishing a reduced separate OEL for RCFs and this leads to the need to establish a definition of what substances the existing limit for MMMFs should cover.	-	5	-	-	
Respirable Crystalline Silica (RCS)	Recent evidence has shown a much higher risk of silicosis associated with the MEL value than was previously realised. Also, since the MEL was established it has been recognised that RCS is a cause of lung cancer in humans. This substance is of urgent priority for establishing a reduced OEL.	-	0.3	-	-	

Rubber process dust	It needs to be established whether the rubber industry could achieve a more stringent level of control than the current MEL of 6 $mg.m^{-3}$ (8-hr TWA).	-	6	-	-	Carc
Softwood dust	Wood dust is the fourth highest cause of occupational asthma and SCOEL have judged that to control against respiratory problems the limit would need to be considerably lower than the current MEL value.	-	5	-	-	Sen
Styrene	Since the MEL was established a large amount of new toxicity information has been published on styrene and it needs to be determined if there are any implications for the current MEL. Also, industry has a more stringent voluntary OEL than the MEL indicating that a more stringent OEL can be established.	100	430	250	1080	
Trichloroethylene	Since the MEL was established this has been classified as a carcinogen (R45) and it needs to be determined whether industry can control to a more stringent level.	100	550	150	820	Sk

Table 3 - OESs not proposed for transfer into the new system

None of the OES values are based on a thorough examination of the available data and in some cases the basis for the limit is very uncertain. Substances listed in the proposed 2nd IOELV Directive are marked with an asterisk. When the Directive has been adopted HSC will consult on WEL values for these substances.

If these OESs were transferred into the new system as WELs it would result in:

- A mixed list of WELs, some of which have a good scientific basis, where the WEL can be demonstrated to be commensurate with an appropriate standard of control based on the known health effects of the chemical, and where HSE can provide either specific control advice or can recommend the generic control advice from *COSHH Essentials.* But in addition there would be WELs that have no documented scientific basis and the appropriateness of the WEL value is not known. For many of these chemicals, *COSHH Essentials* would lead to as good as or a better standard of control than that indicated by the WEL value.

Another option would be to retain these OESs as advisory limits in the new system. This would:

- detract from the aim of making the system easy to understand;
- cause confusion – the status of the numbers would be unclear;
- appear to be perpetuating a two tier system of OELs; and
- inconsistencies with good practice advice requiring better standards of control than the advisory number.

Information on the proposed new system will make it clear that deletion of the OES does not mean that employers no longer have to bother about controlling exposure. The legal duty to comply with good practice will not be less onerous than complying with a number. ACTS consider it is vital that control advice is made available for substances that it is proposed will no longer have an OEL assigned by HSC, except where occupational exposure is minimal. The table is subdivided depending on how HSE propose to provide advice on control.

Table 3a

For all the substances in this table, *COSHH Essentials* can be used to select appropriate control measures. Examination of each substance shows that using the *COSHH Essentials* generic risk assessment scheme to select good practice advice results in control standards as good or better than those needed to comply with the existing OES. Practical advice on control will be of more value to dutyholders than an OES, since many do not know how to determine whether they are to complying with a limit.

Substance
1,1,1,2-Tetrachloro-2, 2-difluoroethane
1,1,2,2-Tetrabromoethane
1,2,3-Trichloropropane
1,2-Dichloroethylene, cis:trans isomers 60:40
1,3-Dichloro-5, 5-dimethyl-hydantoin
1,4-Dioxane, tech. grade
1-Chloro-4-nitrobenzene
1-Nitropropane
2,2'-Iminodi(ethylamine)
2,2'-Iminodiethanol
2,2'-Oxydiethanol
2,4,6-Trinitrotoluene
2,4-D (ISO)
2,6-Dimethylheptan-4-one
2,6-Di-tert-butyl-p-cresol
2-Aminoethanol*
2-Chloro-6-(trichloromethyl)pyridine
2-Chlorobuta-1, 3-diene
2-Chloroethanol
2-Chlorotoluene
2-Diethylaminoethanol
2-Ethylhexyl chloroformate
2-Methylcyclohexanone
2-Methylpropan-1-ol
2-Methylpropan-2-ol
2-sec-Butylphenol
3,5,5-trimethylcyclohex-2-enone
3-Methylbutan-1-ol
4-Methylpent-3-en-2-one
4-Methylpentan-2-ol
4-Nitroaniline
6,6'-Di-tert-butyl-4, 4'-thiodi-m-cresol
Acetic acid*
Acetonitrile*
Acrylaldehyde (Acrolein)
Acrylic acid
Aluminium alkyl compounds
Aluminium salts, soluble
Ammonium sulphamidate
Barium compounds, soluble (as Ba)*
Benomyl (ISO)
Benzyl butyl phthalate
Bis(2-ethylhexyl) phthalate
Bornan-2-one
Boron tribromide

Bromacil (ISO)
Butan-1-ol
Butan-2-ol
Butyl acetate
Butyl lactate
Caesium hydroxide
Calcium carbonate
Calcium cyanamide
Calcium hydroxide*
Calcium oxide
Calcium silicate
Captan (ISO)
Carbon black
Cellulose (pure)
Chloroacetaldehyde
Chlorosulphonic acid
Chlorpyrifos (ISO)
Cresols, all isomers*
Cyanamide*
Cyanides, except HCN, cyanogen & cyanogen chloride
Cyclohexanol
Cyclohexylamine
Diallyl phthalate
Diammonium peroxodisulphate (measured as [S2O8])
Diatomaceous earth, natural, respirable dust
Dibenzoyl peroxide
Dibismuth tritelluride
Diboron trioxide
Dibutyl hydrogen phosphate
Dibutyl phthalate
Dicyclohexyl phthalate
Dicyclopentadiene
Diethyl phthalate
Diethylamine*
Diisobutyl phthalate
Diisononyl phthalate
Diisooctyl phthalate
Diisopropyl ether
Diisopropylamine
Dimethoxymethane
Dimethyl phthalate
Dimethylformamide
Dinitrobenzene, all isomers
Dinonyl phthalate
Diphenylamine

Dipotassium peroxodisulphate (measured as S2O8)
Diquat dibromide (ISO)
Disodium disulphite
Disulphur dichloride
Diuron (ISO)
Emery, total inhalable dust
Endosulfan (ISO)
Ethanol
Ethyl acrylate
Ethyl chloroformate
Ethyl formate
Ferrocene
Formamide
Formic acid*
Graphite
Gypsum
Hexachloroethane
Hexahydro-1, 3, 5-trinitro-1,3,5-triazine
Hydrogen peroxide
Indium and compounds (as In)
Iron salts (as Fe)
Isobutyl acetate
Isooctyl alcohol (mixed isomers)
Isopropyl acetate
Limestone
Lithium hydride*
Lithium hydroxide
Magnesite
Malathion (ISO)
Marble
Mequinol (INN)
Mercaptoacetic acid
Mercury & its inorganic divalent compounds
Mercury alkyls (as Hg)
Methacrylic acid
Methacrylonitrile
Methanol*
Methyl acetate
Methyl acrylate
Methyl formate
Methylcyclohexanol
Methylstyrenes, all isomers except a-methylstyrene
Molybdenum compounds (as Mo)
Morpholine*
N,N-Dimethylaniline

N,N-Dimethylethylamine
n-Butyl chloroformate
n-Butylamine
Nicotine*
Nitric acid*
Nitrobenzene*
Nitroethane
Nitromethane
Nitrotoluene, all isomers
N-Methyl-N, 2, 4, 6-tetranitroaniline
n-Propyl acetate
o-Acetylsalicylic acid
Osmium tetraoxide (as Os)
Oxalic acid*
Oxalonitrile
Paraquat dichloride (ISO), respirable dust
Pentacarbonyliron (as Fe)
Pentaerythritol
Pentan-2-one
Pentan-3-one
Phorate (ISO)
Picric acid*
Piperidine
Plaster of Paris
Polyvinyl chloride
Potassium hydroxide
Prop-2-yn-1-ol
Propan-1-ol
Propan-2-ol
Propoxur (ISO)
p-Toluene sulphonyl chloride
Pyrethrins (ISO)*
Resorcinol*
Rotenone (ISO)
Rouge
sec-Butyl acetate
Selenium and compounds, except hydrogen selenide (as Se)
Silica, amorphous
Silica, fused respirable dust
Silicon
Silicon carbide (not whiskers)
Sodium fluoroacetate
Sodium hydrogen sulphite
Sodium hydroxide
Starch
Strychnine

Sucrose
Tantalum
Tellurium & compounds, except hydrogen telluride, (as Te)
tert-Butyl acetate
Tetracarbonyl nickel
Tetraethyl orthosilicate
Tetrasodium pyrophosphate
Thallium, soluble compounds (as Tl)
Thionyl chloride
Thiram (ISO)
Tin compounds, inorganic, except SnH4, (as Sn)*
Titanium dioxide
Tributyl phosphate, all isomers
Trichloronitromethane
Trimethyl phosphite
Tri-o-tolyl phosphate
Triphenyl phosphate
Tungsten & compounds (as W)
Turpentine
Uranium compounds, natural, soluble (as U)
Warfarin (ISO)
Xylidine, all isomers
Zinc distearate
Zirconium compounds (as Zr)

* - 2nd draft IOELV Directive

Table 3b

The substances in this table are all gases. HSE will produce *COSHH Essentials* type generic guidance on control of health risks from gases.

Substance
Arsine
Boron trifluoride
Bromine *
Bromomethane
Bromotrifluoromethane
Butane
Carbon dioxide *
Chlorine *
Chlorine trifluoride
Chloromethane
Chloropentafluoroethane
Cryofluorane (INN)
Cyanogen chloride
Diborane
Dibromodifluoromethane
Dichlorofluoromethane
Germane
Ketene
Liquefied petroleum gas
Methanethiol
Methylamine
Nitrogen trifluoride
Perchloryl fluoride
Phosphine *
Silane
Stibine
Sulphur hexafluoride
Sulphur tetrafluoride
Sulphuryl difluoride
Trichlorofluoromethane
Trimethylamine

* - 2nd draft IOELV Directive

Table 3c

The substances in this table are all process-generated dusts, mists or fumes. HSE will produce specific *COSHH Essentials* control guidance sheets for the commonly occurring dusts/mists/fumes and generic guidance for the remainder.

Substance
Ammonium chloride, fume
Asphalt, petroleum fumes
Coal dust, respirable dust
Copper
Dichloroacetylene
Diphenyl ether (vapour)
Glycerol, mist
Hydrazoic acid
Iron oxide, fume (as Fe)
Oil mist, mineral
Paraffin wax, fume
Rhodium (as Rh)
Welding fume
Zinc chloride, fume
Zinc oxide, fume

Table 3d

For the substances in this table use of the *COSHH Essentials* generic risk assessment scheme to select control advice, results in a lower standard of control than that needed to comply with the current OES. For the majority of substances this is because of deficiencies in the assignment of the risk phrases. The proposal is to produce a Chemical Hazard Alert Notice (CHAN) for each substance in this list. The CHANs would be made freely available on HSE's web site to coincide with the implementation of the new framework.

Substance
1,1,2,2-Tetrachloro-1,2-difluoroethane
1,3-Dimethylbutyl acetate
2-Chloroacetophenone
2-Hydroxypropyl acrylate
2-Methylpentane-2,4-diol
2-Pyridylamine
4-Ethylmorpholine
4-Hydroxy-4-methylpentan-2-one
Benzenethiol
Biphenyl
Bromine pentafluoride
Bromoform
Carbon tetrabromide
Chromium *
Chromium (II) compounds (as Cr) *
Chromium (III) compounds (as Cr)*
Cyclohexene
Dialkyl 79 phthalate
Diazinon (ISO)
Dibismuth tritelluride, selenium doped
Diisodecyl phthalate
Disodium (peroxodisuplhate (measured as [S208])
Disodium tetraborate, anhydrous
Disodium tetraborate, decahydrate
Disodium tetraborate, pentahydrate
Disulphur decafluoride
Ethanethiol
Hafnium
Indene
Iodine
Iodoform
Isopropyl chloroformate
Methyl ethyl ketone peroxides (MEKP)
Mica
Monochloroacetic acid
Nickel, organic compounds (as Ni)

N-Methylaniline
Octachloronaphthalene
p-Benzoquinone
Phosphorus, yellow
Picloram (ISO)
Platinum compds, soluble except certain halogeno-Pt compds
Platinum metal *
Pyridine *
Pyrocatechol
Silver compounds (as Ag) *
Sodium 2-(2,4-dichlorophenoxy) ethyl sulphate
Terphenyls, all isomers
Tetrachloronaphthalenes, all isomers
Tetramethyl orthosilicate
Tetramethyl succinonitrile
Tin compounds, organic, except Cyhexatin (ISO), (as Sn)
Tricarbonyl(eta-cyclopentadienyl) manganese (as Mn)
Tricarbonyl(methylcyclopentadienyl) manganese (as Mn)
Vinyl acetate
Yttrium

* - 2nd draft IOELV Directive

Table 3e

The substances in this table are either biocides no longer authorised for use or substances subject to the Montreal Protocol. Occupational exposure is likely to be non-existent or very minimal. It is not proposed to provide advice on the control of these substances

Substance
1,1,1-Trichlorobis(chlorophenyl)ethane
1,1,2-Trichlorotrifluoroethane
2,4,5-T (ISO)
2-Methyl-4,6-dinitrophenol
Aldrin (ISO)
Azinphos-methyl (ISO)
Captafol (ISO)
Carbofuran (ISO)
Cyhexatin (ISO)
Dichlorodifluoromethane
Dieldrin (ISO)
Dioxathion (ISO)
Disulfoton (ISO)
Endrin (ISO)
Fenchlorphos (ISO)
Ferbam (ISO)
Lindane
Methomyl (ISO)
Methoxychlor (ISO)
Mevinphos (ISO)
Naled (ISO)
Parathion (ISO)
Parathion-methyl (ISO)
Pentachlorophenol
TEPP (ISO)

ANNEX 8: Regulatory impact assessment for the OEL framework

Purpose and intended effect

Background

1. The Control of Substances Hazardous to Health Regulations (COSHH) came into force in October 1989, and has been amended and re-enacted several times since then. The current version is the Control of Substances Hazardous to Health Regulations 2002. The COSHH Regulations are a useful tool of good management setting out the measures that employers must take to protect both employees and others who may be exposed. They are summarised in a free booklet (*COSHH: a brief guide to the regulations).* At the heart of COSHH is the requirement on employers to prevent their employees being exposed to hazardous substances or where this is not reasonably practicable, ensure exposure is adequately controlled. Under the COSHH Regulations, Occupational Exposure Limits (OEL's) define adequate control by inhalation. Two types are used, the Maximum Exposure Limit (MEL) and the Occupational Exposure Standard (OES).

2. HSC's Advisory Committee on Toxic Substances established a working group to consider how the OEL system could be improved. The objectives of the new approach being that OELs should:

- control risks to health;
- be readily understood/accessible;
- be legally enforceable;
- be comprehensive;
- comply with EU legislation;
- be flexible and able to take on board new developments in science and technology; and
- provide incentives to reduce exposure.

3. In March 2002 the Health and Safety Commission (HSC) published a Discussion Document (DD) setting out the concerns with the current system of occupational exposure limits and proposed options for a new system. The working group had examined the existing system against the 7 objectives and decided that *status quo* was not an option. However they did consider that it would be possible to make minor modifications to the indicative criteria used to set limits, to overcome the difficulties encountered with the current process of setting limits. This was Option 1 in the DD. The options were:

1. maintain the present system with minor modifications;

2. good practice control advice supported by a single type of limit;

2A. good practice control advice supported by a two tier system which flags carcinogens.

4. The majority of respondents agreed with the concerns about the present system (see next paragraph) and only 2 did not support either proposal 2 or 2A. Therefore, Option 1 is included in this RIA for comparative purposes only.

Concerns with the present system of occupational exposure limits

5. In the last few years a number of difficulties have arisen with the present system. These are explained fully in the discussion document "Discussion Document on the Occupational Exposure Limit (OEL) framework" DDE19. Although the comments to this document had to be with HSE by 31 July 2002, it is still available for reference on www.hse.gov.uk/disdocs/. In summary the concerns are:

- Research shows that OESs and MELs are not understood by much of industry, particularly small firms, with many employers not knowing how to determine whether exposure levels in their workplaces comply with the limits;

- The OES purports to be a "safe" limit at which no ill-health will occur. But the concept of a "safe" limit is not secure. In reality, it may not be possible to give an absolute guarantee of complete health protection for all individuals because of uncertainties, for example in the extent of human variability, and gaps in knowledge about the effects of chemicals;

- There are some incompatibilities with the European Commission (EC) system for OELs (there is a need to develop a limit system under COSHH which will readily incorporate Indicative Occupational Exposure Limit Values (IOELVs)); and

- Experience has shown that the criteria used to set OESs and MELs are not wide enough in their scope; some substances of concern meet neither the OES nor MEL criteria, so it has not been possible to establish an OEL for those substances under the current system.

6. As a result of these concerns HSE and stakeholders consider OELs have not realised their full potential as important tools to help employers control exposure.

The proposed new system

Objectives for the new system

7. In 2002 the HSC agreed a strategy for HSE's work on chemicals, which places more emphasis on activities which will have a direct impact in the workplace. The aim is to ensure OELs make a real contribution to this strategy. To achieve this the new system needs to:

- be simple and easy for duty holders to understand;
- provide a tool which will help dutyholders improve standards of control;
- address the difficulties associated with the OES; and
- improve the efficiency of the process for setting limits in the light of the EC system.

Fundamentals of the new system

8. A proposal to meet these aims, Option 2 in this RIA, has been developed by a Working Group of the HSC's Advisory Committee on Toxic Substances and endorsed by the HSC. It combines features of Options 2 and 2A in the DD. The proposal is to:

- move away from the OES/MEL system to good practice advice on how to control exposure underpinned by a single type of OEL;

- introduce a new approach to adequate control, so that dutyholders will have achieved adequate control if:

  the principles of good practice for the control of exposure to substances hazardous to health set out in a new Schedule 2A (of COSHH) are applied; any Workplace Exposure Limit approved for that substance is not exceeded; and for a substance which carries the risk phrase R45, R46 or R49 or for a substance or process which is listed in Schedule 1, the level of exposure is reduced so far as is reasonably practicable.

- set out the principles of good practice for the control of exposure to substances hazardous to health in a new schedule to the COSHH Regulations;

- establish clear linkage between the duties under the COSHH Regulations to apply the principles of good practice for the control of exposure to substances hazardous to health, guidance on controls appropriate for specific situations and the OEL; and

- provide advice to support the principles of good practice for the control of substances hazardous to health and make it readily available free of charge.

Information sources and background assumptions

9. The assumptions in this RIA are based on information collected from the evaluation of *COSHH Essentials*[8] and from internal HSE knowledge. Costs and benefits are discounted over ten years using the Treasury's recommended 3.5% discount rate[9]. The base year for appraisal is year 2001/02.

[8]Wiseman et al (2001) COSHH Essentials: Survey of firms purchasing this guidance

[9]In arriving at 10 year cost figures two adjustments are made. Firstly, earnings are assumed to rise by 2% per year in real terms - the observed increase for the whole economy over the past twenty-five years or so. Secondly, costs are discounted to present value using the Treasury recommended 3.5% discount rate.

Benefits

Health and safety benefits

Option 1

10. There will be no additional health and safety benefits under this option.

Option 2

11. Adding together figures on occupational ill-health for diseases that are predominantly caused by chemicals – such as cancer, asthma, bronchitis etc – gives a rough estimate of the number of cases of exposure related ill health. A variety of sources have been used[10], each of which is known to be subject to incomplete coverage and under-reporting of various kinds. The resulting figure is therefore likely to be an underestimate of the actual annual incidence[11].

12. Based on this method and using figures for 2001, it is estimated that each year approximately 10,000 people suffer non-fatal illnesses as a result of exposure to substances hazardous to health at work, and a further 3000 to 12,000 die from cancers caused by chemicals, including asbestos. However, the proposed OEL framework does not have the scope to control substances that cause a substantial proportion of these cancer deaths (particularly those caused by asbestos, the control of which comes under other regulations). HSE has used an estimate of 4,500 annual cancer deaths that are relevant to the new framework.

13. Under-reporting of diseases which make up this figure will be most significant in industries where knowledge of the hazards of exposure to chemical agents is less well known or where exposure is intermittent.

14. Using unit average costs from HSE (1999) for cases of ill health[12] and for cancer deaths, double the Department of Transport's Value of Prevention of Road Accidents of approximately £1,250,000 in June 2002 prices, to allow for individual aversion to dying from cancer, it is possible to estimate the cost of this exposure related ill health to society.

15. Assuming there are 10,000 cases of non fatal illnesses and 4,500 cancer deaths per year, this gives a total cost to society per year of approximately £11.3 billion. The new OEL framework could impact on only some of these costs.

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[10] New cases seen by specialist doctors reporting to the Health and Occupation Reporting Network (THOR), compensated by the by the DWP Industrial Injuries Scheme (IIS) and reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). The figure also includes an estimated 3000 to 12,000 cancer deaths, ref: Carcinogenic risk: getting it in proportion - Sir Richard Doll (paper in conference proceedings: Cancer in the workplace, 15 October 1992, HSE and Society of Chemical Industry).

[11] Figures from the Self Reported Work Related Illness 1995 (SWI95) survey indicate the annual incidence may be much higher for some diseases. For example, the incidence estimates for skin disease alone from SWI95 was 12,000 (95% confidence interval 3000 to 22,000 is typical of the large uncertainty associated with SWI estimates.) However, SWI estimates may include a substantial proportion of cases not caused by chemicals.

[12] 'The costs to Britain of workplace accidents and work related ill health in 1995/96' HSE (1999). For each person in the working population with a work-related illness, the average social cost is between £11,000 and £11,400 (uprated to 2nd quarter 2002 from 95/96 values using nominal GDP inflator).

16. The evaluation of *COSHH Essentials* gives an indication of the effects similar guidance could be expected to have. The most frequent action taken as a result of seeing the guidance was to check that existing control measures were in place. The second most frequent was to provide training or information to workers. This suggests that guidance of this sort would act to improve compliance and eventually reduce the risk of exposure. It is hoped that there will be health benefits, but there is uncertainty about their extent.

Cost savings

Option 1

17. Option 1 is no more than the rationalisation of the current criteria used by ACTS and WATCH when setting new limits. Currently there are about 1-3 substances where WATCH finds it difficult to decide if an OES or a MEL is the most appropriate limit. This results in lengthy and repeat visits to WATCH. For important chemicals the decision is eventually made in ACTS.

18. The new criteria will shorten the time the substance spends in WATCH. Cost savings are based on[13]:

- 17 national topic experts saving 2 hours each at WATCH;
- 10 HSE people (Band 1 - 3) saving 2 hours each at WATCH; and
- HSE saving 10 days (Band 3) for the preparation of additional papers for additional WATCH discussion.

19. Over ten years this represents a cost saving of approximately £27,000 in net present value terms.

Option 2

20. Under Option 2 there would be some cost savings to firms that are already complying with OELs under the existing framework. These firms will receive clearer guidance about what is expected of them under the regulations and how to achieve lower levels of exposure through the application of good practice. Furthermore, the new framework and good practice guidance will be freely available online from HSE. Increasing numbers of firms are getting access to the internet. Thus, there will be the cost savings to firms who previously paid for the information and who will now get it free of charge. We have not been able to quantify these benefits.

21. There may also be some cost savings in inspector time as clearer guidance makes enforcement activity easier. We have not been able to estimate these benefits.

[13] This assumes hourly wage rates (including non-wage labour costs) of £23.21 and £34 for WATCH experts and HSE staff band 2 respectively. The daily wage including non-wage labour costs used for band 3 policy staff is £178.

Costs

Business sectors affected

22. In 1992, HSE estimated that nearly all of Britain's 1.3 million employers were required to carry out a COSHH assessment. This is unlikely to have changed much. Firms in all sectors come under the scope of COSHH and will therefore be affected by the changes in the OEL framework. Data from the Department of Trade and Industry[14] indicated that firms in those sectors most affected by COSHH[15] number approximately 270,000. That is, about 20% of the 1.3 million firms. The greatest burden will fall upon those industries where there is the greatest exposure to hazardous substances, in the primary and secondary industries. It is therefore likely that the number of companies who will be affected by the changes is actually quite small. HSE estimates that this is about 5% of 1.3 million employers (i.e. 66,000 firms). We use the range 5%-20% in our estimates below.

Compliance costs to business

Option 1

23. The likely outcome is that 1-3 substances are set a MEL rather than an OES. The net cost to industry will be the cost of the MEL less the cost of the replaced OES. Since it is assumed that OESs impose negligible costs to industry the costs will simply be the compliance costs associated with each new MEL. It is difficult to estimate the magnitude of these costs because they will vary considerably. The costs will be dependent on several factors, including:

i. the substance for which a MEL is being set and therefore the industries affected;
ii. the ease with which industry can implement changes in order to comply; and
iii. the actual limit chosen.

24. A brief review of costs of MELs over the last six years indicates a range of approximately £400 to £2,000 per firm per year per MEL. Since important substances get resolved in terms of MELs anyway, we are looking at lower than median MEL costs for most substances affected by these changes.

Option 2

Familiarisation

25. Each firm affected by option 2 will require time to become familiar with the new requirements. As implied in paragraph 22, 80 to 95% of the estimated 1.3 million firms discussed in paragraph 22 will be affected only marginally by the changes to the OEL framework. Managers within these firms will need to take a small amount of time to ensure that the changes will not have a substantial impact on their businesses. HSE has assumed that each of these firms will require half an hour for familiarisation. We have also assumed that the predicted 5 to 20% of firms that will be affected substantially by the changes will require four hours to become familiar with the changes and the good practice guidance. The hourly

[14] DTI (1999), SMEs statistics for the UK

[15] Sectors include: parts of Manufacturing (D) and Wholesale, retail and repairs (G)

cost of management time required for familiarisation is assumed to be approximately £18[16]. Under these assumptions, the one-off familiarisation costs lie in the range of £14.2 to 30.4 million.

Good practice

26. Option 2 includes a new regulatory requirement to apply the principles of good practice. We expect that freely available guidance on the application of the principles to specific workplace situations will result in greater uptake and improved compliance.

27. To help small businesses apply the COSHH Regulations to real life situations, HSE developed *COSHH Essentials.* This is a step by step process which helps identify correct control methods for the products and tasks in the workplace. An evaluation study on its effectiveness suggested that 60% of a random sample of 500 SMEs has taken some action to improve control as a result of using the guidance. The actions taken were:

i. 40% of firms checked existing controls working. In the OEL framework, we assume 1 person taking 1 - 4 hours time;

ii. 5% of firms improved their extraction systems. In the OEL framework, we assume a typical unit cost £500 - £2000;

iv. 10% of firms substituted less hazardous products. We have been unable to get an estimate of cost and so treat as cost neutral;

v. 20% 0f firms changed their control measures used. In the OEL framework, we assume a typical unit cost of between £1000 - £5000 per site [including maintenance]; and

vi. 25% improved training or procedures. In the OEL framework, we assume 1 - 4 hours per person and between 1 and 5 people per site.

28. These percentage changes are costed against the number of firms we hope to influence. We assume that the new limit setting system could have an impact on 30% of firms with the greatest exposure to hazardous substances. This proportion could be underestimated as it relates mostly to SMEs (see paragraph 43). We implicitly assume that large firms have controls in place and will not be so affected by the changes.

29. Table 1 below summarises the costs of these measures. All costs are incurred in the first year and are one-off costs. The only annual costs are maintenance costs that we believe will be taking place anyway in the absence of the proposal.

Table 1 Costs of additional actions (£ '000)

	Check existing working controls	Improve extraction systems	Change control methods	Improve training	TOTAL
HSE enforced premises	39-156	134 - 2,140	1,070 – 21,401	15 - 1,276	1,259-24,972
LA enforced premises	14 - 55	74 – 1,189	594 – 11,889	6 – 491	689-13,624
TOTAL	53-211	208-3,329	1,164-33,290	21-1,767	1,947-38,596

Implications of Workplace Exposure Limits

[16] Hourly wage labour cost of £13.98 (SOC 396) plus 30%for non-wage labour costs.

30. In moving from OESs to a single limit with good practice, there are some other cost implications for industry. Currently it is possible for the OES levels to be exceeded but steps must be taken to meet it as soon as is reasonably practicable (within CAD[17], if a limit is exceeded, exposure must be reduced as soon as possible). Part of the proposed new approach to adequate control is that "any Workplace Exposure Limit approved for that substance is not exceeded" (paragraphs 62 - 66 of the CD explain the practical application of the new approach in the workplace). Therefore some additional costs may be incurred in industry. It is not possible to quantify the extent of these costs. However, set against these costs, benefits from the framework would result from the increased clarity in what is expected from industry.

31. Under existing MELs, limits must not be exceeded, and therefore there would be no changes (and no costs) in moving from the limits in the old OEL framework to those in the proposed new version.

Costs for a typical business

32. Information from previous MEL RIAs suggests that ten year present value costs under Option 1 for the limited number of firms that will be affected will have a ten year net present value of between £3,000 and £17,000 per firm.

33. Using information from the *COSHH Essentials* survey, the one-off costs to a typical business under Option 2 two would lie in the range £570 to £5070. Policy costs would range between 500 and 5000, while implementation costs[18] would be approximately £70.

Total compliance costs

Option 1
34. HSE has been unable to give an estimate of total compliance costs because the total number of potentially affected businesses is not known.

Option 2
35. Total compliance costs to business will be approximately £16.2 million to £69.0 million. All costs are borne in the first year of compliance.

36. Of this total, £1.9 to 38.6 million can all be classified as policy costs (refer to table 1), while £14.2 to £30.4 are implementation costs.

Costs to HSE

Option 1
37. There are no additional costs to HSE under Option 1.

[17] Chemical Agents Directive

[18] Cabinet Office Regulatory Impact Unit, ' Good policy making: A guide to regulatory impact assessment' (2001) policy costs are the costs directly attributable to the policy goal. Implementation costs are the red-tape costs associated with the regulation's implementation.

Option 2

38. An analysis of SIC codes suggests that the workforce inspection is split equally between HSE and LA.

39. We estimate that for HSE inspected premises, 90% of the workforce have exposure via inhalation. For LA inspected premises 50% of the workforce have exposure via inhalation.

40. Enforcement will be easier for FOD, HID and LA, because inspectors will look at good practice, for which they will have clear guidance, rather than at the level of emissions. There will therefore, be cost savings, but it is difficult to quantify.

41. There will also be additional costs of staff time in the development and issue of guidance. We have not been able to estimate this cost.

Total costs to society

42. These are the same as the costs to industry and are in the range £16.2 to £69.0 million. All costs in Option 2 are incurred in the first year. Of this total, £1.9 to 38.6 million can be classified as policy costs (refer to table 1), while £14.2 to £30.4 are implementation costs. This apparent imbalance between policy and implementation costs is explained by the large number of firms that will have to spend a small amount of time familiarising themselves with the new requirements (implementation costs). This compares with the relatively small number of firms that will have to take action to meet the new requirements (policy costs). The cost per firm for the majority of firms will therefore be negligible.

Small firms impact test

Option 1

43. There would be no disproportionate impact on small firms.

Option 2

44. The major impact of the changes will be amongst small firms as these are the least likely to understand OELs and thus less likely to have access to professional advice on appropriate control. However small firms are also likely to be the major beneficiaries of the changes to the framework due to guidance on good practice.

45. HSE contacted five small businesses to assess the impact of the proposed changes under Option 2. Three were engineering firms and the other two were food manufacturers. All contacts said that the proposed changes seemed sensible, particularly as health and safety managers in small firms often find difficulty in interpreting and responding to the existing OEL framework. The simplification of the limit structure and the availability of good practice guidance were welcomed. Although some respondents expected that there would be some cost implications of applying the new framework, none believed that the costs would place a disproportionate burden on their business.

Competition assessment

46. The effects on competition under Option 1 are difficult to predict without knowledge of which OESs would be converted to MELs. However, although the duties would change, there is no reason to believe that the effects would vary substantially between firms.

47. A large majority of manufacturing firms, and a substantial number of wholesale and retail firms would be affected by the changes proposed under Option 2. The markets that fall into the scope of the competition assessment are therefore numerous and diverse. In these circumstances OFT recommends selecting markets that have a high degree of supplier concentration (dominated by a relatively small number of firms). Two such examples are the markets for washing powder and cement.

48. The washing powder market in Great Britain is dominated by four firms. However, Option 2 would not affect any firm in the industry more than the others, and new firms would not face higher entry or on-going costs as a result of the new OEL framework. Technological change within the market exists but cannot be characterised as rapid. Commercial choice within the market would not be restricted.

49. The cement industry has a highly concentrated market structure, with 90% of production controlled by three large firms. However, the proposed changes to the OEL framework would not affect any one of these firms more than the others. Since there will not be any differential effects, the proposed changes should not affect market structure or competition in the cement industry. Nor should it lead to higher set-up costs for new firms, that existing firms would not have to meet. Costs should fall on firms in proportion to their cement production. There may be some downstream effects in other markets but these will be negligible.

Environmental impacts

Option 1
50. There are no environmental implications under Option 1.

Option 2
51. There will be some environmental improvement due to reduction in fugitive emissions, but this is unquantifiable.

Balance of costs and benefits

Option 1
52. Total costs could potentially be up to £400-£2,000 per affected firm per year, with a ten year present value of £3,000 to £17,000 per firm (the total number of firms can not currently be predicted). These costs would be offset by total cost savings to HSE of £3,260 per year, with a ten year present value of £27,000.

Option 2
53. It is expected that there will be health benefits from improved risk control of this proposal, but it has not been possible to estimate them. There will also be benefits to HSE from easier enforcement.

54. Total compliance costs are estimated to lie in the range of £16.2 to £69.0 million. All costs under Option 2 are incurred in the first year. Of this total, £1.9 to 38.6 million can be classified as policy costs, while £14.2 to £30.4 are implementation costs. This apparent imbalance between policy and implementation costs is explained by the large number of firms that will have to spend a small amount of time familiarising themselves with the new requirements (implementation costs). This compares with the relatively small number of firms that will have to take significant action to meet the new requirements (policy costs). The cost per firm for the majority of firms will therefore be negligible.

55. In order to put compliance costs in context, a rough calculation can be made of how many cases of ill health and death would need to be prevented for the benefits to balance the costs. Assuming 4,500 cancer deaths and 10,000 cases of ill health fall within the scope of the proposed framework (implying a ratio of 0.45 deaths to one case of ill health), the following would apply[19]: Over a notional ten year period, in order to balance the lower compliance cost estimate of £16.2 million, 7 deaths and 15.2 cases of ill health would have to be prevented (0.001% of the estimated ten year incidence). For the upper compliance cost estimate of £69 million, 29 deaths and 65.1 cases of ill health would have to be prevented (approximately 0.065% of the estimated ten year incidence). These required levels of prevention appear modest.

Uncertainties

56. The total costs of compliance are based on an estimated range of the number of firms affected and the number of firms estimated to take action.

57. On the benefits side, we have not been able to estimate the health improvement brought about by the new OEL framework. This is due to uncertainty over which substances (and corresponding industries) may be affected by the new framework.

Arrangements for monitoring and evaluation

58. Compliance with this will be through the enforcing authorities of the Health and Safety at Work etc. Act 1974. The enforcement of health and safety law is informed by the principles of *proportionality*, in applying the law and securing compliance, *consistency* of approach, *targeting* of enforcement action and *transparency* about how the regulator operates and what those regulated may expect. Paragraphs 62 - 66 of this CD, and annex 4, explain what this means in practice.

[19] For the purposes of this illustration, cancer deaths and ill health are assumed to be distributed evenly over time. The health benefits have been uprated by 2% for real GDP growth and then discounted at 3.5% over ten years. Deaths have been rounded to the nearest whole unit.

ANNEX 9: Acronyms and abbreviations used in this CD

ACoP	Approved Code of Practice
ACTS	Advisory Committee on Toxic Substances
ALARP	As Low As is Reasonably Practicable
BOELVs	Binding Occupational Exposure Limit Values
CAD	Chemical Agents Directive
CD	Consultative Document
CHAN	Chemical Hazard Alert Notices
CHIP	Chemicals (Hazard Information and Packaging for Supply) Regulations
COSHH	Control of Substances Hazardous to Health
EC	European Commission
eCOSHH Essentials	Electronic version of *COSHH Essentials*
EH40	EH40 Occupational Exposure Limits
EH64	EH64 Summary criteria for occupational exposure limits
EMM	Enforcement Management Model
FOD	HSE's Field Operations Division
HID	HSE's Hazardous Installations Division
HSC	Health and Safety Commission
HSE	Health and Safety Executive
IOELVs	Indicative Occupational Exposure Limit Values
LAs	Local Authorities
LEV	Local Exhaust Ventilation
LOAEL	Lowest-Observed Adverse Effect Level
MEL	Maximum Exposure Limit
MWFs	Metal Working Fluids
NOAEL	No-Observed Adverse Effect Level
OEL	Occupational Exposure Limit
OES	Occupational Exposure Standard
OFT	Office of Fair Trading
PPE	Personal Protective Equipment
PPM	Parts Per Million
RIA	Regulatory Impact Assessment
RPE	Respiratory Protective Equipment
SCOEL	Scientific Committee on Occupational Exposure Limits
SIC	Standard Industrial Classification
TWA	Time Weighted Average
WATCH	Working Group on the Assessment of Toxic Chemicals
WEL	Workplace Exposure Limit

ANNEX 10: List of organisations and people consulted

National Government

Cabinet Office:
- European Secretariat
- Regulatory Impact Unit

Central Office of Information
Department for Environment, Food and Rural Affairs: Chemicals and Biotechnology Division
Department of Health
Department of Trade and Industry:
- Chemical and Biotechnology Branch
- Small Firms Policy Branch

Department for Transport
Department for Work and Pensions: Health and Safety Sponsorship Division
Foreign and Commonwealth Office: European Union Department
HM Customs and Excise: Safety, Health and Absence
HM Treasury
Home Office:
- H.M. Fire Services Inspectorate
- Health and Safety Services

Lord Chancellor's Department
Ministry of Defence, Directorate of Safety, Environment and Fire Policy
National Assembly for Wales
Northern Ireland Office
Office of the Deputy Prime Minister
Scottish Executive
Scotland Office: Industry Department
Wales Office:
- Environment Division
- Industry & Training Policy Division

Other Government Organisations

Civil Aviation Authority
Countryside Commission
Environment Agency
Environment Council
Government of Gibraltar
Health and Safety Executive Northern Ireland (HSENI)
House of Commons Library
House of Lords Library
Laboratory of the Government Chemist
Law Commission
Maritime and Coastguard Agency
National Consumer Council
Natural Environment Research Council
Scottish Environmental Protection Agency

Scottish Law Commission
Scottish Parliament Information Centre
Small Business Service
UK Permanent Representation to the European Union
Welsh Development Agency

Local Government Organisations

Association of Local Authorities of Northern Ireland
Convention of Scottish Local Authorities
Local Government Association

Government Advisory Committee

Members of the Advisory Committee on Toxic Substances

Representatives of small firms and the self-employed

Alliance of Independent Retailers
Association of Independent Businesses
CBI Smaller Firms Council
Federation of Small Businesses
National Federation of Self-Employed and Small Businesses Ltd
Small Business Service

Employers' Organisations

Association of British Insurers
British Association of Chemical Specialities
British Chemical Engineering Contractors Association
British Coatings Federation Ltd
British Printing Industries Federation
British Safety Industry Federation
Chemical Industries Association Ltd
Confederation of British Industry
Construction Confederation
Electrical Contractors Association Ltd
Engineering Employers Federation
Federation of Bakers
Forum of Private Business
Foundry Trade Equipment and Supplies Association
National Association of Master Bakers
National Association of Waste Disposal Contractors
Nationalist Specialist Contractors Council
Solvents Industry Association
UK Petroleum Industry Association
Water Companies Association
Water Services Association of England and Wales

Representatives of Workers

Amalgamated Union of Engineering Workers (Foundry Section)
Association of Occupational Health Nurse Practitioners
British Institute of Occupational Hygienists
Chartered Institute of Environmental Health
Chief and Assistant Chief Fire Officers' Association
GMB
Manufacturing, Science and Finance
National Association of Fire Officers
Prospect
Royal College of Nursing
Scottish Trades Union Congress
Trades Union Congress
Transport and General Workers Union
Union of Construction, Allied Trades and Technicians

Other organisations

Ad-Qual Group
Advanced Colour Coatings
Advanced Finished Technologies Ltd
ALPS Electric (UK) Ltd
Alvin J Wooley Associates
Architectural Building Products Ltd
BAA plc
Baxi Heating Ltd
Blue Circle Industries plc
Briggs Environmental Services
British Health and Safety Society
British Nuclear Fuels Plc
British Occupational Hygiene Society
British Safety Council
British Transport Police
Cancer Research UK
Castings Development Centre
Castings Technology International
Chartered Institute of Environmental Health
Chartered Institute of Water & Environmental Management
Chemical and Industrial Consultants Association
Chemical Hazards Communication Society
Corus Group PLC
Council of Independent Inspecting Authorities
Croner Publications
Cyclacel Ltd
Doctrine and Bond
Du Pont (UK) Plc
Electricity Association
Engineering Construction Industry Association
EnviroDerm Services

Environmental Services Association
Euro-Environmental Ltd
Friends of the Earth
Genesis Environmental Ltd
Greenpeace
Gwent Safety Consultancy
Hillsdown Holdings
ICI Chemicals and Polymers Ltd
ICI Chlor Chemicals
ICI Halochemicals
Industrial Health Control
Industrial Liaison Services
Innogy Ltd
Institute of Cancer Research
Institute of Occupational Medicine
Institute of Safety in Technology and Research
Institute of Trading Standards Administration
Institute of Wastes Management
Institution of Occupational Safety and Health
Linx Printing Tech
Metal Treatments Birmingham Ltd
Monitor Environmental Consultants
National Power Plc
National Society for Clean Air & Environmental Protection
Owen Williams Consultants
Omnikote Ltd
Pearlvale Ltd
Peateys Coatings Ltd
Petrochem Carless Ltd
Pfizer Ltd
QinetiQ Ltd
Refined Bitumen Association
Rhodia Chirex Ltd
Rolls Royce Plc
Royal Environmental Health Institute of Scotland
Royal Society for the Prevention of Accidents
Royal Society of Chemistry
Sandwell Metropolitan Borough Council
Sankey Safety Consultants
Scottish Power
Seeboard Plc
Sericol Ltd
Society of Occupational Medicine
Solvents Industry Association
S P Shutler Associates Ltd
Transco
UK Petroleum Industry Association
University of Birmingham, Institute of Occupational Health
University of Glasgow
University of Warwick

Water Research Council Plc
Water UK
Water Services Association of England and Wales
Yellowpatter Ltd

Individuals

Mr D J Bourton
Dr L Bowcock
Dr D H Lohmann
Mr A K Watson
Mr J Westmoreland

ANNEX 11: Reply form and questions for consideration

Advisory Committee for Toxic Substances
Proposals for changes to the Occupational Exposure Framework

PLEASE TYPE OR WRITE IN BLOCK CAPITALS

Name of Organisation or individual…….

Address…….
……..
……..
……..

Post Code…….….

Name of contact….……...

Telephone…….

Email……

QUESTIONS FOR CONSIDERATION

Please circle the appropriate answers and fill in the blanks, adding comments where necessary

Question 1 *(Paragraphs 34 - 37, page 10)*

a)Do you agree with the proposed new approach to adequate control?

Yes ***No***

Comments

Question 2 *(Paragraphs 39 - 44, pages 11 – 12)*

a) Do you agree with the proposed principles of good practice for the control of exposure to substances hazardous to health as listed in Box 1?

Yes ***No***

Comments

Question 3*(Paragraph 45, page 12)*

Do you agree with the proposed changes to the COSHH Regulations?

Yes ***No***

Comments

Question 4 *(Paragraph 46, page 13)*

Do you agree with the proposed changes to the COSHH ACoP?

Yes ***No***

Comments

Question 5

a) Do you agree with the definition of a WEL? *(Paragraphs 47 - 49, page 13)*

Yes ***No***

Comments

b) Do you agree with the proposed duties associated with the WEL? *(Table 1, page 13)*

Yes ***No***

Comments

c) Do you agree with the proposed criteria for setting WELs in Annex 3?
(paragraphs 50 – 56, page 14 and annex 3, pages 50 - 54)

Yes ***No***

Comments

<u>Question 6</u> *(Paragraphs 57 - 61, page 15)*

Do you agree with the proposals for good practice advice?

Yes ***No***

Comments

Question 7 *(Paragraphs 62 - 66, page 16)*

Will the new system make it easier for you to comply with the COSHH Regulations?

Yes ***No***

Comments

Question 8 *(Paragraphs 68 - 70, page 17)*

Do you agree with the proposal to use the COSHH Essentials system to provide the primary route to good practice advice?

Yes ***No***

Comments

Question 9 *(Paragraphs 71 – 76 page 19 and Table 2, page 20)*

Do you agree with the proposed method for publishing WELs?

Yes ***No***

Comments

Question 10 *(Paragraph 77, page 20)*

Do you agree with the proposals to link WELs, COSHH Essentials and EH64?

Yes ***No***

Comments

Question 11 *(Paragraphs 77 – 78, pages 20 - 21 and Boxes 3 and 4, pages 21 - 22)*

Is the link between the principles of good practice and good practice guidance, such as COSHH Essentials clear?

Yes ***No***

Comments

Question 12 ***- Integration of existing OELs into the new framework*** *(paragraphs 79 – 80, page 22)*		
Table 1 – OESs proposed for transfer into the new system as WELs *(Annex 7, pages 62 - 68)*		
Do you agree with the proposed approach for Table 1?	***Yes***	***No***
Do you agree with the substances and limit values in this table?	***Yes***	***No***
Comments		

Table 2a - MELs proposed for transfer into the new system as WELs *(Annex 7, pages 69 - 71)*		
Do you agree with the proposed approach for Table 2a?	***Yes***	***No***
Do you agree with the substances and limit values in this table?	***Yes***	***No***
Comments		
Table 2b - MELs going into the new system (flagged as under/needing further review) *(Annex 7, pages 72 - 74)*		
Do you agree with the proposed approach for Table 2b?	***Yes***	***No***
Do you agree with the substances and limit values in this table?	***Yes***	***No***
Comments		
Table 3a - OESs not proposed for transfer into the new system (*COSHH Essentials* can be used to select appropriate control measures) *(Annex 7, pages 75 – 80)*		
Do you agree with the proposed approach for Table 3a?	***Yes***	***No***
Do you agree with the substances in this table?	***Yes***	***No***

Comments		
Table 3b - OESs not proposed for transfer into the new system (gases) *(Annex 7, page 81)*		
Do you agree with the proposed approach for Table 3b?	***Yes***	***No***
Do you agree with the substances in this table?	***Yes***	***No***
Comments		
Table 3c - OESs not proposed for transfer into the new system (process-generated dusts, mists or fumes) *(Annex 7, page 82)*		
Do you agree with the proposed approach for Table 3c?		
Do you agree with the substances in this table?	***Yes***	***No***
	Yes	***No***
Comments		
Table 3d - OESs not proposed for transfer into the new system (Chemical Hazard Alert Notices (CHANs) would be produced for these) *(Annex 7, pages 83 -84)*		
Do you agree with the proposed approach for Table 3d?	***Yes***	***No***
Do you agree with the substances in this table?	***Yes***	***No***

Comments		
Table 3e - OESs not proposed for transfer into the new system (biocides no longer authorised for use or substances subject to the Montreal Protocol) *(Annex 7, page 85)*		
Do you agree with the proposed approach for Table 3d?	***Yes***	***No***
Do you agree with the substances in this table?	***Yes***	***No***
Comments		

<u>Question 13</u>

HSE would welcome views on the Regulatory Impact Assessment (RIA). *(Annex 8)*

Comments

Question 14

Additional comments

Question 15

In your view how well does this Consultative Document represent the different policy issues involved in this matter

a) Very Well ***b) Well*** ***c) Not Well*** ***d) Poorly***

Question 16

a) Is there anything you particularly liked about this consultation exercise?

Yes ***No***

If Yes – please let us know about it

b) Is there anything you particularly disliked about this consultation exercise?

Yes ***No***

If Yes – please suggest how we could do better in future consultative documents

Please return this form to:
Mr Tony Gissane
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CONSULTATIVE DOCUMENT

The full text of this and other Consultative Documents can be viewed and downloaded from the Health and Safety Executive web site on the internet:

www.hse.gov.uk/condocs/

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