

# AMENDMENTS TO THE CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH REGULATIONS AND THE CONTROL OF LEAD AT WORK REGULATIONS

## REGULATORY IMPACT ASSESSMENT

### PURPOSE AND INTENDED EFFECT

#### Issue and Objectives

##### **Chemical Agents**

1. To implement in Great Britain the health requirements of Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (14th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). The Directive addresses existing risks to health and safety in the workplace.
2. The Directive's health requirements, insofar as they apply to the presence in the workplace and exposure to hazardous chemical agents, will be implemented by amending the Control of Substances Hazardous to Health Regulations 1999 (COSHH), the Control of Lead at Work Regulations 1998 (CLAW) and the Control of Asbestos at Work Regulations 1987 (CAW). New replacement COSHH, CLAW and CAW Regulations will be brought into force in 2002. Proposals to amend the CAW Regulations were the subject of a separate RIA contained in the CD published in June 2000 'Proposals for amendments to the Control of Asbestos at Work Regulations 1987; a New Approved Code of Practice; and a minor amendment to the Health and Safety (Enforcing Authority) Regulations 1998'. A further consultative document setting out revised proposals to amend the Asbestos Regulations to implement the Directive will be published in the autumn of 2001 entitled *Revised proposals for amendments to the Control of Asbestos at Work Regulations and supporting Approved Code of Practice*".
3. The Regulations will be supported by revised Health and Safety Commission COSHH, CLAW and CAW Approved Codes of Practice. These will provide employers with clear practical guidance on good practice in complying with the Regulations, and in particular, with the new requirements introduced to implement the Directive.

##### **Biological Agents**

4. The Biological Agents Directive (90/679/EEC) was implemented using the COSHH Regulations 1994, including a new Schedule 9 (now Schedule 3 of COSHH 1999), and the relevant provisions have recently been evaluated. One finding was the confusion about their application to incidental exposures in normal workplaces (rather than laboratories and production plants). This indicated a need to promote some of the general duties from the Schedule into the main regulations.
5. Experience has also shown difficulties in applying the Regulations to certain types of laboratory leading to the unsatisfactory reliance on a COSHH exemption certificate. Operational experience

and a review of HSE's operational requirements on biological agents mean that the notification requirements for high hazard laboratory work need reviewing.

6. The objectives of the proposed changes to the biological agents provisions of COSHH are to:
- review and update the provisions in both COSHH and the ACoPs (which implemented 90/679/EEC) in the light of evaluation and experience, clarify certain requirements and phase out use of the COSHH exemption certificate; and
  - more closely integrate assessment and control of biological agents within COSHH and the General ACoP, in parallel with work on the implementation of the Chemical Agents Directive (CAD) because the Biological Agents Directive and CAD contain a number of similar requirements.

## **Risk assessment**

### **Chemical Agents**

7. An estimated 1.3 million businesses are engaged in activities which involve the use or production of substances hazardous to health including chemicals and which bring those businesses within the scope of the COSHH Regulations. Each year approximately 16,000 to 25,000 people become ill as a result of exposure to substances hazardous to health at work. However, this range, derived by adding together figures from a variety of sources<sup>1</sup> for diseases where the majority of cases are likely to be caused by exposure to chemicals, is likely to underestimate the actual annual incidence<sup>2</sup>. The activities of some 500 businesses in the various sectors of the lead industry bring them within the scope of the CLAW Regulations. In 1999/00, some 17,650 employees were under medical surveillance in accordance with the requirements of CLAW because their exposure to lead was assessed as "significant" as defined by the Regulations. That year, 124 employees were temporarily removed from work involving exposure to lead because the amount of lead in their blood reached a "suspension level" defined by the Regulations. Their removal from work involving exposure to lead (or suspension from work) prevented the lead in their blood from accumulating to a level at which it could have a serious adverse effect on their health. Medical inspectors and appointed doctors monitor the employees concerned and certify when they must be removed from work involving exposure to lead and when they can resume work. Incidences of occupational lead poisoning are now rare because of the stringency of the CLAW Regulations.

### **Biological Agents**

8. Occupational exposure to biological agents can result from intentional work with agents, (e.g. in a microbiology laboratory) or else exposure can be incidental to the main purpose of the work,

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<sup>1</sup> Occupational Disease Intelligence Network (ODIN), DWP Industrial Injuries Scheme (IIS) and The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). The figure also includes an estimated 3000 to 12,000 cancer deaths mostly related to chemicals (including asbestos), ref: Carcinogenic risk: getting it in proportion - Sir Richard Doll (paper in conference proceedings: Cancer in the workplace, 15 October 1992, HSE and Society of Chemical Industry).

<sup>2</sup> Figures from the Self Reported Work Related Illness 1995 (SWI95) survey indicate the annual incidence may be much higher for some diseases. For example, the incidence estimates for skin disease alone from SWI95 was 12,000 (95% confidence interval 3000 to 22,000 is typical of the large uncertainty associated with SWI estimates.) However, SWI estimates may include a substantial proportion of cases not caused by chemicals.

(e.g. in agriculture, health care or waste disposal). The scope for assessing the risk and controlling exposure is greater in the former and this is reflected in the legal duties and guidance.

9. It is difficult to estimate the number of people in occupations where there may be an exposure to biological agents. Over two million are employed in the health services sector and approximately 230,000 workers in biomedical sciences (including laboratory technicians). Around 300,000 farmers, food and animal care workers are potentially exposed to zoonoses.

10. Some occupational infections must be reported under RIDDOR. However, underreporting is a significant problem: only 107 cases were reported in 1998/9. Data from UK surveillance schemes reported 1398 cases of occupationally acquired infections in 1998. This probably underestimates the true incidence; other studies of infections among specific groups and self-reported surveys suggest these figures considerably underestimate the scale of work-related infections. Estimated infection rates<sup>3</sup> (per million per year) are 458 (social work activity; with or without accommodation), 433 (meat production), 260 (livestock farming) and 109 (health care).

11. A survey of laboratory-acquired infections showed a reduction in infection rates in laboratories from 827 per million per year in 1988/9 to 162 per million per year in 1994/5<sup>4</sup>. A cohort study of farmers showed evidence of seroconversion and illness to common zoonoses and suggests that RIDDOR reports underestimate work-related zoonotic infections by about 10-fold<sup>5</sup>.

## OPTIONS

### Chemical Agents

12. The need to implement an EU Directive means that Regulations are the only satisfactory solution. The Health and Safety Commission considered three possible options:

- i) introduce a new single set of regulations designed specifically to implement all the Directive's health and safety requirements;
- ii) introduce two new sets of regulations covering health and safety risks respectively;
- iii) amend COSHH, CLAW and the CAW Regulations to implement the Directive's requirements for control over health risks, and to introduce a new set of regulations to implement the safety risk requirements and replace the various separate pieces of legislation presently covering flammable substances.

13. Options (i) and (ii) have not been costed. They are discarded on the grounds that it would be necessary to remove all existing health and safety legislation on flammable substances and

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<sup>3</sup> Ross, D J, Cherry, N M and MacDonald, J C (1998) *Occupationally acquired infectious disease in the United Kingdom: 1996 to 1997* Communicable Disease and Public Health 1(2) June 1998 pp 98-102.

<sup>4</sup> Scottish Centre for Infection and Environmental Health (1998) *Infections in UK Clinical Laboratories 1994 to 1995* Contract Research Report.

<sup>5</sup> Thomas, D Rh, Salmon, R L, Kench S M et al (1994) *Zoonotic illness - determining risk and measuring effects: association between current animal exposure and a history of illness in a well characterised rural population in the UK* J Epid and Comm Health 48 pp 151-155.

substances hazardous to health. This would mean significantly higher implementation costs and costs to HSE.

14. The COSHH, CLAW and CAW Regulations are well established and employers are familiar with their structure and requirements. COSHH has been in force since October 1989; CLAW since 1981 (the CLAW Regulations 1980 were replaced by CLAW 1998 in April 1998); and the CAW Regulations since 1988. For those reasons, COSHH, CLAW and the CAW Regulations are being used as the regulatory implementation vehicles which will be amended to reflect the specific requirements of the Directive that are not already explicitly set out in those Regulations. This use of familiar, well established Regulations to implement the Directive's health requirements should help prevent the confusion that completely new regulations would almost certainly have caused and so reduce the burden on industry arising from the regulatory change.

### **Biological Agents**

15. COSHH 1994 came into force on 16 January 1995, implementing the EC Directive on the protection of workers from risks related to exposure to biological agents at work (90/679/EEC). The changes included a new Schedule 9 "Special provisions relating to biological agents", minor changes to the main part of COSHH, a revised General ACoP and a new supplementary ACoP "Control of biological agents".

16. In keeping with HSE policy, the new Regulations were formally evaluated. Information was gathered from a range of work activities which involve deliberate work with biological agents to those where there may be incidental exposure during the course of work, (e.g. food preparation, nursing, farming, textiles industry, engineering, water treatment and waste handling).

17. In sites intentionally working with biological agents in laboratories, awareness of COSHH was good, but not necessarily of Schedule 9. There was awareness of biological agents and COSHH among management and health and safety practitioners in industries where staff may be incidentally exposed to biological agents. However, this did not appear to result in greater awareness among other staff or to affect work practices. Small firms had difficulty conducting risk assessments for biological agents.

18. To address the above issues it is proposed to use the opportunity presented by the implementation of CAD to amend the biological agents provisions of COSHH. This will involve amendment of the Regulations and Schedule and of the General and Biological Agents ACoPs and supporting guidance.

19. The primary aim will be to make it clear that COSHH applies to both chemical and biological agents. The main change is to move the general provisions on the assessment and control of biological agents into the main COSHH Regulations. Specific measures relating to deliberate work with biological agents, (e.g. laboratory and large scale plants) will continue to be addressed in a slimmed down Schedule. The Schedule will be supplemented by a biological agents appendix to the main COSHH ACoP.

### **INFORMATION SOURCES AND BACKGROUND ASSUMPTIONS**

20. Most of the information to derive the likely impact to society from implementing CAD has been supplied by industry. Three questionnaires (one for COSHH, one for CLAW and one for the changes to Schedule 3) were sent to a sample of small (less than 50 employees), medium (between 50 and 250 employees) and large (more than 250 employees) companies that HSE believes will be affected by CAD. The questionnaire relating to the changes to COSHH was also posted on HSE's web site. The response rate for the questionnaires is given in Table 1 below. Other sources of information are reported in the relevant paragraphs.

**Table 1: Response rates for the questionnaires.**

Questionnaire	Number sent	Number received <sup>6</sup>	Response rate
COSHH	24	11	46%
CLAW	4	3	75%
Schedule 3	24	15	63%

21. There is uncertainty surrounding some of the cost estimates due to the wide variety of responses to the questionnaire. Wherever possible we have provided a range of figures or have made a best estimate based on available information.

22. The base year for appraisal is 1999/2000. Costs and benefits are calculated in 1999/2000 prices over a ten year period from 2001/2002 to 2010/2011<sup>7</sup>.

## **BENEFITS**

### **Health and safety benefits**

23. Many of the requirements of CAD are already included in current UK legislation. Where CAD goes further than current requirements it is difficult to assess the health benefits, although it is likely that they will be limited. However, familiarisation with the requirements under CAD may help increase awareness of the risk to health from chemical agents. Indeed, many of the companies and trade associations that responded to our questionnaire stated that this was a potential benefit and made reference to the cost of having employees absent from work due to work-related ill health.

24. Cases reported under the RIDDOR injury provisions as caused by exposure to harmful substances are approximately 1760 per year. Allowing for under reporting using a scale factor based on RIDDOR reports and Labour Force Survey (LFS) injury estimates, this figure increases to over 3700 cases per year<sup>8</sup>. Moreover, in 1999, there were 1118 work-related asthma cases (some of which will be due to exposure to biological agents) and 154 inhalation accidents (SWORD/OPRA) and 3934 recorded cases of work-related dermatitis (EPIDERM/OPRA). As far as exposure to lead is concerned, there were 17,645 lead workers under medical surveillance in

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<sup>6</sup> Two replies were received from posting the questionnaire on HSE's web site.

<sup>7</sup> In arriving at ten 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>8</sup> The LFS indicates that, in 1997/98 there were 380,000 reportable injuries to workers, of which 341,000 injuries were to employees. Employers, however, made injury reports on only 164,000 employees. This suggests that employers reported around 47% of the injuries that should have been reported under RIDDOR in 1997/98.

1999/00, of whom 124 were suspended from work due to the high level of lead measured in their blood. There is, however, no information on the duration of absence from work that this implied. Finally, there were approximately 1400 estimated cases of occupationally acquired infections reported to SIDAW and other surveillance schemes in 1998, although this figure probably substantially underestimates the true incidence of occupational infections.

25. 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. Without more detailed information about the occupational health cases due to exposure to chemical and biological agents (in particular, on the length of absence from work and whether the diseases force workers to change job or leave the labour market) it is not possible to estimate their total cost to society. Furthermore, even though the implementation of CAD will introduce some more stringent requirements and it is therefore likely to reduce risks from exposure to hazardous substances, it is impossible to quantify the reduction, and therefore to estimate the health benefits of the proposed changes to the COSHH and CLAW Regulations. Similarly, it is hoped that the additional changes to the provisions of COSHH which relate to biological agents, will lead to a better awareness of when exposure to biological agents should be considered and also make some of the requirements simpler to apply. This should reduce the incidence, and therefore the cost, of ill health caused by exposure to biological agents. However, it is not possible to predict the number of cases that will be avoided.

26. In 1998, members of the fire brigade sustained 678 non-fatal injuries<sup>9</sup> while tackling fires. During the preceding ten years there was also a total of 13 fatal injuries. In the majority of these cases the firefighters were either burned or overcome by gas or smoke. Article 7(5) will result in the emergency services having access to additional risk based information that supports firefighter safety. Given the particularly dangerous nature of their job, this information may prove to be extremely valuable in reducing the risk of work-related injury and ill health arising from exposure to substances hazardous to health during emergency situations. Again, it is very difficult to predict how many injury cases may be avoided thanks to the introduction of this requirement.

27. To conclude, complying with the requirements of CAD and with the changes which relate to biological agents should improve the standard of health across employees, but it is impossible to quantify the extent of this improvement and therefore to estimate the health and safety benefits.

### **Cost savings**

28. COSHH currently requires the prior notification of the consignment of Part V biological agents whether they are being moved to another premises or imported into Great Britain. This duty does not apply to the movement of material being transported for diagnostic purposes or animals and patients being transported for medical reasons. Notifiers have to provide the information detailed in paragraph 12(3) of Schedule 3 plus details of the route to be taken, name of transport operator, name of individual(s) accompanying the consignment and the packaging precautions that will be taken.

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<sup>9</sup> Statistic supplied by the Home Office, February, 2000.

29. Because of the proposed changes to Part V (see below) it is proposed that this duty will be restricted to Group 4 agents only.

30. To calculate the cost saving of this change we assume that 50% (in line with the answers to the questionnaire) of the establishments deliberately working with biological agents save between 30 minutes and one hour per year through not having to complete an average of one notification. This translates to a cost saving of between £68,000 and £248,000 per year<sup>10</sup>. Over ten years the present value cost saving equals between £0.6 million and £2 million.

### **Other benefits**

31. CAD will be implemented in all European Union (EU) countries. As a result, all companies operating within the EU, who use chemical agents, will have to comply with the same Directive. UK companies may well be among those least affected by CAD because many of its requirements are currently contained, at least implicitly, within existing UK legislation. Consequently, UK companies may be less affected than other Member States by the tightening of regulations on chemical agents. Less stringent regulatory regimes may have provided the UK's competitors with cost advantages in the past, but without a detailed analysis of the current regulatory regimes of other EU countries it is not possible to quantify any benefit.

## **COSTS**

### **Business sectors affected**

#### *COSHH*

32. 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, so we assume that all British employers with at least one employee (about 1.3 million<sup>11</sup>) complete a COSHH assessment and are affected by the changes to COSHH. Even though firms in all sectors come under the scope of COSHH and will therefore be affected by the changes required to incorporate CAD, the greatest burden will fall upon those industries where there is the greatest exposure to hazardous substances, in the primary and secondary industries. The number of copies of the General ACoP sold in the last few years seems to suggest that only a small percentage of firms finds it necessary to buy a copy of any one edition (about 20,000 copies per edition). It is therefore likely that the number of companies who find that their risk of exposure is more than slight - see Article 5(4) of CAD - is actually quite small. HSE estimates that this is about 5% of 1.3 million employers (i.e. around 65,000 employers).

#### *CLAW*

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<sup>10</sup>As an example, the lower value of the range is calculated as follows. Cost saving through not having to complete notification of consignment forms = 3,000 firms x 50% x 0.5 hours x £15.03 = £11,300 per year. Time saved by Biological Safety Committees (BSCs) = 3,000 x 0.5 x 0.5 hours x £15.03 x 5 members = £56,400 per year. Total cost saving = £11,300 + £56,400 = £67,700 per year.

<sup>11</sup>Based on *Small and medium enterprise (SME) statistics for the United Kingdom, 1999*, SME Statistics Unit, Department of Trade and Industry, September 2000. Companies with zero employees are not included.

33. Table 2 presents the number of lead workers reported (to HSE) as being under medical surveillance during 1999/00 by industry sector. Some employees are currently placed under medical surveillance whose exposure to lead is not significant under CLAW, but there are also likely to be employees who should be under surveillance but are not or who are under surveillance but are not reported by their employer as being so. There were 17,645 employees under medical surveillance in 1999/00, of which 95% were males. The table shows that “smelting, refining, alloying and casting” and the “lead battery industry” each account for over one fifth of the total number exposed. Excluding “other processes”, the sectors with the next largest shares are “work with metallic lead and lead alloys” (11%) and “manufacture of organic and inorganic lead compounds” (8%).

**Table 2:** Lead workers under medical surveillance by sex and industry sector in 1999/00<sup>12</sup>

<b>Industry Sector</b>	<b>Males</b>	<b>Female</b>	<b>Total</b>
Smelting, refining, alloying and casting	3,788	112	3,900
Lead battery industry	3,673	99	3,772
Badge and jewellery enamelling and other vitreous enamelling	11	2	13
Glass making	779	126	905
Manufacture of pigments and colours	423	34	457
Potteries, glazes and transfers	204	177	381
Manufacture of organic and inorganic lead compounds	1,434	26	1,460
Shipbuilding, repairing and breaking	231	0	231
Demolition industry	523	4	527
Painting buildings and vehicles	837	0	837
Work with metallic lead and lead containing alloys	1,848	126	1,974
Other processes	2,701	97	2,798
Scrap industry	380	10	390
<b>All sectors</b>	<b>16,832</b>	<b>813</b>	<b>17,645</b>

34. The exact number of firms that will be affected by the changes to CLAW is uncertain. However, a 1997 HSE Cost-Benefit Assessment (CBA) for the Control of Lead at Work Regulations used a figure of 500 firms. The estimate of 500 firms was made after consultation with a number of trade associations representing companies working with lead. The number of firms working with lead is unlikely to have changed much in the last few years and we therefore use the same figure.

### *COSHH Schedule 3*

35. It is estimated that there are about 3,000 establishments, where there is a deliberate intention to work with biological agents, which will be affected by the proposed changes to Schedule 3. Many of these organisations will be involved in biological research and development, diagnosis of diseases and teaching.

<sup>12</sup>Health and Safety Statistics 1999/00, Page 202, Table A2.33, ISBN 0 7176 1716 5

## **Compliance costs to business**

36. In this section the costs of changes to COSHH and CLAW are discussed by examining each Article individually. It is assumed that all firms having to comply with CLAW will also have to comply with COSHH. If the company is principally concerned with lead, the related COSHH requirements would probably be less of a burden on the presumption that the other hazardous substances present would not be for primary use. However, the employer would still be required to apply all the COSHH/CAD requirements if employees were liable to be exposed to hazardous substances other than lead. In cases where the two sets of regulations overlap, therefore, the cost of compliance has been calculated both for COSHH and CLAW, relying where possible on the replies to the two questionnaires. We have assumed that all companies dealing with lead conclude that the risk to health is more than slight. For firms affected by COSHH, instead, we have assumed that about 95% are likely to conclude that the risk is only slight. This estimate is broadly in line with the number of copies of the General COSHH ACoP sold over the last few years.

### **Article 4: Determination and assessment of risk of hazardous agents**

#### *COSHH/CLAW*

37. CAD's assessment requirements mean that COSHH and CLAW will have to be amended to require the employer to do the following:

- to assess any risk to health of employees arising from work which is liable to expose employees to substances hazardous to health (including lead), taking into account a number of specific considerations set out in Articles 4(1)(3)(4) and 6(5);
- to implement any preventive measures identified by the assessment.

38. Most, if not all of the requirements concerned are either implicit within the Regulations or covered by the guidance contained in the General COSHH and CLAW ACoPs. Therefore, HSE believes that industry is already implementing CAD's requirements and so, although it is necessary to introduce the Directive's specific considerations into both sets of Regulations, this should not impose any additional burden on the businesses affected.

39. The majority of companies consulted agreed with this opinion although some did express concern that the proposed changes would have an additional burden in view of the more prescriptive nature of CAD.

### **Article 4(2)**

#### *COSHH/CLAW*

40. CAD requires the employer to be in possession of an assessment of the risk and for the risk assessment to be documented in a suitable form. Regulation 3 of the Management of Health and Safety at Work Regulations 1999 (the Management Regulations) already requires employers with five or more employees to record the significant findings of the assessment. HSC is concerned that extending the recording requirement to all employers who use or produce hazardous substances at the workplace would place a new burden on thousands of small employers. In larger companies, where there is greater diversity of work and a more sophisticated management structure, the risk assessment record can be used to check that no areas of work have been overlooked, and all significant hazards and risks have been assessed. In very small businesses, frequently only one person is involved in assessing risks, and producing a written record is likely to make little or no contribution to standards of health and safety. In fact, additional requirements on small firms may lead to poor levels of compliance, perhaps putting completion of the assessment itself in jeopardy. HSC believes that it is more important that the very smallest businesses focus their attention on practical measures to protect employees' health and safety.

41. The well established arrangement in the Management Regulations, which exempts employers with fewer than five employees from having to record the significant findings of their assessments, has not been shown to be detrimental to health and safety in small businesses. It is far more likely that failure to carry out a risk assessment would contribute to an accident rather than the absence of a written record. Therefore, to implement the recording requirements in Article 4(2), HSC proposes an approach that is consistent with the Management Regulations. Duties to record the significant findings of the assessment have been inserted into regulation 6(4) and 5(4) of COSHH and CLAW respectively, but they apply to employers with five or more employees. Therefore, it is assumed that there will be zero incremental cost associated with Article 4(2).

42. The Directive does not specify when the record of the assessment should be recorded. However, it clearly makes sense to record the assessment at the time when it is made or as soon as is practicable thereafter, so that an employer can use it to demonstrate to safety representatives, health and safety inspectors etc. that he has taken a comprehensive and structured approach in considering the risks to employees' health and the measures needed to control those risks. Therefore, HSC has included in the proposed recording requirements at regulations 6(4) and 5(4) of COSHH and CLAW respectively, that the significant findings should be recorded as soon as is practicable after the risk assessment has been made. HSC recognises that it will not always be practicable to record **all** the significant findings when the assessment is made, and so guidance in the supporting ACoP states that where appropriate, the employer may have to add information to the record of the significant findings as it becomes available. HSC does not believe that this requirement will impose any additional burden on industry.

## **Article 4(5)**

*COSHH/CLAW*

43. This article requires that the steps to prevent or control exposure are not only identified by the assessment but also implemented. Implementation of control measures is implicitly required by regulations 6 and 7 of COSHH and regulations 5 and 6 of CLAW, both supported by regulation 3 of the Management Regulations. The companies which were consulted and HSE believe that making this requirement explicit should not impose additional burdens on industry.

### **Reviewing the assessment**

44. CAD requires that the risk assessment is kept up to date, and sets out some specific circumstances when the assessment should be reviewed. These are when the results of health surveillance show it to be necessary (Article 4(2)) and when it is necessary to take into account the results of measuring employees' exposure to substances hazardous to health (Article 6(5)). These review circumstances are currently set out in the COSHH and Lead ACoPs to illustrate when an assessment may no longer be valid and therefore in need of review. The companies consulted and HSE believe that transposing the requirements from the ACoP to the Regulations should not impose an additional burden on industry.

45. Regulation 6 of COSHH refers to the assessment of health risks created by work involving substances hazardous to health. This regulation will be revised to introduce a specific reference to biological agents and require that the employer considers the approved classification of any biological agents (see draft regulation 6(2)(k)). HSE believes that this will not impose any additional costs on employers. However, one company was concerned that its industry had little experience of dealing with biological agents and that expensive specialist advice would be required to ensure compliance.

### **Article 6: General and specific protection measures**

#### **Article 6(2)**

##### *COSHH/CLAW*

46. To ensure that the risk to employee's health is eliminated or reduced to a minimum, Article 6(2) requires that by preference employers substitute for hazardous chemical agents, a chemical agent or process which under its conditions of use is either non-hazardous or less hazardous to the safety and health of employees. Under COSHH Regulation 7(3), a similar substitution duty exists but only in respect of exposure to carcinogens. The current COSHH ACoP explains how preventing exposure to other substances hazardous to health can be achieved in a number of ways including substitution. However, inserting a substitution requirement into the Regulations covering all substances hazardous to health may encourage more employers to comply with COSHH's first priority of preventing exposure, rather than relying on securing adequate control of exposure.

47. The COSHH questionnaire asked a number of questions about this requirement, but the very different replies, and the comments received, suggest that it is very difficult to quantify this cost. There are going to be costs associated with changing to a system of preventing exposure, but the extent of substitution and the resulting cost will not only vary between industries, but also within industries. For example, within the lubricants industry the extent of substitution will depend on what type of lubricant is being produced. Manufacturers involved in the production of metal working

fluids will be heavily involved in substitution because of the increasing number of lubricants which are now being recognised as hazardous. In contrast, manufacturers of automotive engine oils will be relatively unaffected by this requirement because the ingredients they use are regarded as being largely non-hazardous.

48. The guidance in paragraph 58 of the current CLAW ACoP explains how measures to control all possible routes of exposure to lead should include using substitute lead-free materials or low-solubility lead compounds where it is reasonably practicable to do so. However, the trade associations consulted stated that employers in various sectors of the lead industry may not find it easy to substitute an alternative material for the lead they use and that while a legal duty to substitute would provide a greater incentive to do so, such steps may still not be taken because it is not reasonably practicable to do so.

49. It is possible that some of the costs involved in substitution will be partially offset by cost savings, through not having to purchase personal protective equipment (PPE) and undertake health surveillance when exposure to a hazardous substance has been eliminated. If exposure can be prevented by substitution, there is also the prospect of savings from employers needing less engineering controls, local exhaust ventilation, enclosed systems, and the need to carry out air monitoring. There is uncertainty over the number of firms that would enjoy these cost savings.

50. For the reasons explained, it is not possible to quantify the additional cost implied by this requirement.

#### **Article 6(4)**

##### *COSHH*

51. Article 6(4) sets out the circumstances when the employer must carry out measurements of workers' exposure to show that control measures are achieving adequate prevention and control of exposure. The COSHH Regulations will be amended to require that monitoring should be carried out when any change occurs in the conditions which may affect employees' exposure to substances hazardous to health. The revised ACoP will explain that monitoring need only be carried out in these circumstances if the employer's review of the assessment arising from the changed conditions raises any doubt whether adequate control is still being achieved.

52. Article 6(4) also requires that monitoring is carried out "on a regular basis", and this frequency requirement will be inserted into COSHH. The COSHH ACoP will continue to advise employers that if they conclude from their assessments that monitoring is necessary, then they should also decide how frequently it should be carried out having regard to the factors considered by the assessment. Both HSE and almost all the companies consulted believe that no extra work will be imposed on industry as a result of Article 6(4). One company disagreed and stated that more companies will have to carry out air monitoring.

#### **Proposal relating to biological agents**

53. Regulation 7 of COSHH refers to the prevention or control of exposure to substances hazardous to health and will be amended to incorporate the measures in COSHH Schedule 3,

paragraph 6 (Control of exposure to biological agents). Although the wording differs in places, most of the measures listed in Schedule 3 are already present in Regulation 7 either explicitly or implicitly. The main exceptions for biological agents are the need for disinfection and decontamination measures, displaying the biohazard sign and offering vaccination to exposed workers. HSE believes that other than familiarisation (see later section on familiarisation costs) with the revised regulation 7 and Schedule 3 these additions will not impose any additional costs on employers. However, one company was concerned that companies will have to devise a recording system to ensure employees are regularly vaccinated and that employees will have to take time off work to have the vaccinations; another company also thought that the vaccinations would impose additional costs.

**Article 7: Arrangements to deal with accidents, incidents and emergencies**  
*COSHH/CLAW*

54. In accordance with requirements set out in the ACoP to the Management Regulations, many employers will already have established procedures to be followed by their employees if situations arise which present serious and imminent danger. These procedures will include evacuating the affected area and only allowing access by those workers wearing any appropriate PPE, who are needed to do the necessary repair and other work. Many employers will already have extended their emergency procedures to include some of CAD’s provisions: e.g. holding safety drills at regular intervals (Article 7(1)); providing alarms or communication systems to warn employees of any increased risk to their health and safety posed by an incident (Article 7(4)). However, those CAD requirements not covered by the Management Regulations will be incorporated in both COSHH and CLAW.

55. This requirement does not apply to all employers, because only those employers who determine that the quantity of substances hazardous to health at the workplace pose more than a slight risk to the health of employees, (i.e. about 5% of 1.3 million firms) will need to comply. Using the information provided by the questionnaires a range has been estimated for the percentage of firms who will have to change their current procedures to comply with this Article and for their costs. Both one-off costs associated with setting up the new systems and recurring costs incurred to maintain them have been calculated for small, medium and large firms over a ten-year period. Most of the companies consulted found it difficult to say how much this requirement would cost them and the three companies who replied gave contrasting responses. HSE considers that the employers will not have to spend much to comply, since the Management Regulations section on what employers should do in the event of emergency situations already covers most of what CAD requires. The table below lays down all the assumptions made. By adopting these assumptions, recurring costs (£1.7 million to £5.1 million per year) are assumed to be half of one-off costs (£3.4 million to £10.3 million). The total ten-year costs<sup>13</sup> for all firms are estimated to be between £17.7 million and £53 million in present value terms. A breakdown of these totals is given in Table 5.

**Table 5:** Costs of complying, changing and maintaining procedures for incidents, accidents and emergencies (changes to COSHH). (NB Totals may not add up due to rounding.)

	Small firms	Medium firms	Large firms	Total
Percentage of firms changing	40-60	10-20	10-20	

<sup>13</sup>As an example, the lower value of the range for small firms is calculated as follows. 1.26m x 0.4 (proportion of firms changing procedures) x 0.05= 25,819 firms changing their current procedures. One-off costs = 25,819 x £125 = £3.2 million. Recurring costs = 25,819 x £62.5 = £1.6 million per year .

current procedures				
Number of firms facing costs	25,819 - 38,729	117 235	33 - 66	
One-off additional costs per firm (£)	125-250	1,000-1,500	2,000-2,500	
Recurring additional costs per firm (£)	62.5 - 125	500 - 750	1000 - 1250	
Total one-off costs (£m)	3.2 - 9.7	0.1 - 0.4	0.07 - 0.2	3.4 - 10.3
Total recurring costs (£m)	1.6 - 4.8	0.06 - 0.2	0.03 - 0.08	1.7 - 5.1
Total 10-year discounted costs (£m)	16.8 - 50.3	0.6 - 1.8	0.3 - 0.9	17.7 - 53

56. As far as CLAW is concerned, one respondent replied that very few companies (less than 10%) will change the current procedure. Another association said instead that the majority of companies would have to change their procedure to comply. The third association estimated that 50% of small companies and 25% of medium companies would face changes. In view of the uncertainties emerging from the responses, we assume that between 30% and 70% of the 500 firms will face changes to the current procedure. Respondents indicated that costs per firm may be between £1000 and £2000 in the first year, and half of this in the following years to keep the system in place. Therefore, total one-off costs are £150,000-700,000, and recurring costs are £75,000-350,000. Over ten years, total costs equal approximately £0.8-3.6 million in present value terms.

## Article 7(5)

### *COSHH/CLAW*

57. Article 7(5) requires that the relevant external accident and emergency services have access to the employer's plans to deal with accidents, incidents and emergencies. Furthermore, those plans must contain the detail set out in the two subparagraphs to Article 7(5). Employers whose activities make use of or produce large quantities of hazardous substances may already have a legal duty under other regulations to liaise with the emergency services to provide copies of their plans to deal with incidents and emergencies. However, many more employers including relatively small concerns that use particularly hazardous materials will have to liaise with their Chief Fire Officer to offer to provide a copy of the business emergency plans covering the information specified by the Directive.

58. This requirement again only applies to firms whose assessment of the risk to the health of employees is more than slight (5% of firms). To calculate the cost of this requirement we use the information provided by the companies surveyed to make assumptions about the percentage of small, medium and large firms facing extra work. Respondents maintained that the amount of time spent setting up the new system and then keeping it in place may vary between 14 to 28 hours in the first year, and half a day to a day in the following years. This estimate seems excessive. All that the Directive requires is for the employer to make a copy of his emergency procedures available to the external emergency services, i.e. the local Chief Fire Officer (CFO). So the action on the employer might comprise a letter or telephone call to the CFO advising him of the availability of the

procedures, and asking him whether he wants a copy, and if he does, arranging to send a copy. In some cases this may be followed by a short meeting. We, therefore, estimate that all this may entail between 1 hour and 4 hours the first year, followed by between half an hour to two hours to keep the system in place in the following years. We assume that this time will be spent by a health and safety officer in medium and large firms at a cost of £17.07 per hour<sup>14</sup> and a manager at a cost of £19.44 per hour in small firms<sup>15</sup>. The total one-off cost to all firms of these changes is, therefore, between £0.6 million and £3.5 million and the recurring annual costs are between £0.3 million and £1.8 million per year. The total cost to all firms of these changes is between £3.3 million and £18.4 million over ten years in present value terms<sup>16</sup>. Details of the assumptions and the resulting costs are shown in Table 6.

**Table 6:** Assumptions and costs of supplying the accident and emergency services with details of employers plans to deal with incidents, accidents and emergencies.

	Small firms	Medium firms	Large firms	Total
Firms undertaking additional work (%)	50 to 70	10 to 30	5 to 10	
Total number of firms facing costs	32,274 - 45,184	117 - 352	16 - 33	
Time spent on one-off tasks (hours)	1 to 4	1 to 4	1 to 4	
Time spent on recurring tasks (hours)	0.5 to 2	0.5 to 2	0.5 to 2	
Cost per hour (£)	19.44	17.07	17.07	
Total one-off costs (£)	0.6m - 3.5m	2,000 - 24,000	279 - 2,260	0.6m - 3.5m
Total recurring costs (£)	0.3m - 1.8m	1,000 - 12,000	139 - 1130	0.3m - 1.8m
Total 10-year present value discounted costs (£)	3.2m - 18.3m	10,400 - 138,800	1,400 - 13,000	3.3m - 18.4m

NB Totals may not add up due to rounding

59. As far as CLAW is concerned, the replies to the questionnaire suggest that between 25% and 50% of 500 firms will face additional work to comply. According to two associations, the average time spent may be five days in the first year, and two to three days in the following years. However, as explained above, HSE considers that the time actually spent will be much less, probably between 1 and 4 hours on one-off tasks, and half this time to keep the system in place during the following years. At an average hourly costs of a Health and Safety Officer of £17.07, this equals between

<sup>14</sup>The New Earnings Survey 2000 shows that the hourly wage of a Health and safety officer is £13.13. We increase this by 30% to take account of non-wage labour costs such as employers' national insurance contributions, contributions to superannuation, and pension and insurance funds.

<sup>15</sup>The New Earnings Survey 2000 shows that the hourly wage of "other managers and administrators" is £14.95. We increase this by 30% to take account of non-wage labour costs such as employers' national insurance contributions, contributions to superannuation, and pension and insurance funds.

<sup>16</sup>As an example, the lower value of the range for small firms is calculated as follows.  $1.26 \times 0.5 \times 0.05 = 32,274$  firms facing extra costs. One-off costs =  $32,274 \times 1 \text{ hours} \times £19.44 = £0.6 \text{ million}$ . Recurring costs =  $32,274 \times 0.5 \text{ hours} \times £19.44 = £0.3 \text{ million per year}$ .

£2,100 and £17,000 total one off costs, and total recurring annual costs of about £1,000-£8,535. Total costs over a ten year period in present value terms equal between £7,800 and £63,095.

### **Proposal relating to biological agents**

60. Paragraph 10 of Schedule 3 (Information for employees) will be incorporated into the main body of COSHH. The need for such arrangements should sensibly apply to biological agents and there is a similar requirement in the Biological Agents Directive. Industry and HSE agree that changing the position of this requirement within COSHH should not impose any additional costs on industry. However, one company (a training centre) replied that most employers probably ignore or are not aware of this requirement, and if it became more high profile it would involve additional costs.

### **Article 8: Information and training for workers**

#### *COSHH/CLAW*

61. Both the COSHH and CLAW Regulations contain comprehensive requirements on the information, instruction and training that employers must give to employees. Those requirements identify a number of specific matters which must be covered by the employer and further topics are identified in the supporting ACoPs. The list of specific subjects on which CAD requires employers to provide employees or their representatives with information and training is either explicitly or implicitly covered by the appropriate COSHH and CLAW Regulations and their supporting ACoPs. However, the specific CAD topics will be inserted explicitly into COSHH and CLAW. HSC therefore believes that CAD's requirements do not introduce any items that are not already covered in practice by employers. One company (a training centre) replied that responsible employers are currently a minority and for this reason there might be additional costs, but the rest of companies surveyed agree that implementation of the Article should not impose any further burden on industry.

### **Article 10: Health surveillance**

#### **Article 10(1)**

#### *CLAW*

62. For exposure to lead, Article 10(1) sets two triggers to activate the need to carry out air monitoring. The first of these conditions - where exposure to lead exceeds a certain level - is covered by CLAW's definition of "significant" in relation to exposure. The second condition - where an employee's blood-lead concentration exceeds a specified level - is currently set out in paragraph 35 of the Lead ACoP. This requirement will now be transposed to the Regulations but because it is already being implemented by employers, HSE and the companies surveyed believe it will not involve any extra work.

#### **Article 10(2)**

## COSHH/CLAW

63. Article 10(2) requires that where an employee is subject to health surveillance, exposure and health records are made and kept up-to-date for individual employees. As presently drafted, COSHH and CLAW only require that employers keep suitable records of monitoring and do not specifically require that they keep records for individual employees, though COSHH Regulation 10(3)(a) does refer to the “personal exposures of identified employees”. This requirement will be introduced in such a way that allows employers to add monitoring (exposure) results to an employee’s health record if there is one, as a way of keeping the work to a minimum.

64. To calculate the cost of this requirement we rely on the responses to the questionnaire to make assumptions about the percentage of employees for whom health records will have to be kept. This percentage is then multiplied by the total 18.5 million British employees. It is then assumed that each employee’s record takes between 15 and 30 minutes to complete and maintain each year and that this time will be spent by a filing and records clerk at a cost of £9.39 per hour<sup>17</sup>. As a result, total recurring costs to all firms of keeping health records for individual employees are between £2.7 million and £16.1 million per year. The total cost is between £25.3 million and £151.4 million over 10 years in present value terms<sup>18</sup>. Details of the assumptions and resulting costs are shown in Table 7.

**Table 7:** Assumptions and costs for keeping health and exposure records for individual employees (changes to COSHH).

	Small firms	Medium firms	Large firms	Total
Total number of employees	6.7 million	2.4 million	9.6 million	
Percentage requiring health and exposure records	1	5 to 20	10 to 30	
Time spent on recurring tasks per firm (hours)	0.25 to 0.5	0.25 to 0.5	0.25 to 0.5	
Cost per hour (£)	9.39	9.39	9.39	
Total recurring costs (£m)	0.16 - 0.3	0.3 - 2.2	2.3 - 13.5	2.7 - 16.1
Total 10-year discounted costs (£m)	1.5 - 2.9	2.7 - 21.4	21.2 - 127	25.3 - 151.4

NB Totals may not add up due to rounding

65. As far as CLAW is concerned, HSE’s lead exposure records show that about 18,000 employees may be affected each year. Respondents to the questionnaire indicated that the time taken by a clerk to comply with this requirement is about 30 minutes per employee each year. At the hourly cost of £9.55, this equals a total of £85,900 per year, and over a 10-year period total costs are £720,700 in present value terms.

<sup>17</sup>The New Earnings Survey 2000 shows that the hourly wage of a Filing and Records Clerk is £7.22. We increase this by 30% to take account of non-wage labour costs.

<sup>18</sup>As an example, the lower value of the range for small firms is calculated as follows. Total number of employees in small firms = 6.7 million. 6.7 million x 0.01 (proportion requiring health and exposure records) = 67,000 employees requiring health records. Recurring costs = 67,000 x ¼ hour x £9.39 = £157,200 per year.

66. Furthermore, under CLAW, air monitoring has to be carried out whenever exposure to lead is liable to be significant as defined by the Regulations. Although CLAW does not specifically require that air monitoring records are kept up-to-date, in practice they are likely to be updated with results as they become available. Therefore, HSC and the trade associations consulted believe that CAD's updating requirement will not burden employers with additional work.

### **Article 10(3)**

#### *COSHH/CLAW*

67. This requires that copies of the appropriate exposure and health records are supplied to the competent authorities on request. A comparable requirement will be introduced into COSHH and CLAW. HSE believes that enforcing authorities are unlikely to invoke the regulation very often, and so it is not expected to impose any additional work on employers.

68. When an employer ceases to trade, s/he must notify the Executive in writing and make available to the Executive all air monitoring records. The requirement to provide health records under similar circumstances is already covered by COSHH regulation 11(4). We have asked companies working with lead how much time they estimate it would take to comply with this requirement. One organization replied that it was difficult to quantify. The others replied that it would take between 1 and 2 days. HSE believes that it would take much less time to comply, and that since this requirement is only triggered when a business ceases to trade, it is likely to impose only a small cost to industry.

### **Article 10(4)**

#### *COSHH/CLAW*

69. Article 10(4) imposes requirements on an employer if one of two conditions is satisfied. The conditions are:

- an employee under health surveillance is found to have an identifiable disease or adverse health effect which the doctor considers to be the result of exposure to a substance hazardous to health; or
- a binding biological limit value is found to be exceeded (Note: lead is the only substance hazardous to health for which such a limit value has been assigned).

70. COSHH will be amended to require that if the first condition is satisfied, the employer ensures that the employee concerned is told the medical result that relates to him personally, and is given any information and advice about continuing health surveillance after exposure to the substance concerned has ceased. In these circumstances COSHH will also be amended to require that the employer takes the following steps:

- review the risk assessment made pursuant to Article 4(1);
- review the measures provided to eliminate or reduce risks pursuant to Articles 5 and 6;

- take into account the advice of the occupational health care professional or other suitably qualified person in implementing any measures required to eliminate or reduce risk, including the possibility of assigning the employee to alternative work where there is no risk of further exposure;
- arrange continued health surveillance; and
- provide for a review of the health status of any other employee who has been similarly exposed.

71. CLAW will also be amended to require the same action as proposed under COSHH, but if either condition is satisfied.

72. To a large extent, these measures will already be carried out by employers because the occurrence of an identifiable disease or adverse health effect will, under COSHH and CLAW and their ACoPs, trigger a review of the risk assessment and the effectiveness of the measures identified to control exposure. In these circumstances, the employer is also likely to do what the Directive requires, i.e. seek the advice of any doctor responsible for carrying out the health surveillance on any further action that should be taken, and to review the state of health of any other employees who may have been similarly exposed to the conditions that produced the identifiable disease or adverse health effect. Therefore, HSC and the companies consulted believe that implementation of the Article is unlikely to create much additional work for industry.

73. Our questionnaires suggest that each year between 5 and 10 employees in small, medium and large firms may be expected to suffer from an adverse health effect. However, from the risk assessment section we know that between 16,000 and 25,000 become ill as a result of exposure to substances hazardous to health. This figure may decrease over time due to compliance with CAD. We assume that in each case of adverse health effect it will take between half a day and one day to comply with the requirements of CAD at a cost of £17.07 per hour (health and safety officer hourly cost). The total annual recurring cost of this requirement is therefore between £0.96m (16,000 x 3.5 hrs x £17.07) and £3m per year. This translates to a ten-year total cost of between £8m and £25m in present value terms.

74. As far as CLAW is concerned, 124 lead workers were suspended from work in 1999/00. One respondent has indicated that the average time spent per affected employee is between one and two days of a manager's time in small firms and of an health and safety officer in medium and large firms, whereas another respondent found this difficult to quantify. The medical surveillance procedures under CLAW are very stringent and are carried out by appointed doctors or by HSE medical inspectors. In HSE's view, the CAD requirements described in paragraph 70 are already being carried out in practice, either when an employee's blood-lead level reaches or exceeds a defined action level, or it reaches the suspension level, when the employee is removed temporarily from work involving further exposure to lead. Therefore, HSE believes that setting out the CAD requirements in CLAW should not impose any additional burden on the various sectors of the lead industry.

## **Familiarisation**

### *COSHH*

75. Both employers and employees will have to become familiar with the changes required by the Directive. The replies to the questionnaire varied between half a day and several days. The employer will not only have to familiarise himself with the requirements of the Regulations but also with the supporting ACoP. However, we know that only a very small percentage of the 1.3 million firms who make COSHH assessments buys a copy of the ACoP. We therefore assume that it will take half a day of one health and safety officer, or manager, in 95% of firms (1.2 m firms), and about 1 day per firm with higher risk to health (5% - 65,000 firms) to become familiar with the changes to COSHH. In small firms we assume that this task will be undertaken by the manager at a cost of £19.44 per hour, in medium and large firms it will be undertaken by a health and safety officer at a cost of £12.87 per hour. This equates to a total one-off cost of £94 million for all firms completing COSHH risk assessments.

76. In line with the responses to the questionnaires we also assume that between 35% and 65% of the 924,000 employees working for the 5% companies with higher health risk (assuming 5% of GB employees work for those companies with higher risk to health) will be briefed about the changes in a seminar. This briefing will take 2 hours at a cost of £9.35 per hour<sup>19</sup> per employee and between £6.1 million and £11.4 million in total. Some firms may need to employ consultants to organise these seminars at a cost of about £500 per day. One day should be sufficient to prepare and give a seminar. We assume that two thirds of firms make employees aware of the Regulations through internal seminars and one third use consultants. Using these assumptions gives a further cost of £11 million and a total one-off cost of familiarising employees of between £17.1 million and £22.4 million.

### *CLAW*

77. Some 500 companies will also have to become familiar with the changes to CLAW. Again we assume that it will take one health and safety officer in each medium and large firm and one manager in each small firm 3.5 hours to become familiar with the changes at a total one-off cost of about £31,500<sup>20</sup>.

78. We assume that in these companies, time will be allocated in the seminars explaining the changes to COSHH where they will apply, at no much further cost. The costs associated with explaining the changes to CLAW to employees are therefore incorporated in the costs of explaining the changes to COSHH.

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<sup>19</sup>The New Earnings Survey 2000 shows that the hourly wage of a manual worker is £7.19. We increase this by 30% to take account of non-wage labour costs.

<sup>20</sup>Assuming 40% of companies that must become familiar with the changes to CLAW are small firms, the cost of familiarisation is calculated as follows: (500 firms x 0.4 x £19.44 x 3.5 hours) + (500 firms x 0.6 x £17.07 x 3.5 hours) = £31,500.

## **Proposed changes to COSHH Schedule 3**

### **Proposed changes to exemption certificates**

79. A number of agents in Hazard Group 3 (HG3) are known to present a low risk of infection via the airborne route. Currently, some of the containment measures to be applied to such agents may be dispensed with, taking into account the nature of the activity etc. In the UK, HSE has made use of exemption certificates, listing those agents where the derogation applies. The exemption is dependent on Advisory Committee on Dangerous Pathogens (ACDP) guidance, which takes two approaches to the derogation:

- a. for most agents, the ability to use lower containment is restricted to non-intentional work with the agent, mainly diagnostic work where there are uncertainties about the presence of the agent. Where there is a likelihood of such agents being present or propagated by the procedures, full containment level 3 measures must be used;
- b. for a few agents with unique biological properties the ACDP guidance allows some measures to be dispensed with as they are not necessary to control a risk of infection.

80. As well as legal problems with continuing with the exemption certificate, there are practical problems regarding the status of guidance. There is considerable confusion about the derogation, and this can lead to a perception that these agents are in some way less hazardous, and the containment less rigorous than for other Group 3 agents.

81. For those agents where the derogation mainly relates to diagnostic work, it is proposed to rely on the references to HSC-approved guidance in Schedule 3, paragraph 8(4)(e). However, this does not apply to those Group 3 agents where the properties of the agent mean that some level 3 measures are not necessary even for intentional work with the agent (see (b) above). So, it is proposed to introduce a similar requirement to follow HSC-approved guidelines into paragraph 8(4)(b), using a similar form of words to the current paragraph 8(4)(e). The current ACDP guidance could then form the HSC-approved method. The result of these changes will be to provide clearer signposts to the guidance for those organisations working with derogated HG3 agents.

82. It is also proposed to extend the use of HSC-approved guidance to the containment of animals. Currently the Regulations require that all of the containment requirements in the Schedule 3 Part II table would apply to large (domestic) animals infected with biological agents. HSE proposes to introduce a new provision to approve certain lower containment measures for such cases via HSC-approved guidance.

83. One company stated that the time savings from this proposed change could be significant. However, all the other respondents either did not answer this question or believed that no time would be saved. In view of this we conclude that it is likely that in the majority of cases no time will be saved.

## Proposed changes to subsequent use notification requirements

84. COSHH requires the notification of subsequent use of a Part V agent 30 days in advance of work starting. This includes all Group 4 agents whether or not they have an approved classification. It also requires the notification of subsequent use of Group 3 agents 30 days in advance of work starting where the agents do not have an approved classification.

85. HSE proposes to introduce a new duty to require the notification of subsequent use of each new Group 3 agent and the following three Group 2 agents which require additional containment measures because they present a greater occupational risk:

- Bordetella pertussis;
- Corynebacterium diphtheriae;
- Neisseria meningitidis

86. This duty will apply to agents that already have an approved classification, (i.e. appear on the Approved List of Biological Agents) and those which do not (e.g. newly discovered agents). Work will be allowed to start on receipt of HSE's acknowledgment. The duty will not apply to diagnostic services unless there is an intention to propagate or concentrate the agents.

87. Information from the questionnaires suggests that, on average, 75% of the establishments, which have a deliberate intention to work with biological agent, will now have to notify subsequent use of Group 3 agents with an approved classification and about 1% of all Group 2 agents. Based on the replies to the questionnaires we assume that each notification will take between one and two hours to complete and between 30 minutes and 1 hour for a BSC to discuss at a cost of £15.03 per hour (average hourly wage of a lab technician and a scientist). In line with the replies to the questionnaire we also assume that each of these establishments will have to complete on average between 5 and 10 Group 3 notifications each year and one Group 2 notification each year. As a result the annual cost of this proposal is between £0.8 million and £5.5 million per year<sup>21</sup> and between £7 million and £46.1 million over ten years in present value terms. A breakdown of these costs is given in Table 8 below.

**Table 8:** Costs of the changes to subsequent use of notification requirements.

	Recurring annual costs (£ million)	Ten year discounted present value costs (£ million)
Group 2 agents	0.04 to 0.09	0.4 to 0.7
Group 3 agents	0.79 to 5.4	6.6 to 45.4
Total	0.8 to 5.5	7 to 46.1

<sup>21</sup>As an example the lower value of the range would be calculated as follows. Cost of completing notification forms = 3,000 x 6 (1 Group 2 agent and 5 Group 3 agents) x 1 hour x £15.03 = £271,000. Cost of time spent by BSCs = 3,000 x 5 (Group 3 agents) x 0.5 hours x 5 members x £15.03 = £564,000.. Total cost = £271,000 + £564,000 = £834,000.

## **Information which has to be notified**

88. It is proposed that the identity of the agent, as opposed to only the Group, is notified in all cases. HSE believes that establishments working with biological agents will already know the name of the agents they use and so this requirement is not expected to impose any additional costs.

## **Proposed changes to the requirements for the notification of the consignment of agents.**

89. Part V of Schedule 3 was based closely on a similar Schedule that appeared in the Dangerous Pathogens Regulations. Part V has not been updated since COSHH 1994 and has not taken account of the various updates to the Approved List of Biological Agents - some agents listed have been reclassified into Group 4 and one group does not have a clearly corresponding entry on the Approved List.

90. There are two proposed options for change:

- i) remove Part V completely, all the agents would still be subject to first use and subsequent use but those Group 3 agents remaining would no longer be subject to prior notification of consignment;
- ii) keep Part V but refer to it in the approved list so that it can be easily updated as necessary (this option will not require an amendment to the COSHH Regulations themselves).

91. The decision about which option to adopt will be taken after consultation although the organisations consulted were asked which option they preferred. None of the organisations expressed strong views about a particular option although the majority did prefer option (ii). HSC considers that neither option will have an impact on costs.

## **Familiarisation**

92. All employers who complete notification forms will have to become familiar with the proposed changes to Schedule 3. This is not expected to be a lengthy process and so we assume that an average of two people per organisation<sup>22</sup> will have to become familiar at an average cost of £30.06 per hour (2 times the average hourly wage of a lab technician and a scientist)). This equates to a total one-off cost of £90,200 for the 3000 organisations affected by the proposed changes.

## **Costs to HSE**

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<sup>22</sup>Replies to the questionnaire suggest that in larger organisations there may be more than two people with notification tasks (eg the head of the department, the senior research manager and the health and safety officer), whereas in smaller companies only one person will have this responsibility.

93. HSE currently employs about 1500 Health and Safety inspectors<sup>23</sup>. All of these inspectors will have to spend 3 hours (2 hours for COSHH and 1 hour for CLAW) familiarising themselves with the amended regulations and ACoPs at an average cost of £37.80 per hour per inspector<sup>24</sup> and £170,100 one-off costs.

94. About 1150 of the total 1500 inspectors are members of the Field Operations Directorate (FOD) and the Hazardous Installations Division (HID). FOD inspectors spend about a third of their time dealing with health issues and we assume the same for HID inspectors. Therefore, in 1998, FOD and HID inspectors completed about 47,000 inspections where compliance with COSHH was investigated<sup>25</sup>. We also assume that during the first two years of the amended Regulations, FOD and HID inspectors will take between 15 and 30 minutes extra on each health-related inspection, checking compliance with the amended Regulations. After two years the inspectors are expected to be sufficiently conversant with the changes to incorporate any additional checks into their regular inspection routine. Based on these assumptions, FOD and HID inspectors will spend between 12,000 and 23,000 hours extra during their health-related inspections in each of the first two years of the amended Regulations. This translates to an annual cost of between £440,000 and £890,000. Over two years this equates to a total present value discounted cost of between £0.9 million and £1.7 million.

95. The total cost to HSE is therefore between £1 million and £1.9 million over ten years in present value terms.

## **Other costs**

### **Costs to Local Authorities**

#### *COSHH*

96. There are currently about 6,000 health and safety inspectors working for Local Authorities (LAs). As part of their duties each of these inspectors has to check compliance with COSHH Regulations and will therefore need to familiarise themselves with the changes required by the Directive. Information from HSE's Local Authority Unit (LAU) indicates that each inspector will need to spend about 2 hours making themselves familiar with the changes at a cost of £34.50<sup>26</sup> per

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<sup>23</sup> *Health and Safety Commission Annual Report and the Health and Safety Commission/Executive Accounts 1998/99*, Page 59, Table 7, HSE Books, ISBN 0 10 281499 6.

<sup>24</sup> HSE inspectors are in pay bands 2, 3 and 4. The HSE Full Cost Ready Reckoner states that the hourly cost of Band 2, 3 and 4 inspectors is £60, £42 and £32 respectively. If we assume that for every Band two inspector there are three Band 3 inspectors and six Band 4 inspectors, the average weighted hourly cost would be  $(£60 \times 0.1 + £42 \times 0.3 + £32 \times 0.6) = £37.80$ . Familiarisation with the changes to COSHH and CLAW therefore costs  $£37.80 \times 1,500 \text{ inspectors} \times 2 \text{ hours} = £110,000$ .

<sup>25</sup> *Health and Safety Commission Annual Report and the Health and Safety Commission/Executive Accounts 1998/99*, Page 45 (HSE Books, ISBN 0 10 281499 6) shows that HSE inspectors made a total of 183,292 inspections in 1998/99. FOD and CHID inspectors make up about 77% (1150 out of 1500) of the total of all inspectors and so we assume that they carried out 77% (140,524) of inspections. One third of these inspections concerned health issues so the total number of inspections involving COSHH or CLAW is estimated to be 46,841.

<sup>26</sup> HSE's Full Cost Ready Reckoner states that the cost to HSE of employing a Band 3 and 4 factory inspectors is £42 and £32 per hour respectively. Assuming that for every Band 3 inspector there are three Band 4 inspectors, the average cost is  $£42 \times 0.75 + £32 \times 0.25 = £34.50$  per inspector per hour. The elements that form the basis of this cost are: average salary, central service overhead, accommodation, office services, other charges, computer current charges, depreciation, cost of capital, notional insurance and early retirement costs.

hour. Multiplying the number of inspectors by the number of hours familiarisation and the cost per hour gives a total one-off cost of £414,000.

97. LAU also estimated that the additional requirements of CAD will increase the length of the average COSHH inspection by between 15 and 30 minutes. We assume that this increased inspection time applies to the first two years of the amended Regulations. From the third year onwards it is likely that the inspectors will be sufficiently familiar with the changes to simply incorporate any additional checks into their existing inspection routine and that no additional time will be necessary. It was also stated that COSHH will be dealt with at all preventive planned inspections. Assuming half of all visits made by LA inspectors are preventive planned inspections, this increased time will apply to about 178,000 inspections<sup>27</sup>. Using these assumptions the total cost of initially more lengthy COSHH inspections is between £1.5 million and £3.1 million per year and between £3 million and £6 million over ten years in present value terms.

98. Local Authority inspectors do not inspect firms for compliance with CLAW. The changes to CLAW required to implement the Directive will therefore not impose any extra cost on Local Authorities.

99. The total cost to Local Authorities is therefore between £3.4 million and £6.4 million in present value terms over ten years.

### **Costs to the emergency services**

100. CAD Article 7(5) requires that the relevant external and emergency services have access to emergency arrangements involving hazardous chemicals. In order to determine the impact on the emergency services of this requirement HSE contacted the London Fire Brigade. The matter was subsequently raised nationally with the Chief and Assistant Chief Officers Association Health and Safety Committee and with the Home Office.

101. There is currently a provision within the Fire Services Act 1947 which allows fire brigades to obtain information on a range of risk and hazards including several that would be included in COSHH. This is generally carried out at the local level by firefighter crews visiting premises as part of routine duties with information added from other sources as appropriate. It is likely, therefore, that the particular requirements relating to chemical agents will be subsumed into the wider information collection and processing system.

102. The extent of further work required to satisfy specific legislated requirements is difficult to predict but it is likely to involve a start up phase - which in effect will realign current information collection and handling systems and a maintenance phase which will ensure that new information (including amended information) is entered. This is likely to involve local level input by the fire stations which will be managed by the station commander at Assistant Divisional Officer rank/watch commander at Station Officer rank, but undertaken by firefighters of all ranks. Additional extra work will entail system design and specification and IT development for data handling as well as associated training and familiarisation.

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<sup>27</sup>The HELA Annual Report 1999, Page 9 states that "during 1997/98 local authority inspectors made 356,000 visits in connection with their health and safety duties".

103. At this stage it has not been possible to quantify the cost to the emergency services. However, it is reasonable to conclude that it may be significant.

### **Total costs to society**

104. The total cost of the changes to COSHH and CLAW required to implement CAD are shown in Table 9 below.

**Table 9:** Total costs to society resulting from the changes to COSHH and CLAW.

Article	Cost of changes to implement CAD (£m), 1999/2000 prices		
	One-off costs	Annual recurring costs	Total ten-year discounted costs
4(2)	-	-	-
6(2)	unquantifiable	unquantifiable	unquantifiable
7	3.4 - 10.3	1.7 - 5.1	18 - 56
7(5)	0.6 - 3.5	0.3 - 1.8	3 - 18
10(2)	-	2.7 - 16.1	26 - 152
10(4)	-	0.96 - 3.0	8 - 25
Familiarisation	111.2 - 117.4	-	111 - 117
HSE/LAs	0.6	2.0 - 4.0 (over 2 years)	4 - 8
<b>Total</b>	<b>116.1 - 132.5</b>	<b>7.7 - 30</b>	<b>172 - 378</b>

NB Totals may not add due to rounding

105. The total costs to society of the changes to COSHH and CLAW are equal to between £172 million and £378 million over ten years, in present value terms. The total costs of the proposed changes to Schedule 3 are shown in Table 10 below.

**Table 10:** Total costs to society resulting from the proposed changes to Schedule 3.

Proposed change	Cost of changes to Schedule 3 (£m), 1999/2000 prices		
	One-off costs	Annual recurring costs	Total ten-year discounted costs
Notification of subsequent use	-	0.8 to 5.5	7 to 46.1
Notification of consignment	-	0.07 to 0.2 (saving)	0.6 to 2.0 (saving)
Familiarisation	0.09	-	0.43
<b>Total</b>	<b>0.09</b>	<b>0.7 to 5.0</b>	<b>6.5 to 44.2</b>

106. The total costs to society of the proposed changes to Schedule 3 are equal to between £6.5 million and £44.2 million over ten years, in present value terms.

### **Total Annual Costs**

107. The total annual costs associated with CAD are shown in Table 11 below.

**Table 11:** Total undiscounted annual costs of CAD over 10 years (£ millions).

	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Yr10
Min	121	8	6	6	6	6	6	6	6	6
Max	155	35	32	32	32	32	32	32	32	32

### **Policy Costs**

108. The following have been classified as policy costs: Articles 4 and 4(2), Articles 6(2), 6(4) and 6(5), Article 7 and 7(5), Article 10 and Schedule 3. However, it is important to note that some of these Articles either have no cost or the costs are unquantifiable.

109. Total policy costs of CAD are approximately between £ 36 million and £ 141 million.

### **Implementation Costs**

110. The following have been classified as implementation costs: Articles 8, 10(2), familiarisation costs and costs to LAs/HSE.

111. Total implementation costs of CAD are approximately between £141 million and £277 million.

## **IMPACT ON SMALL BUSINESSES, CHARITIES AND VOLUNTARY ORGANISATIONS**

### *COSHH*

112. HSE contacted four small firms which it believed would be affected by the proposed changes and received replies from three of them. The first company contacted was aware of CAD and its requirements. It had recently been visited by an HSE inspector who believed that the requirements of CAD would not impose any additional requirements on the company. The second company operated in the pest control industry and was generally aware of CAD. It does not use concentrated chemicals and those which it does use are low risk and classified only as “harmful” and are used in small quantities. It already carries out risk assessments before starting every job and so is already complying with most of CAD’s requirements. It could not see any health benefits from CAD because its employees do not use enough hazardous chemicals. However, it was concerned that CAD would simply mean more red tape and prescriptive regulations. The third company was unaware of CAD and employs consultants to deal with all health and safety matters. Risk assessments are carried out every two months although the extent of exposure to hazardous chemicals is limited. Consultants would have to be employed to explain the changes to both the management and employees which will involve an extra cost.

113. Based on the comments of these companies it is unlikely that the proposed changes to COSHH will impose disproportionate costs on small businesses.

## CLAW

114. HSE contacted two small firms that currently have to comply with CLAW. The first company is a manufacturer of industrial paints and had been made generally aware of CAD by its trade association, the British Coatings Federation (BCF). The company already carries out risk assessments for processes and procedures that involve the use of lead and reviews these assessments when a different type of lead-based pigment is introduced and when an existing pigment is used on new equipment. It has been working on introducing lead-free substitutes for lead for some time, but because of the increased cost and poorer coverage of lead-free organic substitutes, customers have been reluctant to purchase them. Using lead-free substitutes is therefore not a practical proposition at present although the company did state that future improvements in technology may well make them more viable. The company currently organises regular safety drills and has a close working relationship with the local fire brigade due to the high risk nature of the materials used. The impact on this company of the proposed changes to CLAW is therefore likely to be relatively small.

115. The second company also manufactures paints but was unaware of CAD. It already carries out risk assessments where lead is used in the manufacturing process and reviews these assessments when there is any change to a manufacturing procedure. The company's use of lead was reduced many years ago after an internal review which resulted in the discontinuation of many lead-based products. The remaining lead-based paints are not produced using lead-free substitute ingredients because such substitutes are too expensive and produce poorer quality paint. Safety drills, alarms and communication systems are not used to warn employees of incidents that are hazardous to health. However, the area in which the lead is used is sufficiently small for colleagues to communicate normally if a hazardous incident occurs. The local emergency services do not have copies of the company's accident and emergency plans although they do inspect the factory regularly during familiarisation visits. This company is complying with the majority of CAD's requirements and should not face disproportionate costs in achieving total compliance.

116. Both companies consulted are already complying with most of CAD's requirements. If these companies are representative of others in the industry it should be possible for small firms to comply with the proposed changes to CLAW without incurring disproportionate costs.

### *Proposed changes to Schedule 3*

117. HSE contacted ten small firms it believes will be affected by the proposed changes to Schedule 3. It received two replies. Both were generally aware of the proposed changes to Schedule 3 before receiving the questionnaire and are involved in research and development on a small scale. The number of notifications to HSE for first use, subsequent use, storage and consignment made by both firms is very low and in keeping with the scale of their operations. Examination of all the replies to the questionnaire indicates that the number of notifications, and therefore the burden on companies, increases proportionately with the size of company. The proposed changes to Schedule 3 are therefore not expected to have a disproportionate effect on small firms.

## **SECURING COMPLIANCE**

118. As far as possible, current compliance levels for the components of the proposal have been taken into account. These are made explicit in the individual article sections.

119. It is not known to what extent compliance will be changed as a result of the proposal but it is not envisaged that the more prescriptive requirements of CAD will reduce compliance. However, one company was concerned that its industry had little experience of dealing with biological agents and that expensive specialist advice would be required to ensure compliance.

## **ENVIRONMENTAL IMPACTS**

120. Article 6(2) requires employers to substitute for hazardous chemical agents, a chemical agent or process which under its conditions of use is either non-hazardous or less hazardous to the safety and health of employees. Reducing the use of more hazardous substances may lead to a reduction in harmful emissions that are released into the environment. It is not possible to quantify this potential benefit.

## **BALANCE OF COSTS AND BENEFITS**

121. Over a ten year period, the total cost to society due to CAD (excluding Schedule 3) is estimated to be between £172 million and £378 million

122. Over a ten year period the total cost savings to society of the proposed changes to Schedule 3 are equal to between £0.6 million and £2 million, whereas total costs are estimated to be between £6.5 million and £44.2 million. Thus, if the assumptions made are satisfied, the costs of implementing the proposed changes will be substantially larger than the cost savings.

123. The assumptions made throughout this RIA, for both the changes required to implement CAD and the proposed changes to Schedule 3, are based as far as possible on information supplied by consultees and on other empirical evidence. However, these assumptions are subject to the uncertainties explained in the following section.

124. It is worth noting that even though the total costs to society due to CAD and the changes relative to biological agents equal between £178 million and £422 million, the additional cost per company equals, on average, £137 - £325, over ten years, in present value terms. The total cost to society is comparatively large because of the large number of firms (some 1.3 million employers) affected by the changes to the Regulations.

125. Implementation of the Directive is also expected to result in benefits to health and safety and intra-EU trade. However, we are unable to quantify these benefits and so a quantitative comparison of the costs and benefits is not possible. Each year an estimate of between 16,000 and 25,000 people become ill as a result of exposure to substances hazardous to health at work. It is very unlikely that the changes proposed here will eliminate altogether these cases of ill health, but it is interesting to note that if this were the case, the cost per ill worker to achieve this would be between approximately £7,200 and £23,000.

## **Uncertainties**

126. The companies and trade associations which completed our questionnaires provided a very wide range of responses to each of the questions. Consequently, we have only been able to use this information to create a range of possible costs rather than point estimates. The ranges are intended to illustrate the uncertainty surrounding the estimates. For example, in Article 7 most of the companies consulted found it difficult to say how much this requirement would cost them and the three companies who replied gave contrasting responses.

127. Also, there is uncertainty over the benefits. As discussed above, there are likely to be benefits accruing to this Directive, but we have been unable to quantify them.

## **ARRANGEMENTS FOR MONITORING AND EVALUATION**

### **Chemical Agents**

128. The Directive's requirements will be monitored by inspectors employed by HSE's Field Operations Directorate and by Environmental Health Officers employed by Local Authorities during their planned and preventive visits to workplaces, and through any feedback received from industry. The Directive requires that Member States report to the European Commission every 5 years on the practical implications of the Directive, indicating the views of employers and employees. HSE will review the effectiveness of the requirements in the years following the implementation of the Directive, and prepare a first 5 year report for the European Commission by May 2006.

### **Biological Agents**

129. The impact of the changes to the regulations and ACoP will be continually monitored by HSE in the course of normal scrutiny of notifications and inspection of laboratory containment facilities. It is likely that a more formal evaluation will be conducted after amended regulations have been in force for three years - the previous evaluation serving as a baseline.

HSE  
Health Directorate, Chemicals Policy Division  
August 2002

## **DECLARATION**

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister.

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Date.....

Contact point: Mike Reeves, Chemicals Policy Division, Workplace Risk Management Unit, Health and Safety Executive, 2 Southwark Bridge, London SE1 9HS; Tel. 020-7717-6259; e-mail: [mike.reeves@hse.gsi.gov.uk](mailto:mike.reeves@hse.gsi.gov.uk)