

## Discussion document on Occupational Exposure Limits (OEL) framework

The Health and Safety Commission hopes that publication of this paper will stimulate consideration and discussion of the issues raised.

Any responses to the document would be welcome and should be sent to:

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to reach her no later than 30 July 2002

The Commission tries to make its consultation procedure as thorough and open as possible. Responses to this discussion document will be lodged in the Health and Safety Executive's Information Centres after the close of the consultation period where they can be inspected by members of the public or be copied to them on payment of the appropriate fee to cover costs.

Responses to this discussion document are invited on the basis that anyone submitting them agrees to their being 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 (Under the Code of Practice on Access to Government Information; Environmental Information Regulations 1992 and the Data Protection Act 1998). 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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## DISCUSSION DOCUMENT

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<sup>&</sup>lt;sup>1</sup> Annex 4 and 5 are available from the address on the front cover of this discussion document on request

## **EXECUTIVE SUMMARY**

1. This discussion document has been produced by the HSC's Advisory Committee on Toxic Substances. It considers ways to improve the contribution occupational exposure limits (OELs) make to the protection of workers' health. Under health and safety law, OELs are standards that determine the amount of a substance allowable in the workplace air. Under the current system in the UK there are two types of OEL, the Occupational Exposure Standard (OES) and the Maximum Exposure Limit (MEL). This document explains the difficulties with the current system, sets out objectives for a revised system and examines the merits of three options. It seeks your views on all these issues.

## The current system

2. The current system was set up when the Control of Substances Hazardous to Health (COSHH) Regulations came into force in 1989. During the last 12 years a number of difficulties have arisen with the present system:

- 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 and gaps in knowledge about the effects of chemicals;
- There are some incompatibilities with the recently established EC system for OELs; and
- Experience has shown that the OES/MEL criteria are not wide enough in their scope; some substances meet neither the OES nor MEL criteria, so it has not been possible to establish an OEL for some substances under the current system.

## **Objectives for a revised system**

3. The overall objective is a system in which OELs realise their potential as tools to help employers control exposure. To achieve this, a new system needs to:

- Make it easier for employers to understand the OEL system and take appropriate action in their workplace;
- Tackle the difficulties associated with the OES; and
- Improve the efficiency of the process for setting limits in the light of the newly established EC system.

## **Options for a new approach**

- 4. The document suggests three options for a new approach:
  - Option1: Maintain the present system with minor modifications to the criteria for setting limits;
  - Option 2: Good practice control advice supported by a single type of limit;
  - Option 2A: Good practice control advice supported by a two tier system which flags carcinogens.

## <u>Option 1</u>

5. This option proposes modification to the criteria for setting limits to provide a system compatible with the EC system and which has the MEL as a default, if the OES criteria is not met. This should provide a totally comprehensive system such that an OEL could be set for any substance. In other respects the OES/MEL system would remain unchanged.

#### Option 2

6. This option proposes to move away from the OES/MEL system to a system with a single type of limit explicitly linked to good practice advice on how to control exposure to the substance. The idea is that if employers apply the good practice, they will be complying with the limit. The proposal would not place new demands on employers but would reduce the need for monitoring and make it easier for employers to protect their employees. In the current COSHH Regulations OELs define adequate control of inhalation exposure, ie. they tell employers how much of the substance is allowed in the air breathed in by their employees. This option proposes a new definition of adequate control:

apply the principles of good occupational health/hygiene practice; and comply with the limit value.

7. Compliance with good practice would become the primary duty under the COSHH Regulations, with the OEL as a "back stop" which must not be exceeded. This is the most innovative feature of the proposal. The good practice requirement would represent what a good employer currently does to ensure that exposure to a substance with an OEL is not exceeded. It would reflect the nature of the hazard posed by the substance, so that, for example, advice for a substance which is a mild nasal irritant will be less stringent than that for a substance causing occupational asthma.

8. For substances which may cause cancer and consequently are subject to the EC Carcinogens Directive the good practice advice would need to follow the requirements in the Directive. These are to reduce exposure to "as low a level as is technically possible". It would therefore reflect the need for very stringent control and for employers to seek ways to improve control so as to further reduce exposure.

9. The current COSHH Regulations set out the principles of good occupational hygiene practice. This would not change. The detailed good practice control advice would be given in guidance and would explain how these principles are applied to specific task/substance combinations.

## Option 2A

10. An alternative approach to dealing with the legal requirement to apply very stringent control to substances which may cause cancer would be to develop a new two-tier system in which the OELs for carcinogens would be listed separately from other substances. This would provide an alternative, and more visible, way of flagging up these substances and distinguishing them from other chemicals. In all other respects this option is the same as Option 2.

## Criteria for setting OELs – Options 2 and 2A.

11. Two criteria are proposed, if an OEL cannot be set using the first criterion, the second would be used. The employers' duty associated with the OEL would be the same irrespective of the criterion used. The first criterion derives an OEL from scientific data on the health effects of the substance and is aimed at identifying a level at which there is no evidence of effects on human health, but, because of the uncertainties which generally surround our understanding of the health effects of chemicals, would not purport to be a "safe" limit. The second criterion bases an OEL on what is considered to represent good control, taking account of the severity of the likely health hazards and the cost and effectiveness of control solutions. As with the current system, OELs would be established by the HSC, following public consultation.

## **Comparison of the 3 options**

12. Option 1 would retain a system familiar to health and safety professionals, but would not address other concerns as it would retain the concept of the OES as a "safe" limit and would not help employers understand what they have to do to comply with OELs. In contrast, Options 2 and 2A propose a simpler, more user-friendly system, by providing a direct link to good practice control advice. This would set out in straightforward, practical terms what employers have to do to comply with the OEL. For all options, OELs established by the EC would normally be incorporated directly into the Great Britain system saving HSE and stakeholder resource in not having to carry out an additional review.

#### Impact of Options 2 and 2A on existing OESs and MELs

13. The document suggests two ways forward:

- incorporate all the existing limits into the proposed new limit system, be that 2 or 2A (unless there is positive evidence to indicate the limit is unsound, ie. adverse health effects might be predicted to occur at the level of the limit); or
- incorporate only those substances for which HSE has supporting information showing that the limit would clearly meet the proposed new criteria. The second approach would reduce the list of OELs by about 2/3.

In either case there would be a need to ensure that, overall, standards are maintained.

## **Providing Good Practice Advice**

14. The proposal is to link OELs to COSHH Essentials. This is a guidance package which leads employers through a simple generic risk assessment scheme to practical, easy to understand guidance on the controls they need. Evaluation shows that employers find it easy to use and many make improvements to their controls. COSHH Essentials guidance covers most uses of substances which currently have an OES. For substances that currently have a MEL, specific good practice advice would be prepared in the same format as that in COSHH Essentials and incorporated into the system.

15. The publication *EH40 Occupational Exposure Limits*, which contains the current list of OESs and MELs, would be modified by the addition of information to direct the reader to the

appropriate COSHH Essentials control advice for the substance. This could not include every conceivable use but would cover the way the substance is normally used and supplied.

16. In addition it is proposed to develop a fully interactive electronic system, freely available on the Internet, that links COSHH Essentials to OELs. An internet version of COSHH Essentials is scheduled to be launched in April 2002.

## INTRODUCTION

17. Chemicals have brought society considerable economic and social benefits. They and their products and technologies are essential to most manufacturing and many service operations and to all of us in our daily lives. But chemicals can harm human health and the environment and therefore risks from their use have to be assessed to ensure that exposures are properly controlled.

18. To achieve this protection a complex array of legislation has evolved, mainly over the last 30-40 years, governing the supply and use of chemicals. European Community schemes have come to dominate domestic legislation on chemical supply. Suppliers of chemicals are required to give their customers information on hazards posed by the chemical and protection measures. They also have to assign a "risk phrase" to the chemical, which gives information on the nature of the hazards it poses (eg. May cause cancer, toxic by inhalation).

19. Worker protection legislation has largely been the responsibility of individual member states. But this is changing with the recent adoption of the Chemical Agents Directive, which has started to harmonise legislation in this area. This follows the same principles as existing UK legislation. Employers are required to assess the risks arising from the chemicals in their workplace and apply control measures to protect their employees and the public.

20. To guide decisions on controlling individual chemicals Great Britain, in common with many industrialised countries, established a system of occupational exposure limits (OELs). They were originally developed as a tool to help professional occupational hygienists decide what controls were needed and then monitor to see if they were effective. In Great Britain, they are an important part of the legislative arrangements, in that they define, under health and safety legislation, adequate control by inhalation.

21. The Health and Safety Executive (HSE) and stakeholders consider OELs to be an important tool for achieving health protection. In consequence, HSE has committed considerable resource over a number of years to a rolling programme of setting OELs. But recent investigations by HSE have shown that OELs are not being used by much of industry and difficulties have arisen with the procedures for setting OELs. The Health and Safety Commission (HSC) wishes to ensure that a robust cost effective system is in place for setting OELs and that they realise their maximum potential as tools to help employers control exposure. To achieve this the HSC's Advisory Committee on Toxic Substances (ACTS) established a Working Group to consider how the OEL system could be improved.

22. This discussion document gives the results of their deliberations. It:

- summarises the current system for setting OELs;
- explains the difficulties with the current system;
- presents a summary of the evidence that OELs are not being used by many firms handling chemicals;
- explains how HSE inspectors have used OELs in enforcement:
- gives a summary of the results of a stakeholder survey on what they would like from an OEL system;
- sets out objectives for an effective OEL system; and
- examines the merits of three options for revising the OEL system.

23. The options cover two equally important aspects of the OEL system – procedures for setting OELs and the way OELs are integrated with other guidance on controlling chemicals and how this information is presented to duty holders.

## **Revitalising Health and Safety**

24. This review of the OEL system is in tune with the Revitalising Health and Safety Strategy initiative, which recognised the need for new energy and a new strategic direction to improve occupational health and safety over the early part of the 21st century. The discussion document explains how proposed options for the OEL system can make a real contribution to 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

25. Discussion Documents are issued to explore and develop various policy options and to draw in new ideas. 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.

26. Please consider the analysis of the current system and proposals for a new OEL framework presented in this discussion document and let us have your views. We would like all replies to arrive no later than **31 July 2002.** HSE will acknowledge all responses but it will not be possible to give detailed relies to them all. We may also contact you again if, for example, we have a query.

27. The Working Group will give full consideration to the substance of arguments in the responses to this document alongside other research on the operation of the current system and make formal proposals for changes to the OEL framework. Subject to approval by HSC, these will be published in a formal consultation document in 2003. Any changes to the COSHH Regulations would not occur until 2004.

28. Thus the issues raised in this discussion document will not be implemented in the proposed COSHH Regulations 2002. Nevertheless the new COSHH Regulations, the imminent launch of an Internet version *COSHH Essentials: Easy steps to control chemicals* and these proposals from part of a new and developing approach to the control of chemicals in the workplace.

29. Specific questions are listed in bold text throughout the document and in the tear-out reply form at the back of the document (Annex 3). 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.

30. This discussion document may be freely copied and is also available on the HSE website at <u>www.hse.gov.uk/condocs/</u>. Alternatively you may request further copies from HSE books from the address on the back cover.

31. The Health and Safety Commission 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 discussion document will be lodged in HSE's Information Centre 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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33. The Information Centres are located at:

London Information Centre	Sheffield Information Centre
Rose Court	Broad Lane
2 Southwark Bridge	Sheffield S3 7HQ
London SE1 9HS	

34. 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.

35. 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

36. The background and role of OELs in the UK before the implementation of the Control of Substances Hazardous to Health Regulations (COSHH) is set out in Box 1. These Regulations, made under the Health and Safety at Work Act, came into force in October 1989 following extensive consultation and negotiation throughout the 1980s. Launching the Regulations the then Secretary for State, Norman Fowler, told the press conference "about 50 sets of outdated, restricted and inflexible regulations and orders are being replaced with a clear statement of good occupational hygiene practice. This is the kind of deregulation we need in the safety and health field. With COSHH we are getting the best of both worlds: simplification of the law and extension to all employees of the protection afforded by specific health provisions".

37. The regulations provide a useful tool of good management setting out seven basic 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, then ensuring exposure is adequately controlled. The control advice set out in previous guidance notes became incorporated into the COSHH Approved Code of Practice (ACoP).

38. COSHH introduced substantial changes to the system of OELs. Control limits were replaced by Maximum Exposure Limits (MEL) and recommended limits by Occupational Exposure Standards (OES). Both OESs and MELs are expressed as airborne concentrations averaged over a period of time, either a long term exposure limit (8 hour Time Weighted Average (TWA)) or a short term exposure limit (15 minute reference period). The duties associated with these two types of limit are summarised in Box 2.

## Box 1

## OELs in Great Britain before implementation of the COSHH Regulations

In Great Britain airborne standards for the workplace were established for a few substances such as cotton dust and asbestos back in the 1930s, but the history of systematic setting of OELs began when the American Conference of Governmental Industrial Hygienists (ACGIH) published, in 1948, the first list of OELs, known as the Threshold Values (TLVs). Subsequently the list has been updated annually.

The ACGIH introductory text explains that TLVs are intended for use in the practice of industrial hygiene as guidelines or recommendations in the control of potential workplace health hazards. This text states that they are not fine lines between safe and dangerous concentrations and although serious adverse health effects are not believed to be likely as a result of exposure at the TLV, the best practice is to maintain concentrations as low as practical. TLVs are set by expert committee established and issued by the ACGIH, they do not have any legal status.

Great Britain, in common with many industrialized countries, adopted this list. It was published annually from 1969 until 1980. Following the establishment of the Health and Safety Commission (HSC), Control Limits were introduced, in 1979, for a limited number of substances. HSC's policy in relation to the control of hazardous substances as set out in EH 15/79 was that exposure should be kept as low as is reasonably practicable by the application of occupational hygiene principles and techniques appropriate to the route of entry into the body (inhalation, ingestion or absorption through the skin.)

During the early 1980s, HSC and its Advisory Committee on Toxic Substances (ACTS) established their own system for setting exposure limits. This culminated in the publication in 1984 of the first issue of *EH40 Occupational Exposure Limits 1984*. This contained two types of OEL – Control Limits and Recommended Limits.

Control Limits were adopted by HSC after detailed consideration of the available scientific and medical evidence and were deemed to be 'reasonably practicable' for the whole spectrum of work activities in Great Britain. Exposure was not to exceed control limits and should also be reduced still further until the point is reached where the costs of control measures were not justified in terms of the additional reduction in risk.

Recommended Limits, based on the advice from ACTS and the newly established Working Group on the Assessment of Toxic Chemicals (WATCH) were considered to represent good practice and realistic criteria for the control of exposure, plant design and use of personal protective equipment. EH 40/1984 states "HSE inspectors will use these exposure limits as part of their criteria for assessing compliance with the Health and Safety at Work (HSW) Act and other relevant statutory provisions." EH40 guidance continues "exposure to all substances should be kept as low as is reasonably practicable at all times. In addition, for listed substances, the exposure limits specified should not normally be exceeded. To help in maintaining operational control it may be appropriate to select action levels, ie arbitrary levels at which remedial action is necessary in order to ensure that exposure will remain within the relevant limits".

Although the introductory text to EH 40/84 states Recommended Limits are ACTS recommendations, in fact the list was based on the ACGIH 1980 TLV list. From then on, WATCH/ACTS embarked on a programme of reviewing these limits and establishing new ones. Agreed changes were published annually in Toxic Substances Bulletin and then incorporated into the next edition of EH40.

Box 2 Duties associated with OESs and MELs			
Occupational Exposure Standard	Maximum Exposure Limit		
Standard must be met	Limit must be met		
No requirement to further reduce exposure	Exposure must be reduced below the limit so far as is reasonably practicable		
Standard can be exceeded providing steps are taken to meet it as soon as reasonably practicable	Limit must not be exceeded		

39. HSC also established specific criteria for setting OESs and MELs. In essence, OESs are set for substances for which it is possible to identify, with reasonable certainty, a level of exposure at which it is judged there is no significant risk to health and with which compliance by industry is reasonably practicable. Where such a level cannot be identified and the chemical has serious health implications for workers, then a MEL is considered. The criteria are reproduced in Box 3.

## Box 3 Indicative criteria for setting OESs and MELs

For a substance to be assigned an OES it must meet **all** the following three criteria:

<u>Criterion 1</u>: The available scientific evidence allows for the identification, with reasonable certainty, of a concentration averaged over a reference period, at which there is no indication that the substance is likely to be injurious to employees if they are exposed by inhalation day after day to that concentration: and

<u>Criterion 2:</u> Exposure to concentrations higher than that derived under criterion 1 and which could reasonably occur in practice, are unlikely to produce serious short or long-term effects on health over the period of time it might reasonably take to identify and remedy the cause of excessive exposure; and

<u>Criterion 3:</u> The available evidence indicates that compliance with the OES, as derived under criterion 1, is reasonably practicable.

For a substance to be assigned a MEL it must meet **either** of the following criteria:

<u>Criterion 4:</u> The available evidence on the substance does not satisfy criterion 1 and/or 2 for an OES and exposure to the substance has, or is liable to have, serious health implications for workers; or

<u>Criterion 5</u>: Socio-economic factors indicate that although the substance meets criteria 1 and 2 for an OES, a numerically higher value is necessary if the controls associated with certain uses are to be regarded as reasonably practicable

40. The OES is widely assumed to be a "safe" limit, although the criteria state they are based on *available* evidence and that there is *no indication* of adverse health effects. Inevitably there are areas of uncertainty inherent in the assessment of every substance, such that cast-iron guarantees can never be given with absolute security. However, the concept that

the OES is reliably known to be a "safe" limit is strengthened by the legal duties - that employers are required to meet the standard, do not have to go below it and it is permissible to exceed it provided the employer takes appropriate action to remedy the situation as soon as is reasonably practicable (Box 2).

41. While the original concept behind the ACGIH TLVs was to provide tools for occupational health and safety professionals, under the COSHH Regulations OELs became legal limits which all employers have to understand and apply.

42. When the COSHH Regulations were implemented all the Control Limits (except asbestos and lead which have their own regulations) automatically became MELs. The list of Recommended Limits was reviewed to remove any limits which manifestly did not meet the new OES criteria. These were published as a separate table in EH40 as advisory limits (1989-1993). Reviewing these substances formed a major part of the substance review programme from 1989 to around 1994. The remainder (approximately 500) were converted directly into OESs without any thorough scientific review by ACTS, although some had been subject to a brief examination in the years immediately preceding the introduction of the COSHH Regulations.

## **Procedures for Setting Limits**

43. The introduction of OESs and MELs with the COSHH Regulations also brought about a reshaping of the way in which OELs were set. The reshaped system has stayed relatively constant since the introduction of the COSHH Regulations. OESs and MELs are set by HSC and therefore have multipartite consensus and endorsement. HSC is advised by ACTS and its technical subcommittee, the Working Group on Assessment of Hazardous Chemicals (WATCH).

44. To initiate the process of setting an OEL, WATCH first considers a package of scientific/technical information on a chemical. If the committee considers it meets the criteria for an OES, it will recommend a value to ACTS. If it doesn't, it will refer the substance to ACTS for further consideration, normally the setting of a MEL. ACTS considers proposals for OESs; if the WATCH recommendations are agreed, the proposals are subject to public consultation. Proposals are published in an annual supplement to *EH64 Summary criteria for OELs*, this sets out the physico-chemical properties of the chemical, a summary of the available toxicological data, information on exposure and the basis for the limit. HSC also issues a separate consultation document containing the same information. Finally, and subject to consultation, HSC is invited formally to endorse the proposals, which are then published in *EH 40, Occupational Exposure Limits*.

45. If ACTS agrees a MEL is appropriate, HSE is normally asked to issue a Chemical Hazard Alert Notice (CHAN), to inform industry that there are serious health hazards associated with the chemical. These are issued because it may take some time to establish a MEL and it is important to inform industry of health risks. If only a few workers are exposed to the chemical, ACTS may consider the resources needed to set a MEL are not justified and employers are expected to establish suitable control regimes on the basis of the information in the CHAN.

46. If ACTS decides to set a MEL, HSE will gather the information on good occupational practice in relation to the usage of the chemical and make proposals for a MEL. A Regulatory Impact Assessment is prepared for each MEL proposal which sets out the socioeconomic factors of balancing risks to health against the costs and effort of reducing exposure. Once ACTS has agreed a MEL proposal, permission is sought from the HSC to consult on it. Finally, HSC informed by the outcome of the consultation, decides whether or not to endorse the MEL. MELs, like OESs, are published in *EH 40, Occupational Exposure Limits*. From the first consideration of a substance by WATCH to the implementation of a MEL typically spans 3-5 years.

## OELs and the EC

47. During the last decade the EC has established its own procedure for setting OELs. A Scientific Committee on Occupational Exposure Limits (SCOEL) has the remit to make recommendations for health-based OELs for inhalation exposure, based solely on current scientific evidence, such that it is judged that exposure repeated for 8 hours per day, 5 days a week over a working lifetime will not result in adverse effects to workers or their progeny. Members of SCOEL are scientific experts nominated by member states for their expertise; they do not represent national positions. To guide its deliberations SCOEL has developed a series of Key Documents, which set out the general principles and approaches taken by SCOEL in dealing with setting OELs. These have been summarised in *Methodology for the derivation of occupational exposure limits*.

48. This document defines EC OELs as broadly falling into two categories:

- **'health based' OELs**: where the total available scientific data base leads to the conclusion that it is possible to identify a clear threshold dose below which exposure to the substance in question is not likely to lead to adverse health effects. In the EC system these become Indicative Occupational Exposure Limit Values (IOELVs).
- **'pragmatic' OELs:** where for some adverse effects (eg genotoxicity and carcinogenicity) it is not possible on present knowledge to define a threshold of activity and therefore any level of exposure represents a risk. In the EC system these become Binding Occupational Exposure Limit Values (BOELVs).

49. Summaries of the SCOEL proposals for each substance are made available to government officials in EC member states, industry and workers representatives for comment on the scientific rationale for the limit proposal. SCOEL considers any comments received, then the proposals go forward to a tripartite group of government, employer and employee representatives, which consider issues of feasibility. Finally the proposals go the European Commission for inclusion in an Indicative Occupational Exposure Limit Value Directive. The proposal for a European Commission Directive is put formally to a committee of Member State representatives (often referred to as a Technical Progress Committee (TPC)) which acts by qualified majority voting to adopt the limit proposals in the proposed Directive.

50. There were two EC Indicative Limit Value Directives, issued in 1991 and 1996, which between them contained what were then termed Indicative Limit Values (ILVs) for 50 substances. The Directives required Member States to consider these ILVs in setting national

limits, but there was no obligation to set a limit. However, the adoption of the Chemical Agents Directive (CAD) changed all this. Under this Directive there is an Indicative Occupational Exposure Limit Value (IOELV) Directive. The IOELV Directive requires Member States to set a limit for all substances in the Directive, taking account of the IOELV. The CAD sets out the requirements on EC Member States in relation to compliance with limits established for substances with an IOELV. However, SCOEL's advice on the application of OELs is: "It should, however, be emphasised that it is always prudent to reduce exposure as far below OELs as can reasonably be achieved, in order to provide the greatest degree of health protection".

51. BOELVs are set through a different process of consideration at EC level. Member states are required to set a limit based on, but not exceeding, the value of the BOELV. So far only a few BOELVs have been set either under CAD or under the Carcinogens Directive. Although the EU has these two types of limit the duties on employers for both IOELVs and BOELVs set under CAD are the same. For BOELVs set under the Carcinogens Directive the duties in that Directive apply, ie. to reduce exposure to as low a level as is technically possible.

## **OPERATION OF THE CURRENT SYSTEM AND THE NEED FOR CHANGE**

#### Introduction

52. The key issue of concern is whether the current system of OELs is effectively delivering worker protection. There is very little information on the impact of individual OELs on the behaviour of firms, although there is some evidence that once a MEL is proposed firms aware of the proposal will take steps to improve controls. However a survey of a random selection of chemical users showed that the vast majority of firms are unaware of OELs and consequently they play no part in decisions they make on what control measures to use. Thus, although professional occupational hygienists have made good use of OELs, there are serious doubts as to their contribution to worker protection in the majority of firms using chemicals. In addition, some of the concepts underlying the OES/MEL system have not proved robust. These issues are further explored in the paragraphs below.

#### Problems with the current OEL system

53. ACTS have identified five main concerns with the current OEL system:

- The concept of the OES as a "safe" limit is not sustainable.
- The indicative criteria for setting limits have not proved comprehensive;
- The limit setting process and use of OELs in the workplace is resource intensive;
- The system is not entirely compatible with IOELVs established by the EC; and
- Lack of awareness and understanding by employers, particularly in small firms, of OELs and how to comply with them.

#### The concept of the OES as a "safe" limit is not sustainable

54. As discussed in paragraph 40, OESs are considered by many to be "safe" limits, a view reinforced by the fact that once a limit has been met, the employer has fulfilled his legal obligations. Around 350 OESs are unchanged from the values adopted by HSE from the 1980 TLV list. Although HSE has always acted when information has come to light positively indicating that an OES for a particular substance is not appropriate, ACTS/WATCH have not made an assessment of these 350 substances to show the OES criteria are met. In addition the concept of safe is taken by the public and media to imply that government has all the information needed to show that harm will not occur. Since this is rarely, if ever, the case the concept underlying the OES as a "safe" level at which there is no need to further reduce exposure needs a thorough re-examination.

55. The concept of an OES as a "safe" limit offering complete health protection for all individuals is increasingly becoming regarded as no longer tenable, given that for most chemicals there are gaps in scientific knowledge on the potential health effects, and there is also a general lack of information on the ways in which different individuals may respond. Furthermore, the suggestion that employers do not need to further reduce exposure below the OES is out of line with other major limit setting bodies. As explained in Box 1 the ACGIH states "They are not fine lines between safe and dangerous concentrations and although serious adverse health effects are not believed to be likely as a result of exposure at the TLV, the best practice is to maintain concentrations as low as practical." Similarly SCOEL, the EC exposure limit setting committee recommends "It should, however, be emphasised that it is always prudent to reduce exposure as far below OELs as can reasonably be achieved, in order to provide the greatest degree of health protection".

#### *The indicative criteria for setting limits have not proved sufficiently comprehensive*

56. WATCH is required to apply the indicative criteria (see Box 3), when setting OESs and MELs. Experience at WATCH has revealed that some substances do not adequately meet the criteria for either an OES or a MEL, suggesting that the criteria are not comprehensive. In essence, an OES can only be set if WATCH can identify a level judged to be no concern to human health and compliance by industry is reasonably practicable. Where this is not possible, a MEL is considered, but not all such substances have serious health implications for workers, (one of the criteria for setting a MEL). For example, although there were no carcinogenicity studies on bromochloromethane, evidence on similar chemicals raised concern that it might be carcinogenic in animals. In view of this, WATCH agreed that the criteria for an OES were not met. However, the uncertainties in relation to the possibilities of serious health effects in humans were such that WATCH felt that the criteria for establishing a MEL were not met.

#### *The limit setting process and use of OELs in the workplace is resource intensive;*

57. There are approximately 100,000 substances registered in the EC market, of which 30,000 are marketed in volumes of more than 1 tonne. EH40 contains limits for 517 substances. Under the current limit setting process, the resource available in HSE to prepare the detailed documentation for limit proposals and WATCH/ACTS committee time for considering them are such that only 10-20 limits can be set each year. In addition resource is needed to develop, validate and publish measurement methods and carry out the consultation process. Some efficiencies can be gained by using documentation prepared by other limit setting bodies (eg. The Dutch DECOS and the German MAC Commission). In principle greater co-operation between countries with the expertise to establish OELs would reduce resource commitment.

## The system is not entirely compatible with IOELVs established by the EC

58. The first IOELV Directive, implemented in December 2001, contains limits for 63 substances including some, but not all, of the substances in the ILV Directives. Many IOELV proposals meet the criteria for an OES, however for a few substances WATCH considered that criterion 1 for an OES was not met (see Box 3). Thus although SCOEL had concluded that a health based limit could be set, WATCH did not agree, as a consequence a MEL was set for these substances. A further IOELV Directive is in the pipeline, and it is expected that more will emerge on an ongoing basis, so there is a need to develop a limit system under COSHH which will readily incorporate IOELVs. The alternative is for WATCH and ACTS to spend time reviewing data which has already been considered in the EC by SCOEL. This is not a sensible use of resources.

## Lack of awareness and understanding by employers, particularly in small firms, of OELs and how to comply with them.

59. Larger chemical companies and health and safety professionals have no difficulty with the requirements of COSHH to assess risks from chemicals, decide on suitable control measures, and implement and monitor them. But what about the many thousands of smaller firms which use chemicals? A survey carried out by the HSC showed that many small firms wanted to be told exactly what they need, and do not need, to do. To explore small firms' needs in relation to controlling chemicals, HSE carried out market research to determine how firms decide what controls to use and to measure their understanding of the COSHH Regulations and OELs. Managers responsible for health and safety were interviewed at 1000 firms which use chemicals, 400 interviews were with firms engaged in occupations which would involve some exposure to chemicals (all user group) and 600 with firms in which chemicals were in daily use (heavy user group). The profile of respondents reflected that of UK industry in that most respondents (75% from all user group and 57% from heavy user group) were from firms with 10 employees or less. A smaller survey was also carried out on 150 Trade Union representatives.

60. The results of the survey were encouraging in that the majority of chemical users are taking steps to control their employees' exposure, although, of course, we had no information on the suitability or effectiveness of the controls used. This suggests that any failure properly to control chemical exposure arises from a lack of knowledge, rather than an unwillingness to protect employee health.

61. However the respondents' knowledge of COSHH and OELs was very limited. When respondents were asked what legal requirements exist for establishments which manufacture or work with chemicals only 16% of the all user group and 30% of the heavy user group mentioned either complying with COSHH or OELs. Although around 2/3 of respondents claimed to understand the term occupational exposure limit, only 12% of the all user group and 28% of the heavy user group mentioned monitoring (either regular or ad-hoc) when asked how they would assess whether an OEL was being met. Awareness of the different duties associated with OESs and MELs and of the two reference periods, the 8 hr TWA and 15 minute reference period was vanishingly small among the all user group. The Trade Union representatives had slightly greater understanding of OELs than the managers in these small firms.

62. Thus it is apparent that OELs play little part in the decisions these firms make on the management of risks from chemicals. It follows that attempting to move OELs from tools for health and safety professionals to limits which all chemicals users have to understand and apply has not been a success.

## Stakeholder views on the existing OEL system

The study in the previous paragraphs explored the use of OELs by a random selection 63. of chemical users. In addition, HSE investigated stakeholder opinions and knowledge of current OEL system and what additional information they would like, by placing a questionnaire website Toxic Substance Bulletin on HSE and in (www.hse.gov.uk/toxicsubstances). The aim was to get views from a range of stakeholders with an interest in OELs. Nearly 500 responses were received from wide range of stakeholders - employers, safety representatives and health and safety professionals. The analysis of the responses is at Annex 1. In summary, the majority of the respondents (89%)

had heard of OELs before answering the questionnaire and 60% use them in the workplace. Most who do not use OELs say they use controls commonly used in their industry. Nearly half the total sample (48%) take more care with substances with an OEL than those without. Many respondents do not treat substances with an MEL differently from those with an OES, although some pointed out that they treat OESs as strictly as MELs. The questionnaire asked respondents to select from a list the four pieces of information they considered would most help them to control chemicals. The most popular selections were for advice on health effects, how to use a substance safely, exposure limits and how to measure substances. Although exposure limits and advice on measurements were popular, less than 60% of the sample (which contained many health and safety professionals) currently take measurements in their workplaces.

## HSE's enforcement of OELs under the COSHH Regulations

64. To help the formulation of proposals for a revised OEL system, HSE analysed the type of enforcement action taken under COSHH to control exposure and in particular the role of OELs. The full analysis is available on request. In summary, planned activities and campaigns have a pronounced effect on enforcement activity and, where these are concerned with activities creating exposure by inhalation, they tend to focus on the more serious health effects associated with MELs. It is also clear that inspectors are more likely to take enforcement action, particularly in relation to control, when clear guidance is available on good practice, which tends to be produced for substances with MELs. The existence of OELs is often not used directly in this process, but will exert an indirect influence arising from the following sequence of events:

- OEL set;
- control standards required for compliance established;
- guidance issued publicising standards (this is generally given more precedence for MEL substances);
- inspectors enforce on control standards.

# Do you agree with the concerns about the current system and the need for change?<sup>2</sup>

## Do you have any other concerns about the current system?

<sup>&</sup>lt;sup>2</sup> A tear out reply form is provided in Annex 3 for your convenience

## **CRITERIA FOR A NEW APPROACH**

## Introduction

65. As explained in the preceding sections, ACTS consider that OELs are not realising their potential as tools to help employers control exposure. To deliver improvements ACTS agreed there are three main issues which must be tackled:

- the establishment of an effective and efficient system for setting occupational limits;
- integration of OELs into the COSHH Regulations so that they are clearly seen as one element, albeit an important one, in the range of actions which employers have to take to control exposure; and
- a strategy for making employers, safety representatives and trade associations aware of OELs and what needs to be done to comply

66. It is essential that all three issues are considered if OELs are to contribute to worker protection. For example, a highly effective system for setting OELs will achieve nothing if employers are unaware of them. Equally a well publicised OELs will not achieve much if employers do not understand how they relate to COSHH and /or the limits are not robust.

## **ACTS Working Group**

67. To address these issues ACTS established a Working Group with the following remit:

To develop a revised OEL framework, within the context of the COSHH control hierarchy, to provide a robust tool for the management of chemicals in the workplace thereby contributing to the effective protection of workers' health.

## **Objectives for a new approach**

68. The first task of the Working Group was to establish objectives for OELs, which would address the three issues identified in paragraph 65, above. These objectives provide a yardstick against which proposals for a new framework can be assessed. ACTS supported a recommendation from the Working Group that OELs should:

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

• provide incentives to reduce exposure.

## Key Objective 1 - OELs should control risks to health

69. OELs should provide standards which can be used, along with other information on a substance, to decide on appropriate control measures and to assess the adequacy of measures in place.

## Key Objective 2 - OELs should be readily understood/accessible

70. The OEL framework must be based on a clear and coherent set of concepts which employers and employees will understand. But OELs require skilled understanding to put them in proper context in COSHH and therefore the application in the workplace may need professional input. The presentation of the OELs and other substance data pertinent to control under COSHH must take advantage of the opportunities offered by electronic media but also be available to those without IT access.

## Key Objective 3 - OELs should be legally enforceable

71. OELs must be considered as an integral part of the COSHH hierarchy of control measures for health protection. They should provide legally enforceable standards for adequacy of control by inhalation. They are for use when prevention of exposure is not reasonably practicable.

## Key Objective 4 - OELs should be comprehensive

72. The OEL framework must be comprehensive ie. capable of application to all substances. It should be capable of application to generic groups of substances. It must be developed and presented in a way that will not encourage employers to use substances without OELs and which have not been adequately evaluated for the potential to cause adverse effects.

#### Key Objective 5 - OELs should comply with EC legislation

73. OELs must be compatible with the EC IOELVs and BOELVs such that the EC limits can be readily incorporated into Great Britain legislation without necessarily undergoing detailed re-assessment.

## Key Objective 6 - OELs should be flexible and able to take on board new developments in science and technology

74. The framework must be sufficiently flexible to incorporate developments in hazard and exposure assessment eg rapidly updating guidance with changes in technology.

#### Key Objective 7 - OELs should provide incentives to reduce exposure

75. As set out under objective 3, OELs must be seen as an integral part of the COSHH hierarchy of control measures for health protection. They should provide incentives for continuous improvement.

## Do you agree with these key objectives for a new approach?

## Do you think additional objectives are needed?

## **OPTIONS FOR A NEW APPROACH**

## Introduction

76. The Working Group examined the existing system against the 7 objectives agreed by ACTS and decided that *status quo* was not an option. However the working group did consider that it would be possible to make minor modifications to the indicative criteria used to set limits (see box 3), to overcome the difficulties encountered with the current process of setting limits – see paragraphs 56 & 58. Thus:

## • Option 1: Maintain the present system with minor modifications to the indicative criteria

77. The Working Group then considered a number of options for making fundamental changes to the OEL system. The starting point for the group's discussions were the need to develop a system that will contribute to delivery of real improvements in chemical control in the workplace. After discussion of a range of possibilities the working group decided to seek wider views on two closely related options, referred to in this discussion document as options 2 and 2A:

## • Option 2: Good practice supported by a single limit

## • Option 2A: Good practice supported by a two tier system which flags carcinogens

78. The following paragraphs discuss these options in detail. Then follows a table showing the extent to which the options meet the 7 criteria set out in paragraph 68 - 75. Finally there is a table assessing the potential for the options to contribute to aims set out in the Revitalising Health and Safety Strategy statement.

## Option 1: Maintain the present system with minor modifications to the indicative criteria

79. This option proposes minor modifications to the indicative criteria for setting OESs and MELs to address the limitations identified in paragraphs 56 & 58 by:

- using the MEL as a default, so that all substances which do not meet the OES criteria automatically default to a MEL, irrespective of the extent of health concerns; and
- adding an additional criterion for an OES, that an IOELV proposal is adopted as an OES

80. This option would maintain the current OES and MEL system and the duties under the COSHH Regulations associated with them. It therefore has the advantage of maintaining a system familiar to occupational health and safety professionals. But while this approach would address the concerns about the limit setting process it would not address the difficulties many small firms have with understanding and applying OESs and MELs.

81. Furthermore, although this approach would be simple to implement, it would result in an increasingly confused and compromised list of OESs and MELs, with some substances with less serious or uncertain health concerns getting a MEL (eg. bromochloromethane, see paragraph 56), with attendant requirements to reduce exposure as low as is reasonably practicable. On the other hand substances with IOELVs would have to be assigned an OES, although for some substances e.g piperazine, WATCH/ACTS considered a MEL to be more appropriate. For these reasons, this option would almost certainly result in inconsistencies between existing OESs, those set from any "domestic" programme and those emanating from the EC.

82. Options 2 and 2A explicitly link OELs to good practice. Since Option 1 would result in an increasingly confused and compromised list of OELs, it would be very complex to attempt to explicitly link good practice advice to OELs, although existing advice on control would continue to apply.

## **Option 2:** Good practice supported by a single limit

83. Although, as explained in the background, OELs were originally developed for professional occupational hygienists, the implementation of COSHH Regulations made them limits that all employers had to apply to any work involving chemicals. However the OEL perception study (paragraphs 59 - 62) showed that the majority of small firms are unaware of OELs and, of those that are aware, many have little idea how to determine whether they are complying with the limit. Even if HSE developed a communication strategy that resulted in a much higher awareness of OELs among small firms, this would not, of itself, improve control. Most firms do not have access to the specialist advice needed to measure exposure, compare data with OELs and decide whether changes to controls are needed.

84. To overcome these limitations, which are inherent in any list of OELs, the Working Group propose that OELs should be explicitly linked to advice on good practice. The aim being that if firms apply the good practice, they would be complying with the OEL. It would not place new demands on employers, but it would reduce the need for monitoring and make it easier for employers to protect their employees. In addition, the good practice advice would set OELs into context of other COSHH requirements and emphasise that control is not just about using engineering means to reduce exposure, but that process design, housekeeping and maintenance are all important considerations.

85. The principle of linking good practice advice to OELs would apply irrespective of whether a single or dual limit system was adopted, providing suitable criteria were established for setting OELs. This option develops the argument for a single limit, option 2A considers a dual limit system.

86. The Working Group recognised that many employers are unaware of the difference between OESs and MELs and that a considerable proportion of those that are aware, treat both types of limit alike when making decisions on control measures. In addition, discussions with stakeholders on whether an OES or MEL is appropriate have proved on a number of occasions to be contentious and time consuming. Finally the present criteria have not proved comprehensive (see paragraph 56), with some substances not meeting the criteria for either an OES or MEL. One obvious solution is to have a single type of limit. A single type of limit which represented an exposure level that should not be exceeded would be clear, straightforward and easy for duty holders to understand.

87. Inevitably a single type of limit would result in a need to change the definition of adequate control under COSHH, since neither the OES or MEL requirements are applicable to all substances. The proposed scientific basis and associated criteria for setting a new single type of limit are discussed in paragraphs 98 - 108. The Working Group propose the following definition for inclusion in COSHH Regulation 7:

## • apply the principles of good occupational health/hygiene practice; and comply with the limit value

88. This option explicitly links OELs to good practice and makes compliance with good practice the primary duty under COSHH with the limit being a "back stop" which must not be exceeded. It could be argued that the proposal to link control requirements to OELs would mean that all new limits would become more like MELs with the requirement to reduce the inhalation exposure level so far as is reasonably practicable below the established limit. This is not what the Working Group intends. The good practice requirement would represent what a good employer currently does to ensure that exposure to a substance with an exposure limit is not exceeded. The good practice information would include advice on design, degree of containment, maintenance, training, supervision and housekeeping. Its intention is to eliminate bad control and poor work practice rather than force employers towards 'gold plating' targets. HSE would not normally expect employers to have higher standards of control than those set out in the good practice.

89. In effect the current COSHH Regulation 7, in setting out the actions that employers have to take to control exposure, are principles of good practice. Thus while the introduction of principles of good practice into the definition of adequate control would be new in the COSHH Regulations, it would be no more onerous than the current requirements. The starting point for a working definition of good practice is "the standard of control good employers use to control the substance so as to remain below the limit value".

90. The good practice advice would:

- be designed to keep exposure below the limit value;
- reflect the nature of the hazard posed by the chemical (thus good practice advice for a mild nasal irritant would be different from that for a substance causing occupational asthma); and
- take account of the process and physico-chemical properties of the substance being controlled.

91. However, the principles of good health and hygiene practice may need to be articulated separately for category 1 & 2 carcinogens, ie. those subject to the Carcinogens Directive. Articles 5.2 and 5.3 of this Directive require: *"The employer shall ensure that the carcinogen or mutagen is, in so far as is technically possible, manufactured and used in a closed system. Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible."* To meet these requirements the principles of good occupational health/hygiene practice would also include the duties in the proposed COSHH 2002 Regulation 7 (5), which implement the requirements of the Carcinogens Directive (Currently COSHH Regulation 7(3)). The practical control advice would reflect the need for stringent control and for employers to seek ways to improve

control so as to further reduce exposure. The same standards of control apply to substances listed in Schedule 1 of the COSHH Regulations.

92. COSHH Regulation 7 sets out the principles of good occupational hygiene practice. These principles would be further amplified in an approved document, which would be subject to consultation and endorsed by ACTS and HSC. The detailed good practice advice would set out how these principles applied to specific task/substance combinations. This advice would be contained in guidance. To elevate the detailed good practice advice to ACoP status would mean having to carry out a formal consultation exercise for every guidance leaflet/booklet published. This would be overly cumbersome and could inhibit our ability to update guidance as technologies improve or more information becomes available on specific substances.

93. Following specific guidance from HSE would not be compulsory. Providing employers apply the principles good occupational hygiene practice they would be free to follow good practice guidance from any source.

94. A single limit system would inevitably lose the "flag" that MEL substances are "nastier". To overcome this drawback mechanisms would be needed to alert the user to the nature and severity of the health hazards. One option would be a short phrase indicating the key relevant health concern (e.g *breathing the dust can cause lung damage*). Thus although a single limit system may appear to lose the differentiation afforded by OESs and MELs, there are simple ways of indicating the toxicity of substances to lay readers.

## **Option 2A:** A two tier system, flagging carcinogens, supported by good practice

95. An alternative approach to dealing with the regulatory requirement to apply a higher degree of control required for category 1 and 2 carcinogens would be to develop a two-tier system with a separate list for substances subject to the EC Carcinogens Directive and those listed in Schedule 1 of the COSHH Regulations. The use of a two-tier limit would provide an alternative and more visible way of flagging up these substances and distinguishing them other from chemicals.

96. Within this two-tier approach neither type of limit would be promoted as a safe limit and for both types of limit there would be a duty to apply good practice and comply with the limit values as set out in paragraph 84. Thus this proposal would not perpetuate the current OES/MEL with one limit being regarded as "safe" and the other for "nastier" chemicals.

97. The good practice advice for the carcinogens would reflect the full range of controls described in the Carcinogens ACoP. For many carcinogens, substance or process specific advice will be needed. This would be based on existing HSE sector guidance.

## Proposed criteria for setting OELs for options 2 and 2A

98. These options would require a new set of criteria for setting the limits. The criteria must be flexible so that a limit can be set for all types of substances and defined mixtures. Also, the criteria should aim to provide as high a degree of health protection as possible. However, there are various constraints operating; for many substances there are gaps in the scientific knowledge available on potential health effects, and a general lack of information on the ways in which different individuals might respond to particular substances. For such substances it would not be possible to identify with confidence a level of exposure that would be certain to protect all individuals. For substances which can cause cancer by a genotoxic mechanism, and for substances which can cause asthma, it is generally not possible to identify a threshold level of exposure below which there would be no risk to health. For mixtures of varying composition, such as metal working fluids, the hazardous properties can vary such that a fixed position on the human health risks cannot be established.

99. Based on considerations such as these, current thinking is moving towards the realisation that it would not be possible to set a single type of limit that would represent an absolute guarantee of complete health protection for all individuals. Rather, in most instances there will be some degree of uncertainty involved. A further consideration to be borne in mind for the OEL-setting process, is that for an OEL to be legally enforceable and to have practical value in the workplace, it should be reasonably achievable with good standards of occupational hygiene practice. Therefore, the limit-setting process needs to be well informed on what standards of control are achievable in the workplace. Taking into account all of the above considerations and constraints, the following OEL-setting criteria are proposed:

- **Criterion 1.** Wherever possible the OEL value would be set at a level at which no significant effects on human health would be predicted to occur based on the evidence available. If such a level cannot be identified with reasonable confidence or if it is judged that this level would not be reasonably achievable, then,
- **Criterion 2.** The OEL 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 OEL would not be set at a level at which there is positive evidence of adverse effects on human health.

100. In considering how Criterion 2 would be applied, it has to be borne in mind that the concept of "good control" or "good practice" must reflect the severity of the likely health hazard. To illustrate this point, there could be two dusts of similar handling properties, one might be of relatively low toxicity e.g barium sulphate, and the other might be highly toxic e.g cyclophosphamide. What might be considered good control in occupational hygiene terms for the former would by no means represent good control for the latter. Clearly, "good-control" must be informed by the nature and severity of the hazard. Of course for some substances there will be substantial uncertainties concerning the likely health hazards and risks, and expert judgment will be needed determine "good-control" and an appropriate OEL.

101. There are two approaches to setting limits using criterion 2. The first is hazard driven, the second a more iterative process. In the first approach an expert view would be formed, at least in broad terms, on the most appropriate COSHH Essentials hazard group (see

paragraphs 115-127) for a substance. This would act as a starting point for identifying an appropriate limit value and the associated advice on good practice. It is envisaged that for many OELs derived via Criterion 2, COSHH Essentials would offer a suitable basis for identifying appropriate control solutions consistent with good practice. However, in some cases, the generic guidance offered by COSHH Essentials would not be appropriate, examples, are process-generated dusts and fumes, and genotoxic carcinogens. In such cases, dedicated guidance would be required.

102. The second approach would be an iterative discussion taking account of; known hazards of the substance, concerns about data gaps, current standards of good control and the cost of improving control standards. An appropriate OEL would be selected using the information on each of these factors and informed by a regulatory impact assessment. This approach is particularly suitable for substances with extensive data gaps, where the emphasis would need to be on ensuring good practice equals tight control.

103. For the reasons laid out in paragraph 99, it is clear that with OELs set by Criterion 2 there could be no guarantee of complete health protection. However, wherever possible, the OEL would not be set at a level at which there is positive evidence of adverse effects on human health. Unfortunately, there will be a small minority of substances for which this is not possible because of socio-economic considerations. For such substances the OEL value would be arrived at following detailed considerations of the costs of improved control solutions balanced against the estimated health benefits from reducing exposure. These arguments would be set out in regulatory impact assessments.

104. Examples of such substances include crystalline silica and manganese. Each of these substances is capable of causing human health effects at very low levels of exposure. If there is a "safe" threshold for these substances, it is certainly below any level which would be reasonably practicable to achieve across all of the many industries where occupational exposures to these substances occurs.

105. In proposing these criteria, the Working Group is aware of the work of the UK Interdepartmental Group on Health Risks from Chemicals (IGHRC) on the use of uncertainty factors in chemical risk assessment. This draws attention to possible differences in response to chemicals between animals and humans, which is important because evidence from experimental studies in animals is often critical in risk assessment and standard setting activities. In addition, the work of IGHRC highlights the importance of variability in responsiveness to chemicals among the human population. Awareness of these issues underlines the need to acknowledge the existence of uncertainties surrounding the data available on the health effects of chemicals, and supports the view that whichever of the two criteria is used to derive the new OEL, the OEL would not represent an absolute guarantee of complete health protection for all workers. These uncertainties support the proposal for a requirement to comply with the good practice advice which will accompany each limit value.

106. The proposed criteria have parallels with the criteria for setting OESs and MELs. However, a key difference is that the requirement for serious health effects associated with MELs is not a feature of the proposed new criteria. Although there are two alternative criteria for setting the limit, the user would see only a single type of limit value for all substances, and would have to comply in the same way. Limits would be set as 8hr time weighted averages (TWA), with a short limit, 15 minute reference period, being set in addition, as necessary.

107. The basis for each limit value would continue to be explained and published in EH64 to give transparency and openness to the limit-setting process.



Figure 1. Summary of proposed OEL-setting process

108. Any changes to the OEL framework will have implications for the system of biological monitoring guidance values (BMGVs). Biological monitoring does not form part of the legal framework under the COSHH Regulations, therefore possible changes to BMGVs are not included in this discussion document. ACTS will consider the need for changes to the system of BMGVs when the decision has been made on the future structure of the OEL framework.

## Implications for setting OELs - Options 1, 2 and 2A

109. As stated in paragraph 57, the current system for setting OELs is slow and resource intensive. All the options would reduce HSE resource since it would no longer normally be necessary to comprehensively review the IOELVs or BOELVs, listed in future EC Directives. An administrative procedure would be set up to incorporate them into consultative document, then, subject to HSC endorsement, into EH 40. HSE proposes to work with other EU Member States to promote the inclusion into the EU limit setting programme of substances of concern in Great Britain.

110. The simplified criteria associated with options 2 and 2A would offer the opportunity to streamline the limit setting process thereby saving resource in servicing committees and members' time. Both option 2 and option 2A would eliminate the lengthy debates which sometimes occur on whether a MEL or an OES is appropriate for a particular substance. These debates consume considerable HSE and stakeholder resource.

## **Comparison of the three options**

111. To assist judgment of the relative merits of the three options the Working Group examined them:

- against the 7 key objectives set out in paragraphs 68 75;
- for their potential contribution to The Revitalising Health and Safety Strategy Statement; and

113. The following Table gives a summary assessment of the three options against the 7 Key Objectives:

	<b>OPTION 1</b>	<b>OPTION 2</b>	OPTION 2A
OBJECTIVE	Maintain the present system with minor modifications to the indicative criteria	Good practice supported by a single limit	Good practice supported by a two tier system, which flags carcinogens
1 should control risks to health	Partially – some substances may be assigned an OES (with the consequence that employers do not have to further reduce exposure) when the available data does not justify this approach	Yes – a requirement to follow good practice so as to keep exposure below the OEL	Yes – as for option 2, but greater emphasis given to substances subject to the Carcinogens ACoP
2 should be readily understood/acces sible	No – even more complicated than present system	Yes – a single limit applicable to all substances is the simplest system possible.	Yes – although slightly more complex than option 2
3 should be legally enforceable	Yes – for MELs – limited enforcement of OESs	Yes – easier to enforce good practice than compliance with a number	Yes – as for 2, but increased prominence for substances subject to the Carcinogens ACoP
4 should be comprehensive	Yes – but the rationale for assignment to OES or MEL will not be transparent	Yes – the limit setting criteria designed to cover all substances	Yes - as for option 2
5 should comply with EC legislation	Yes – IOELVs will automatically become OESs. BOELVs will become MELs	Yes – IOELVs and BOELVs transposed directly into the system.	Yes – as for option 2.
6 should be flexible and take on board new developments	No – does not easily link with other initiatives eg. COSHH Essentials	Yes – easy to update control advice. May not always be necessary to revise the limit in the light of new data as duty holders have to apply good practice.	Yes – as for option 2
7 should provide incentives to reduce exposure	No – OESs do not provide incentives to reduce	Yes – requirement to follow good practice	Yes – would give greater emphasis to substances subject to the Carcinogens ACoP

Table 1	assessment	of the three	options	against t	he 7 Ke	y Objectives
				0		

114. The Revitalising Health and Safety Strategy Statement commits HSE to a target of reducing occupational ill health by 20% by 2010. It sets out 10 aims which provide a framework for action which will contribute to achievement of the target. Therefore it is important to assess the extent to which the proposals for a revised OEL system contribute to these aims. This is shown in Table 2.

Revitalising aim	OPTION 1	OPTION 2	OPTION 2A
	Maintain the present system with minor modifications to the indicative criteria	A single limit supported by good practice	A two tier system, flagging carcinogens, supported by good practice
The health and safety system needs to do more than just prevent work-related harm. It must <b>promote better</b> <b>working</b> <b>environments</b> characterised by motivated workers and competent managers.	No – maintains the concept of the OES as a "safe" limit	Yes - emphasises in the need to apply good prac practice advice directly type of incentive envise agenda.	COSHH Regulations the stice and by linking good with OELs provides the aged by the revitalising
aim " <b>positive</b> engagement of small firms" this recognises the need to simplfy the law without compromising standards.	No improvement on existing system	Yes - would provide a sin provide the clear practica have told HSE they need	mplified OEL system and al advice that small firms
An innovative response is needed to the challenges presented by the changing world of work. <b>Partnerships</b> <b>on health and safety</b> <b>issues</b> can lead the way for the Government's wider agenda on partnership between employers and workers."	No improvement on existing system	Yes -Linking OELs with guidance, which include employees, and making available on the Interne safety representatives a to access the informa approach will encou envisaged in the revitalis	COSHH essentials style s a simple checklist for all the information freely t will make it easier for nd individual employees tion they need. This rage partnerships as ing strategy statement.

Which of the options for a new approach do you prefer?

Is the assessment of the options against the 7 criteria in Table 1 a balanced reflection of the potential of the options?

Could the options contribute to revitalising health and safety as set out in Table 2?

Do you agree with the proposed criteria for setting limits under options 2 and 2A?

How do you think the limit should be arrived at?

## **PROVIDING GOOD PRACTICE ADVICE – OPTIONS 2 AND 2A**

## Introduction

115. There are various sources of good practice advice; examples are, published HSE guidance, industry sector guidance, and information provided by trade unions, suppliers and consultants. The Working Group propose to provide generic good practice advice for most substances with limit values but replace this advice with substance or process specific advice where the generic advice may be inadequate. HSE has a source of generic good practice advice in COSHH Essentials. The following paragraphs summarise the COSHH Essentials scheme and show how it could be integrated with the OEL framework.

## **Existing COSHH Essentials guidance**

116. COSHH Essentials was designed:

- to be practical and easy to understand;
- to use readily available information; and
- to encompass a wide range of industries and processes using chemicals.

Specific advice for printing has already been developed, and work is in progress to add a series of sheets for firms inspected by Local Authorities eg on the use of cleaning products in catering, childcare etc, and solvents in dry cleaning.

117. During the development of COSHH Essentials, the COSHH Essentials hazard bands were evaluated against target airborne exposure ranges. Substances with recently established health-based exposure limit values (OESs) within these ranges were used to help develop and validate the allocation of R-phrases to these ranges. However, it was recognised that some substances could not be assigned health based limits. These substances, predominantly genotoxic carcinogens and substances which cause occupational asthma, were assigned to hazard group E and the system designed rules to default to a control approach requiring specialist advice to be sought. This table, first published in *The Technical Basis for COSHH Essentials: easy steps to control chemicals* is reproduced in Table 3.

Hazard Group	Target airborne concentration range		
	dust - mg/m <sup>3</sup>	vapour - ppm	
A	>1 – 10	>50 - 500	
В	>0.1 – 1	>5 - 50	
С	>0.01 - 0.1	>0.5 – 5	
D	> 0.001 - 0.01	> 0.05 - 0.5	
E	Genotoxic carcinogens and substances which cause asthma		

 Table 3: Target airborne concentration ranges for the hazard groups used in COSHH

 Essentials

118. The COSHH Essentials scheme was originally designed for substances which do not have an OEL and substances were allocated to particular hazard bands based on their R-phrases. However for substances which do have an OEL, the original validation allows the numerical value of recently established OELs to provide a link to COSHH Essentials hazard band and control advice.

## Applying COSHH Essentials Approach to OELs set under Options 2 and 2A

119. Some R-phrases, such as R37, have no potency consideration associated with them. COSHH Essentials treats these R-phrases in a precautionary way so as to endeavor to provide health protection for the most potent substances within the classification. The downside of this approach is that COSHH Essentials tends to be over-precautionary for the less potent chemicals in these classification groups. An OEL value takes account of potency and therefore provides better resolution than R-phrases for linking to COSHH Essentials hazard bands and control advice. Furthermore, the R-phrases listed in the Approved Supply List for specific substances are not continually updated in line with the emergence of new data, and hence may not always reflect the scientifically correct classification position for some substances. Thus recently established OEL values provide a more appropriate means of assigning a substance to a COSHH Essentials hazard group than its R-phrases.

120. Feedback since COSHH Essentials was first printed in 1999 has been very positive. A large majority of purchasers of the guidance found it easy to use and 60% have used it to make improvement to their workplace control of chemicals.

121. We therefore propose to use as a default the COSHH Essentials good practice advice for substances which currently have OESs in the range  $0.001 - 10 \text{ mg.m}^{-3}$  and 0.05 - 500 ppm. Since the control advice in COSHH Essentials is task specific it will control exposure below any short term limit as well as the 8hr TWA.

122. For former "MEL-type" substances such as those which cause asthma and genotoxic carcinogens, (which COSHH Essentials allocates to hazard band E, seek specialist advice), will each be considered on an individual basis to see if the numerical value of their exposure limit would lead to an 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.

123. For process-generated dusts or fume, it is difficult to use the COSHH Essentials approach, as factors such as 'scale of use' and 'dustiness or volatility' are not applicable. These processes are well addressed by HSE or industry guidance. 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. Mould preparation would be excluded as exposure would be predominantly to supplied substances at this stage of the foundry process.

## Integrating COSHH Essentials, Good Practice and the Limit Value System

124. EH40 and COSHH Essentials are both currently paper documents, but development work on an interactive, Web based, version is underway. It is proposed that options 2 and 2A would be supported by both a paper based and an interactive electronic version of the new EH40. The paper version would ensure that the system is available for all users, while the electronic version would provide an easier to use and more integrated product for the increasing number of users with access to the Internet.

125. In the paper version, it is proposed that the exposure limit tables in the new EH40 would have some similarities with the current EH40 in that it would identify the substance by name and state the exposure limit values, but three new columns will be provided.

126. The first (column 3 in Table 4) would give a simple description of the main health effect of occupational relevance. This would replace the current listing of R-phrases to make the document easier for the majority of users to understand. For example, Xylene, R20/21, R38 would be replaced with '*may cause dizziness and headaches*'.

127. The other two columns relate to the integration of the limit value with good practice advice. The first, 'Hazard group' would identify the COSHH Essentials hazard group to which the substance had been allocated. For some of the former MEL type substances and process dusts and fumes, where COSHH Essentials is not applicable, this column would be left blank. The final column would reference the source of good practice advice. This would either be a COSHH Essentials control approach, or a reference number and descriptor for substance or process specific guidance sheets.

128. The Working Group considered two options for applying the COSHH Essentials approach:

- referring the user to the full COSHH Essentials risk assessment process; or
- applying the COSHH Essentials risk assessment to the substance in the way in which that substance is normally supplied and used.

129. A full COSHH Essentials risk assessment, requires information on the materials hazardous properties (hazard band), its physical state (dustiness or volatility) and the scale of
use. As volatility will vary with process temperature, COSHH Essentials provides a method of calculating volatility at process temperature.

130. The second option, determining the control approach for the way in which the substance is normally supplied and used, introduces some limitations:

- For liquids, volatility can only be assigned at a single temperature, (room temperature), thus the control approach recommended may not be adequate for use of the liquid at elevated temperatures.
- For solids, we can only assign dustiness based on the most usual form of the material. This would remove the cost saving that may be realised by using a low dust form of the material and could remove the incentive for users to consider using low dust materials.

131. Despite these limitations Working Group suggest that the approach would work in more than 80% of applications. The simplicity provided by this approach would outweigh the limitations and added complexity that would result from requiring the user to work through the full COSHH Essentials risk assessment process.

132. An illustration of how this information may be presented is provided on the following page in Table 4.

# Do you support the approach of sourcing good practice advice using COSHH Essentials guidance sheets as the default (complemented by substance or process specific sheets where necessary)?

What is your opinion on the proposed approach to integrating COSHH Essentials into the OEL framework?

Substance	Occupational Exposure Limit		Main Health Effects	Hazard Group	Control Approach for use at Room Temperature		Process specific guidance	
	8 hr TWA	15 min ref. Period			Small* Scale Use	Medim Scale Use	Large scale Use	
Benzene	3 ppm		May cause cancer and disorders of the blood					Use in closed systems
Bromochloro- methane	50 ppm**		Dizziness and eye irritation	B & S	1	2	2	
Ferrous Foundry Particulate	10 mg/m <sup>3</sup>		May cause cancer, lung disease and asthma					Knockout Fettling Casting
Glutaraldehyde	0.05 ppm	0.05 ppm	May cause asthma and irritation of eyes, nose and throat					Sterilisation
Xylenes	50 ppm	100 ppm	May cause dizziness and headache	B & S	1	2	2	
Barium Sulphate	10 mg/m <sup>3</sup>		Lung damage from breathing the dust	A	1	2	2	

Table 4. Proposed layout of EH40 giving examples of hazard banding and good practice control advice

\* as defined in COSHH Essentials

\*\* value recommended in CHAN

a) Does this Table 4 give the information you would like to see in EH 40?

b) Is there any additional information you would like to be included?

# **ELECTRONICALLY LINKING EH40 AND THE REVISED OEL FRAMEWORK**

133. HSE currently makes information on exposure limits available in two priced publications:

- EH40/2002 Occupational Exposure Limits 2002. This is updated annually and includes:
  - ➤ a full list of OELs for specific substances
  - definitions of OELs
  - ➤ a summary of how OESs and MELs are set
- **EH64 Summary Criteria for Occupational Exposure Limits**. This is a substance specific summary of information used in the limit setting process including toxicology, physical properties and typical uses.

134. HSE would continue publishing a paper version of EH40 (or its successor under the revised framework) until such time as electronic media has taken over as the primary source of information. There are, however, distinct advantages why this information should be freely available on the Internet. These are:

- users can access and print out only as much information as *they* need;
- information is available immediately 24 hours a day;
- information can be combined from a variety of sources eg EH64 and EH40, with links to other publications such as COSHH Essentials.
- the information can be made available **free of charge** to anyone with Internet access

135. HSE is planning to launch an electronic version of COSHH Essentials in April 2002. This will be freely available on the Internet and users will be able to access it through its own website address www.coshh-essentials.org.uk and via the HSE website or the HSEdirect website. It would be important to plan carefully how an electronic version of EH40 and EH64 would interact with this system so that users could readily access all the information they need.

136. People who are not familiar with the structure of HSE's web site would be able to use the search facility using keywords, either by:

- searching for information on a specific substance eg methanol or
- searching on general terms such as exposure limits. There would be be links to make the guidance easy to navigate eg to an introduction page; a search page for information on different substances; and general information pages.

# Would an electronic package which linked together OELs, COSHH Essentials, EH64 and key COSHH guidance be helpful to duty holders?

# IMPACT OF PROPOSED OPTIONS FOR A NEW LIMIT FRAMEWORK ON EXISTING OESS AND MELS

### Background

#### Status of current MELs

137. The majority of MEL values currently listed in EH40 were derived according to the current WATCH/ACTS OEL-setting process. A few MELs (e.g for acrylonitrile, carbon disulphide, dichloromethane) derive historically from former Control Limits which were in existence prior to the introduction of COSHH. These were converted into MELs of the same values on the implementation of COSHH, following a limited review by ACTS. A few of these substances have since been reviewed at WATCH (eg dichloromethane). For a limited number of substances (vinyl chloride, benzene), MELs implement limits derived from EC Directives.

138. One of the requirements associated with MELs is that exposures should be controlled as far below the MEL as is reasonably practicable. About 1/3 of all MELs apply to substances which are classified as Category 1 or 2 Carcinogens, or apply to process generated substances such as rubber fume or hardwood dust.

139. About 1/5 of MELs apply to substances known to cause asthma and which carry a Sen notation. Most of these MEL values have been established relatively recently and are likely to be still appropriate in terms of the numerical values. HSC has recently agreed a strategy for tackling occupational asthma. This includes preparing COSHH Essentials style guidance on good practice for the main causes. In view of the serious health effect this advice will aim to control exposures as low as is reasonably practicable.

140. For most of the remaining MEL substances, the MEL values have been generated via the current national substance review programme and the numerical values of the MEL are likely to remain valid (i.e. represent the lowest level of exposure that is reasonably achievable across industry). These substances would therefore match the proposed new criteria for OEL-setting (criterion 2), indicating that they could be directly transposed into the new single limit system. There are only a small proportion of MEL substances (perhaps 4 or 5) derived from the pre-COSHH era which may possibly be out-of-date, in that due to technological advances over the last 10 years or so a lower numerical value can now be achieved across all industry sectors.

#### Status of current OESs

141. There is a more heterogeneous background to OESs than for MELs. Most current OESs derive historically from ACGIH TLVs which were previously listed as Recommended Limits in Great Britain, and were converted to OESs on the introduction of the COSHH Regulations in 1989. Since that time, about 100 of these OESs have been subject to a full re-assessment by WATCH/ACTS. However, OESs for the remaining ~350 former TLV substances have not been changed or reviewed in that time. Of the approximately 100 former TLV substances which have been reviewed, revised OES positions have been developed for about 80, and MELs have been implemented (or are intended to be implemented) for about 20. A few former TLV substances have had their OESs withdrawn following review by WATCH/ACTS e.g bromochloromethane, naphthalene. No limits are now in place for these substances.

142. Great Britain was not alone in making use of the ACGIH list of TLVs as a source of occupational exposure limits. This has been the case in a number of other European countries. This situation prompted the Dutch authorities to set up a committee of experts to review the scientific basis for 168 of the older TLV limits. Although the final conclusions of the committee are not yet available for all substances, the pattern to emerge is that the majority of substances were judged to have inadequate data to support the setting of a health-protective limit.

143. In conclusion, about 80 OESs listed in EH40 have been established through the current WATCH/ACTS process and would therefore match the proposed criteria for OEL-setting under the revised OEL framework (criterion 1). The outcome of the Dutch-led committee on TLVs implies that the majority of existing OESs which have not been specifically reviewed by WATCH/ACTS since 1989 are not soundly based. It should be noted however, that for most of these substances there are no data to indicate that the limit values would be either "safe" or "unsafe".

# Table 5 Possible consequences of a new OEL Framework on Existing OESsand MELs

	Preference A	Preference B	Preference B1
Current MELs	All existing MELs would be directly transferred into new OEL framework.	All MELs derived through the current WATCH/ACTS process would go forward directly into the new OEL framework. A small number of longstanding MELs derived from pre-COSHH era would be reviewed to check appropriateness of OEL value, plus any for which there was evidence that the current MEL is unsound in the context of the new system	As with preference B
Current OESs	Most OESs would be directly transferred into new OEL framework. About 50 OESs shown to be unsound by the Dutch committee on TLVs would not go forward.	Only those OESs (~80) derived through the current WATCH/ACTS process would go forward. The remainder would be discarded.	As with B, except the discarded OESs would be listed in EH40 as Guidance Values and could be prioritised for review.
Outcome	New system would have about 450 OELs, but most would have no supporting documentation to show that the OEL criteria were met. Most OELs would still reflect the 1980 list of ACGIH TLVs. It follows that there would be no information on the suitability of the COSHH Essentials good practice advice generated using these OELs (see paragraphs 115-123)	New system would have about 150 OELs, all of which would be judged to be soundly based from a scientific/technical standpoint, and would all match the new OEL criteria. There would be resource implications for HSE in reviewing MEL values derived pre-COSHH.	As with B, but this preference could lead to confusion with an additional category in EH40, and detract from the aim of simplicity. It could also pose an enormous resource burden, diverting resource from other potentially more important areas.

Please rank your preferences for dealing with existing OELs, in order or describe your alternative preference and why

# **CONSULTATION PROCESS**

144. The ACTS subgroup will be considering the responses to this discussion document in the autumn 2002, alongside information from:

- further research on how industry, in practice, apply controls to MEL substances compared to OES substances; and
- a study of OEL systems other EU member states and how they are used in practice.

145. Specific questions are listed throughout the text but please do not feel constrained by them – you are welcome to comment on any other issue related to the OEL framework. For your convenience, a tear out form is in Annex 3, but we are happy to receive comments in any form.

146. The subgroup will then make proposals for changes to the OEL framework which, subject to approval by HSC, will be published in a formal consultation document in 2003. Any changes to the COSHH Regulations would not occur until 2004.

# *In your view how well does this Discussion Document represent the different policy issues involved in this matter?*

# *Is there anything you particularly liked or disliked about this consultation exercise?*

### Annexes

- Annex 1: An outline Regulatory Impact Assessment for each of the three options 1, 2 and 2A.
- Annex 2: Report from the Internet survey on current OEL system and what stakeholders would like from a revised system.

147. In addition the following documents are available on request from the address on the cover of this discussion document:

- HSE's enforcement of the COSHH Regulations and the role of OELs.
- Examples of applying the proposed criteria for setting OELs.

# **ANNEX 1: Initial Regulatory Impact Assessment for the OEL Framework**

# **Purpose and intended effect**

### <u>Background</u>

1. To guide decisions on the measures needed to control chemicals Great Britain, in common with many industrialised countries, has established a system of occupational exposure limits (OELs). They were originally developed as a tool to help professional occupational hygienists decide what controls were needed and then monitor to see if they were effective. In Great Britain, they are an important part of the legislative arrangements, in that they define, under Control of Substances Hazardous to Health (COSHH) Regulations, adequate control by inhalation.

2. The COSHH regulations provide a useful tool of good management setting out seven basic measures that employers must take to protect both employees and others who may be exposed. 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, then ensuring exposure is adequately controlled.

3. The COSHH regulations use two types of OEL to define adequate control, Maximum Exposure Limits (MEL) and Occupational Exposure Standards (OES). Both OESs and MELs are expressed as airborne concentrations averaged over a period of time, either a long term exposure limit (8 hour Time Weighted Average (TWA)) or a short term exposure limit (15 minute reference period). The duties on employers in relation to these two types of limit are summarised in the Box below.

Duties associated with OESs and MELs				
Occupational Exposure Standard	Maximum Exposure Limit			
Standard must be met	Limit must be met			
No requirement to further reduce exposure	Exposure must be reduced below the limit so far as is reasonably practicable			
Standard can be exceeded providing steps are taken to meet it as soon as reasonably practicable	Limit must not be exceeded			

Concerns with the present system and objectives for a new approach

4. HSE is concerned as to whether the current system of OELs is effectively delivering worker protection. There is very little information on the impact of individual OELs on the behaviour of firms, although there is some evidence that once a MEL is proposed firms aware of the proposal will take steps to improve controls. However a survey of a random selection of chemical users showed that the vast majority of firms are unaware of OELs and consequently they play no part in decisions they make on what control measures to use. Thus, although professional occupational hygienists have made good use of OELs, there are serious doubts as to their contribution to worker protection in the majority of firms using chemicals.

5. In addition difficulties have arisen with the procedures for setting OELs. HSC/E wishes to ensure that a robust cost effective system is in place for setting OELs and that they realise their maximum potential as tools to help employers control exposure. To achieve this the 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 are 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.

6. The purpose of this Regulatory Impact Assessment (RIA) is to inform stakeholders of the costs and benefits of establishing a new system for setting occupational exposure limits.

### **Options**

7. The working group examined the existing system against the 7 objectives in para 5 and decided that *status quo* was not an option. However the working group 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. Thus:

# • Option 1: Maintain the present system with minor modifications to the indicative criteria

# criteria

8. The working group then considered a number of options for making fundamental changes to the OEL system. The starting point for the group's discussions were the need to develop a system that will contribute to delivery of real improvements in chemical control in the workplace. After discussion of a range of possibilities the working group decided to seek wider views on two closely related options, referred to in this discussion document as option 2 and 2A:

- Option 2: Good practice control advice supported by a single type of limit
- Option 2A: Good practice control advice supported by a two tier system which flags carcinogens.

9. The proposal is that OELs should be explicitly linked to advice on good practice. The aim being that if firms apply the good practice, they will be complying with the OEL. This will reduce the need for monitoring and make it easier for employers to protect their employees. It will not place new demands on employers. In addition, the good practice advice will set OELs into context of other COSHH requirements and emphasise that control is not just about using engineering means to reduce exposure, but that process design, housekeeping and maintenance are all important considerations.

10. The principle of linking good practice advice to OELs would apply irrespective of whether option 2 or 2A, providing suitable criteria were established for setting OELs.

#### Information sources and background assumptions

11. The assumptions in this RIA are based on information collected from the evaluation of COSHH Essentials<sup>1</sup> and from internal HSE knowledge. Costs and benefits are calculated in 2000/01 prices over a 10 year period<sup>2</sup>. The base year for appraisal is year 2001/02.

#### Benefits

Health and safety benefits

#### Option 1

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

#### Option 2 and 2A

13. The latest health effect statistics are used as a baseline. We exclude, dermatitis, stress, hearing loss, etc, and only consider those effects derived from inhalation of chemicals, eg cancer, asthma, bronchitis etc. As the intended guidance would also cover exposure to skin we also include dermatitis cases.

14. Each year approximately 16,000 to 25,000 people become ill as a result of exposure to substances hazardous to health at work. Of these, approximately 8,000 can be attributed to exposure via inhalation and a additional 4,000 are dermatitis cases<sup>3</sup>. Included is an estimated 4,500 cancer deaths mostly related to chemicals.<sup>4</sup> In 1999, there were 1,118 work-related asthma cases (some of which will be due to exposure to biological agents) and approximately 300 cases of other respiratory diseases.

15. It is likely that all the above data will be subject to under-reporting, and that this will be more significant in industries where knowledge of the hazards of exposure to chemical agents is less well known or where exposure is intermittent.

<sup>&</sup>lt;sup>1</sup>Wiseman et al (2001) COSHH Essentials: Survey of firms purchasing this guidance. In publication as part of HSEs Contract Research Report series.

<sup>&</sup>lt;sup>2</sup>In arriving at 10 year cost figures two adjustments are made. Firstly, earnings are assumed to rise by 1.8% 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 6% discount rate.

<sup>&</sup>lt;sup>3</sup>As there is no single source of information about cases of ill health, these estimates are produced by adding together figures for diseases for which the majority of cases are likely to be caused by hazardous substances. In most cases, the figures come from Occupational Disease Intelligence Network (ODIN) schemes. However, as this information is likely to substantially underestimate the true incidence, the data is supplemented by disease figures from the DSS Industrial Injuries Scheme and RIDDOR (The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995). These diseases include, asthma and other respiratory diseases, bronchitis, enphysema and cancer.

<sup>&</sup>lt;sup>4</sup>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). Mesothelioma, asbestos and pneumoconiosis cases total about 2,400 and are included.

16. Using unit average costs from HSE (1999) for cases of ill health<sup>5</sup> and for cancer deaths, double the Department of Transport's Value of a Statistical Life (VoSL) of approximately  $\pounds$ 900,000 in June 1997 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.

17. Assuming there are 12,000 cases per year of exposure related ill health, of which about 4,500 are cancer deaths, this gives a total cost to society per year of approximately  $\pounds 8.1$  billion. The OEL framework could be impacted on only some of these costs.

18. 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

19. 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.

20. The new criteria will shorten the time the substance spends in WATCH. Cost savings are based on<sup>6</sup>:

- 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.

21. Over ten years this represents a cost saving of approximately £34,000 in net present value terms.

### Options 2 and 2A

22. Under option 2 and 2A there may be some cost savings to industry. These may accrue as a result of firms receiving clearer guidance about what is expected of them under the regulations. Also, the new framework will be available online. Increasing numbers of firms are getting access to the internet. Thus, there will be the cost savings to firms who previously

<sup>&</sup>lt;sup>5</sup> '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 £7,900 and £8,200.

<sup>&</sup>lt;sup>6</sup>This assumes hourly wage rates (including non-wage labour costs) of  $\pm 23.21$  and  $\pm 32$  for WATCH experts and HSE staff band 2 respectively. The daily wage including non-wage labour costs used for band 3 policy staff is  $\pm 283$ .

paid for the information and who will now get it free of charge. We have not been able to quantify these benefits.

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

# Costs

### Business sectors affected

24. 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<sup>7</sup> indicated that firms in those sectors most affected by COSHH<sup>8</sup> 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

25. 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.

26. A brief review of costs of MELs over the last six years indicates a range of approximately  $\pounds 400$  to  $\pounds 2,000$  per firm per year. 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 and 2A

27. These options include a new regulatory requirement to apply good practice. Good practice has previously only been subject to guidance status, thus we expect a greater uptake and improved compliance.

28. Recently HSE launched similar good practice advice in a scheme known as COSHH Essentials. An evaluation study on its effectiveness suggested that 60% of a random sample

<sup>&</sup>lt;sup>7</sup> DTI (1999), SMEs statistics for the UK

<sup>&</sup>lt;sup>8</sup> Sectors include: parts of Manufacturing (D) and Wholesale, retail and repairs (G)

of 500 SME purchasers have 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  $\pounds$ 500 -  $\pounds$ 2000;

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

iv. 20% Of firms changed their control measures used. In the OEL framework, we assume a typical unit cost of between  $\pounds 1000 - \pounds 5000$  per site [including maintenance]; and

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

29. 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 the 66,000 firms with the greatest exposure to hazardous substances i.e. 19,800 firms. This proportion could be underestimated as it relates mostly to SMEs. We implicitly assume that large firms have controls in place and will not be so affected by the changes.

30. 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
HSE enforced premises	37-146	134 - 2,140	1,070 - 21,401	15 - 1,187
LA enforced premises	12 - 50	74 – 1,189	594 – 11,889	6 - 464

31. The paper also proposes two additional options within Option 2 for shortening the list of OELs, both of these are cost neutral as (a) we are not introducing anything new and (b) the duty to adequately control remains unchanged.

32. 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 exposure must be brought down within a reasonably practicably time. Within CAD<sup>9</sup>, if a limit is exceeded, exposure must be reduced as soon as possible. The new framework, however, will be more stringent as it will remove the permission of firms to exceed the limits. Therefore some additional costs maybe incurred in industry. However, it is not possible to quantify the extent of these costs. This framework will increase clarity in what is expected in industry, which may increase costs, as shown above but would also make it easier to comply.

<sup>&</sup>lt;sup>9</sup> Chemical Agents Directive

# Total compliance costs

Option 1

33. Not strictly quantifiable but could be within the range  $\pounds$ 3,000 to  $\pounds$ 40,000 per firm affected by the changed framework.

34. These costs would all be classified as policy costs. There are no implementation  $costs^{10}$ .

# Option 2 and 2A

35. Total compliance costs to business over ten years will be approximately  $\pounds 2$  million to  $\pounds 38$  million in net present value terms.

36. These costs can all be classified as policy costs. There are no implementation costs.

# Costs to HSE

# Option 1

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

### Option 2 and 2A

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. All costs in options 2/2A are incurred in the first year.

### Impact on small businesses, charities and voluntary organisations

### Option 1

43. There is no disproportionate impact on small firms.

### Option 2 and 2A

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 appro-

<sup>&</sup>lt;sup>10</sup> 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.

priate control. However small firms are also likely to be the major beneficiaries of the changes to the framework due to guidance on good practice.

### **Environmental impacts**

### Option 1

45. There are no environmental implications under option 1.

#### Option 2 and 2A

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

#### **Balance of costs and benefits**

#### Option 1

47. Total costs could potentially be up to  $\pounds400-\pounds2,000$  per affected firm per year. These costs would be offset by cost savings over ten years of approximately  $\pounds34,000$ .

#### Option 2 and 2A

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

49. Taking the costs we can calculate how many cases of ill health and/or deaths would need to be prevented for the costs to balance the benefits, see Table 2. Given that cancer deaths are responsible for more than half of the ill health incidence, scenario 3 would be the most realistic. That is, if approximately 1-11 exposure deaths and up to 2,000 cases of ill health could be prevented over ten years as a consequence of the OEL framework, costs to society would be recovered. Assuming approximately 8,000 cases of ill health per year, including 4,500 cancer deaths, this represents a 3% reduction in the incidence of ill health and a less than 1% reduction in the number of cancer deaths. See Table 2 below.

Scenarios Over 10 years	Total cost of £2 m	Total cost of £9 m
(1) Cases of ill health prevented	180	3790
(2) Death prevented	1	21
(3) III health/Deaths prevented	1 death, 14 ill health cases	11 deaths & 2,000 cases ill health

### Table 2 Costs of scenarios over 10 years

#### Uncertainties

50. The total costs of compliance are based on estimates of the number of firms affected and the number of firms estimated to take action. At this stage we have not been able to research the compliance costs of the proposal in detail. Further analysis would be necessary in order to produce more accurate data on which to base the cost estimates.

51. 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 unknown information about those substances (and corresponding industries) which may be affected the new framework.

### Arrangements for monitoring and evaluation

52. 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.

# HSE would welcome views and quantitative information on the RIA and on the following points in particular:

- will there be benefits (health or cost savings) to industry under option 1?
- will there be benefits (health or cost savings) to industry under option 2/2A?
- how many sectors and firms are likely to be affected?
- are the costs to industry under options 1 realistic?
- are the assumptions about the compliance costs to businesses when following good practice for option 2/2A reasonable?

### **ANNEX 2: Stakeholder views of the OEL framework**

1. The ACTS Working Group felt it was important to find out more about how exposure limits are currently used in different workplaces. A questionnaire was placed in the paper version of Toxic Substances Bulletin (www.hse.gov.uk/toxicsubstances) and on the HSE web site from March until May 2001. Various stakeholder groups agreed to support this initiative by informing their members about the questionnaire including the TUC, CBI, BIOH and IOSH. The survey was intended to seek views of interested stakeholders. It was not intended to be a study of a statistically representative sample of industry. A previous, representative survey has already shown that many companies are not aware of the COSHH Regulations. It was felt that this trawl for views would add to the previous work by reflecting opinions of respondents using the current system of OELs.

2. This report summarises the 489 responses received by HSE. As not all the questions were relevant to everybody (eg if respondents had not previously heard of OELs, it was not appropriate to ask them if they treat substances with OELs more carefully than substances without), the number of respondents answering is shown for each question.

#### **Survey respondents**

3. The first section was designed to find out more about the respondents. Only 16% (78) of those replying said they had ever replied to Consultation Documents before. This shows that this survey succeeded in reaching respondents who do not usually respond to HSE's formal consultation procedures.

4. Respondents were asked to choose from a list of job descriptions, with multiple choices permitted (Figure 1). It can be seen that the largest single group is health and safety consultants, many of which also ticked the employee category. The types of firms replying varied considerably (Figure 2). Many firms classified themselves as both manufacturers and suppliers of chemicals (multiple responses were permitted in this category). The survey includes both large and small firms, although most respondents came from firms employing more than 200 employees (Figure 3). In many cases not all the employees working for a firm are exposed to hazardous substances (Figure 4).



Figure 1: Job description







Figure 2: Type of firm



Figure 4: Number of people exposed in respondent's workplace

#### Use of existing OEL framework

5. As might be expected of questionnaires placed on the HSE web site and in a specialist magazine, the vast majority of respondents had already heard of the OEL framework (89%, 435) before answering this questionnaire. Approximately 60% (287) respondents say they use OELs in their workplace and 18% (88) say they do not use OELs (Figure 5). The vast majority of respondents who do not use OELs, say they use control systems common in their industry. However, OELs are used by nearly half of the total sample (46%, 225) as a warning that a substance is 'nasty' (Figure 6).

6. Although respondents often treat substances with OELs more carefully than those without, many of the respondents treat substances with MELs and OESs the same (Figure 7). It should be noted that some respondents explained that they treat OES substances as strictly as MELs. This lack of differentiation is interesting considering the effort involved in deciding if a MEL or OES is more appropriate for a substance – particularly as respondents included a high proportion of health and safety specialists.

7. Respondents who use OELs (60%, 287) were asked how often they take measurements of workplace air and nearly all of them stated that their firms take measurements at least once a year. Despite the high proportion of replies from health and safety professionals in this survey, only 57% of the total sample take measurements. Most firms who take measurements do so more than once a year (Figure 8). Firms were also more likely to take measurements as their size increased. However, 61% (300) of the total sample had heard of EH40, which lists exposure limits. Levels of awareness of COSHH Essentials were very similar.



Figure 5: Do you use OELs in your workplace?



Figure 7: Do you treat OESs and MELs differently?



Figure 6: Do you treat OELs substances with more care?



Figure 8: How often does your firm take measurements?

#### Views on information needed to control chemicals

8. The survey also asked what information would help firms to use chemicals safely (Figure 8). Respondents were asked to select the 4 most important items from a list, although many selected more than 4 options. Responses for respondents with different job descriptions and types of firm were not noticeably different to the overall responses. The most popular information can be split into 3 categories :

- advice on potential health effects
- advice on how to use a substance safely
- exposure limits and advice on measuring exposure.

It is interesting to note that although exposure limits and advice on measurement are popular options less than 60% of the total sample (which includes many health and safety specialists and large firms) stated they take measurements at least once a year in their workplaces (paragraph 7).



Figure 9: Priorities for a new OEL framework

#### **ANNEX 3: 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

me of Organisation or individual	•••
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#### **QUESTIONS FOR CONSIDERATION**

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

Quartian 1 (Paragrapha 52 62 page	17 10				
<u>Question 1</u> (Paragraphs 53-62, page 17-19)					
a) Do you agree with these concern	a) Do you agree with these concerns about the current system?				
Yes	Νο				
If No – please state why					
b) Do you have any other concerns	s about the current system?				
Yes No	)				
If Yes – please state why					
c) Do you agree with the need for a	change?				
Yes	Νο				
If No – please state why					

Question 2 (Paragraphs 68-75, pag	ge 21-22)
a) Do you agree with the key obje	ctives for a new approach?
Yes N	0
If No, please state which ones yo	ou disagree with
b) Do you think additional objecti	ves are needed?
Yes	No
lf Yes – please suggest text	

Question 3 (Paragraphs 76-97, page 23-26)				

Question 4 (Paragraphs 98-108, page 27-29)

a) Do you agree with the proposed criteria for setting limits under options 2 and 2A?

Criterion 1 Yes

No

lf no – please state why.

<u>Question 4</u> (continued)		
Criterion 2	Yes	No
If No, please state why		
b) Considering the issue the limit should be arrive	s in paragraphs 101-102 page 27-28, ed at?	how do you think
i) A system of rules		
ii) By discussion		
If you prefer a system of	rules, please suggest what they sho	uld be

<u>Question 5</u> (Table 1, page 31)

Is the assessment of the options against the 7 criteria in Table 1 a balanced reflection of the potential of the options

Option 1	Yes	No
Option 2	Yes	No
Option 2A	Yes	No

*If no – please give reasons* 

Question 6 (Table 2, page 32)

Will the options contribute to revitalising health and safety as set out in Table 2?

Option 1	Yes	No
Option 2	Yes	No
Option 2A	Yes	No

If no – please state why

Question 7 (Paragraphs 115-123, page 33-35)

Do you support the approach of sourcing good practice advice using COSHH Essentials guidance sheets as the default complemented by substance or process specific sheets as necessary.

Yes

No

**Question 8** (Paragraphs 124-131, page 35-36)

The proposed approach to integrating COSHH Essentials into the OEL framework is:

a) Useful

b) Not useful

c) Would prefer users to be directed to a full COSHH Essentials assessment

Question 9 (Table 4, page 37)	
a) Does Table 4 give the inform	nation you would like to see in EH 40:
Yes	Νο
b) Is there any additional infor	mation you would like to be included:
Yes	Νο
If Yes, please specify	

Question 10 (Paragraphs 133-136, page 38)

Would an electronic package which linked together OELs, COSHH Essentials, EH64 and key COSHH guidance....

a) be helpful to most duty holders

b) be helpful to a minority of duty holders

c) not be helpful

Question 11 (Table 5, page 41)

Please rank your preferences for dealing with existing OELs, with 1 being your favourite option

..... Preference A

..... Preference B

..... Preference B1

..... Alternative option not described in the discussion document

If you have suggested an alternative, please describe what your preference is and why

Question 12 (Annex 1)				
HSE would welcome vi following points in part	ews and quantitativ icular:	e information on the RIA	and on the	
<b>a) will there be benefits under option 1?</b> (Annex 1, paragraph 12, 19-21, pages 45, 46)				
Health benefit	Yes	Νο		
If Yes, please specify				
Cost savings	Yes	No		
If Yes, please specify				

Question 12 (continued)		
b) will there be benefits under	<b>r option 2/2A?</b> (Annex pages	( 1, paragraph 13-18, 22-23, 45-47)
Health benefits	Yes	No
If Yes, please specify		
Cost saving	Yes	Νο
If yes, please estimate the s	aving where possible	e eg approximate amount of
Stan time Saved in your mining	oer year	
c) approximately how many f	firms/sectors are like	lv to be affected by changes
to the OEL framework? (Anne	ex 1, paragraph 24, pag	ge 47. Please fill in the blanks)
In my sector,	, approximately	firms will be
affected. Other sectors affect	ed might be	

Question 12 (c	<u>tinued)</u>	
<b>d) are the compliance costs to industry under option 1 realistic?</b> (Annex 1, paragraph 25-26, 33, pages 47, 49)		
Yes	Νο	
lf No, please c	iment.	
e) are the assu good practice (Annex 1, parag	ptions about the compliance costs to industry when followinder option 2/2A reasonable? ph 27-30,35-36, pages 47-48, 49)	
Yes	Νο	
lf No, please c	nment	

**Question 12 (continued)** 

*f)* What percentage of firms currently use the flexibility of being able to exceed an OES? (Annex 1, paragraph 32, page 48)

.....%

Please comment on any cost implications of the removal of permission for firms to exceed the limits

# Question 13 (Page 42)

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

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

Question 14 (Page 42)

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?

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

Please return this form to:

Ms Sara Wassell Health Directorate, Chemical Policy Division Health and Safety Executive 6SW Rose Court 2 Southwark Bridge London SE1 9HS

# DISCUSSION DOCUMENT



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

www.hse.gov.uk/disdocs/

Discussion Documents are available from: HSE Books, PO Box 1999 Sudbury, Suffolk CO10 2WA Tel: 01787 881165 Fax: 01787 313995

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