

# COSHH (AMENDMENT) REGULATIONS 2003

## REGULATORY IMPACT ASSESSMENT

### PART 1 - MUTAGENS

#### PURPOSE AND INTENDED EFFECT

##### Issues and objectives

1. This assessment estimates the costs and benefits of implementing in Great Britain certain requirements of Council Directive 1999/38/EC of 29 April 1999 amending for the second time Directive 90/394/EC *on the protection of workers from the risks related to exposure to carcinogens at work and extending it to mutagens*. The Directive addresses existing risks to health in the workplace.

2. Council Directive of 28 June 1990 (90/394/EEC) *on the protection of workers from the risks related to exposure to carcinogens at work* is implemented in Great Britain by the Control of Substances Hazardous to Health Regulations 2002 (COSHH) and by the Control of Asbestos at Work Regulations 2002. The First Amendment to the 1990 Carcinogens Directive (i.e. Council Directive 97/42/EC of 27 June 1997) introduced a limit value for benzene of 1 part per million (ppm). In accordance with transitional arrangements set out in the Directive and following consultation in 1998, the UK is introducing a more stringent limit value for benzene in stages. The maximum exposure limit (MEL) for benzene under the COSHH Regulations was reduced from 5 ppm to 3 ppm (8-hour time-weighted average) on 27 June 2000, and it will be further reduced to 1 ppm on 27 June 2003.

3. The Second Amendment to the Carcinogens Directive will extend its scope to hardwood dusts and Category (Cat) 1 and 2 mutagens as well as introduce a limit value of 3 ppm for vinyl chloride monomer (VCM) and consolidate the existing VCM Directive. Hardwood dusts are already listed among the other substances to which the definition of "carcinogen" relates in Schedule 1 of COSHH and consequently there are no costs arising from their inclusion in the Directive. The VCM Directive is already implemented under COSHH, and proposals published in October 2001 for new COSHH Regulations 2002 also include the introduction of the 3-ppm limit value for VCM earlier than 29 April 2003 set by the Directive. Furthermore, the provisions of the Carcinogens Directive already apply where they are more stringent than the provisions of the VCM Directive. As regards extending the requirements of the 1990 Carcinogens Directive and the comparable requirements in COSHH to include substances classified as Cat. 1 or Cat 2 mutagen, the only substance classified as a mutagen (Cat 1 or 2) that is not already classified as a carcinogen (Cat 1 or 2), and therefore not subject to the requirements for carcinogens under COSHH, is triglycidyl isocyanurate (TGIC).

4. In considering the implications of the Second Amendment to the Directive, this RIA is therefore primarily concerned with the use of TGIC (there is no UK manufacture of TGIC). On 1 January 1997 an amendment to COSHH introduced a MEL for TGIC of 0.1 mg/m<sup>3</sup> (8 hour time-weighted average). This RIA considers only those requirements for carcinogens under COSHH which are additional to the requirements to comply with a MEL but which the Second Amendment to the Carcinogens Directive will extend to substances classified as Cat.

1 or Cat. 2 mutagens. These requirements are set out in regulations 7(5)(a) to 7(5)(e) of the COSHH Regulations 2002.

5. The additional control requirements in the COSHH Regulations 2002 with which users of TGIC will need to comply are as follows:

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

However, in developing this RIA, HSE has not attempted to cost the requirement in draft regulation 7(5)(a) - "totally enclosing the process and handling systems, unless this is not practicable" This is because there are no manufacturers of TGIC in the UK, and the main use of the substance is in the form of coating powders which are used for architectural applications and for providing the finish for a multitude of industrial and household products, e.g. parts for the automotive industry, central heating boilers, washing machines, refrigerators etc. Coating powders containing TGIC are generally applied using automated or manual spray systems; work often carried out in a partially enclosed conveyerised spray system or in a spray booth fitted with exhaust ventilation. For these applications, it is unlikely to be reasonably practicable to enclose the work totally, but the consultative document seeks consultees' views on this, and for any estimated costs where it might be practicable to enclose completely work activities involving substances containing TGIC.

### **Risk Assessment**

6. The powder coating industry is relatively young (30 years) and has been working for many years with materials often perceived to be low in hazard. However, some powders contain curing agents such as triglycidyl isocyanurate (TGIC). The powder application technique is relatively simple and often thought to require minimal operator training. However, poor working practices have developed, e.g., leaning into the enclosure whilst spraying, and the use of brushes and compressed air for cleaning. In 1994 HSE carried out 21 surveys throughout Great Britain at companies manufacturing or using TGIC containing powder coatings. Occupational exposures up to 131 mg/m<sup>3</sup> 8hr TWA for total inhalable particulate (TIP) and 1.5 mg/m<sup>3</sup> 8-hour TWA for TGIC were found. These high exposures usually occurred as a result of poor working practices as described above.

## **OPTIONS**

7. The need to implement a European Union Directive means that Regulations are the only satisfactory solution. As the COSHH Regulations were used to implement the principal 1990 Carcinogens Directive, the only feasible option for transposing the requirements of the Second Amendment into domestic regulations is to amend COSHH. Therefore, COSHH (Amendment) Regulations 2003 will be used to implement the Directive by amending the COSHH Regulations 2002.

### **Sectors affected**

8. There are two main uses of TGIC, namely:

- (a) as a curing agent for polyester coating powders; and
- (b) as a "solder mask" for inks used on printed circuit boards.

9. There are reported to be about 15 manufacturers of coating powders in the UK. A major manufacturer has suggested that there could be 3,000 to 5,000 applicators of powder coatings. The large majority of these are very small users, perhaps using only one box of powder coating a month. About a third of the market for powder coatings is in architectural finishes. The large majority of these powder coatings are likely to contain TGIC. It may be, therefore, that about a third of the total number of applicators (i.e. 1,000 to 1,667) use TGIC-based powder coatings. Of these, HSE thinks that only about 200 firms use significant quantities on a regular basis.

10. In view of the uncertainties over the number of small-scale applicators of TGIC powder coatings and the patterns of exposure and hygiene practices at these firms, this RIA focuses on the impact on the 200 'significant' users. Cost estimates to these firms should therefore be best interpreted as minimum costs to users as a whole. An assessment of the possible impact on small-scale users is included in the sections 'Impact on Small and Medium-Sized Businesses' and, particularly, 'Appraisal of Uncertainties'.

11. There are 3 companies manufacturing TGIC containing solder "mask" inks for the printed circuit board industry in the UK and about 20 companies using these inks.

12. HSE asked the following organisations for information to prepare the RIA:

- (a) The British Coatings Federation (BCF) - representing coating powder manufacturers;
- (b) The Aluminium Finishing Association (AFA) - representative of applicators for aluminium;
- (c) The Metal Finishing Association (MFA) - representative of applicators in general;
- (d) A manufacturer of raw materials for the coating powders industry;
- (e) A manufacturer of coating powders;

(f) Two coating powders applicators;

(g) A manufacturer of "solder mask" inks for the printed circuit board industry;

(h) A user of "solder mask" inks.

13. HSE received replies from all except (b) and (h). However, none of the respondents were able to provide cost data. In some key areas we do not therefore have enough information to quantify costs and so the assessment is necessarily qualitative.

14. All costs are in 2001 prices. Staff time costs are projected to rise by 1.8 per cent per year in real terms - the observed increase over the past 25 years or so. Recurring costs are discounted to present value using the Treasury's recommended real discount rate of 3.5 per cent. The first year in which the proposals would be implemented is taken as the base year, i.e. 2003/4.

## **COSTS**

### ***Familiarisation***

15. The firms involved will have to familiarise themselves with the duties under regulation 7(5)(b) to 7(5)(e) of the proposed COSHH 2002 and consider the implications. For 238 firms (15 manufacturers of coating powders, 200 'significant' applicators, 3 manufacturers of solder mask inks and 20 users of these inks) we assume this would take a maximum of one day's time of a manager or equivalent. Based upon earnings data plus an allowance for non-wage labour costs the hourly cost is estimated to be about £21. Overall, this gives a cost of about £40,000. (See 'Appraisal of Uncertainties' for possible impact on small-scale users of TGIC-based powder coatings.)

### ***Substitution of TGIC***

16. Raw materials' manufacturers are active at developing alternatives to TGIC and about 4 or 5 are currently commercially available. There are likely to be some instances where applicators of coating powders are using TGIC when a non-TGIC coating will suffice. TGIC coatings are sometimes cheaper as they can be purchased off-the-shelf, as opposed to commissioning a new non-TGIC batch, so the effect of switching to them would result in higher raw material costs. However, these costs would probably diminish over time. Increasing awareness by the industry of the availability of suitable substitutes means that those who can switch to non-TGIC coating powder are steadily doing so and use of the proportion of off-the-shelf coating powder that is non-TGIC should increase. (The cost of *producing* non-TGIC coating powder is thought to be not much different from that of TGIC coating powder).

17. However, the primary use of TGIC is in coatings used for architectural applications, which require a 25-year guarantee on the finish. TGIC is currently the only curing agent that meets this standard for a wide variety of finishes, and therefore non-TGIC coatings are unlikely to make significant inroads into this market. A raw material supplier predicted that TGIC would still be in use for at least the next 10 to 20 years.

18. The use of TGIC in solder "mask" inks was reported to be diminishing by one manufacturer. The firm estimated that only about 20 users of these inks are using ones containing TGIC, as alternatives have been developed which are generally as good. Most of their production for TGIC based inks is for export.

19. To summarise, in some instances there is scope for switching to non-TGIC substitutes, but we do not have the information to quantify the additional costs involved. However, in the large majority of cases substitution is not an option. Providing there is no absolute requirement to use substitutes then the impact of this requirement should be limited.

***Regulation 7(5)(b) - the prohibition of eating, drinking and smoking in areas that may be contaminated by carcinogens***

20. The BCF and the AFA representing manufacturers and users of coating powders considered it unlikely that companies would allow eating, drinking and smoking in the factory workshop. The manufacturer and two applicators confirmed this. The manufacturer of solder "mask" inks also reported this. This regulation is therefore expected to have no impact.

***Regulation 7(5)(c) - cleaning floors, walls and other surfaces at regular intervals and whenever necessary***

***Cleaning***

21. Manufacturers and applicators of coating powders work to reasonably high standards of plant and workshop cleanliness to avoid cross contamination between products. Plant is thoroughly cleaned between different production runs, which may mean several times a day. Other surfaces are not cleaned as frequently, although one applicator reported that floors and low-level surfaces are cleaned once a week and high-level surfaces once every three months. It is likely, however, that many companies would need to improve their cleaning regimes for areas other than the process plant.

22. Solder "mask" ink manufacturers do not have the same considerations for cleaning plant to avoid contamination. The inks, however, are likely to result in a solidified patch of contamination with exposure during cleaning. The only exposure to TGIC dust would therefore be during manufacture, for which the three manufacturers may need to improve cleaning regimes.

23. We assume that at each manufacturer and 'significant' applicator, two production workers spend an extra half a day a week cleaning. Every three months they may need to spend an extra two days each to clean high-level surfaces. Overall, this would involve an extra 68 person days a year per firm. Based upon earnings data this is estimated to cost about £6,080 per firm per year<sup>1</sup>. We assume that two-thirds, or 145, of the 218 firms (15 manufacturers or powder coatings, 200 'significant' applicators and 3 manufacturers of solder mask inks) will have to do this. This gives a cost of £883,000 per year. Over a ten-year period

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<sup>1</sup> The April 2000 New Earnings Survey gives average hourly pay excluding overtime of workers in 'treatment and coating of metals' (SIC 839) as £8.59. Adding 30 per cent for non-wage labour costs (such as employers' national insurance contributions) gives £11.17. Multiplying by 8 hours gives a daily rate of £89.36. Multiplying by 68 days gives £6,076.

costs would be about £7.6m in present value terms. (See 'Appraisal of Uncertainties' for possible impact on small-scale users of TGIC-based powder coatings.)

***Regulation 7(5)(d) - the designating of those areas and installations which may be contaminated by carcinogens, and using suitable and sufficient warning signs.***

24. Contact with industry suggests that none of the firms affected designate areas where there is potential exposure to TGIC. Coating powders are labelled and in general operators do receive some awareness training, although this is more prevalent among manufacturers than applicators. It is likely that all companies would be affected if designation were necessary.

25. It is difficult to assess what firms might have to do, for example, what sort of sign they might have to put up. Although all firms are affected, the cost per firm is unlikely to be large.

***Regulation 7(5)(e) - storing, handling and disposing of carcinogens safely, including using closed and clearly labelled containers***

26. The storage of TGIC and coating powders is generally in bags within boxes, with only the necessary amount transferred to plant when needed. Industry considered that current arrangements would be sufficient. Waste is kept to a minimum as powders are recycled by applicators and manufacturers are unlikely to have significant quantities of TGIC containing waste. Those contacted reported that specialist contractors remove this as special waste, although they may incur further costs when TGIC receives formal classification as a mutagen. This, however, will happen irrespective of the Second Amendment to the Carcinogens Directive. Therefore, this regulation is not expected to have any impact.

**Costs to HSE**

27. The main cost implications to HSE will fall to Health Directorate's Chemicals Policy Division, which has the responsibility for implementing the Directive. It is expected that costs will be small and be contained within existing resources.

28. To estimate the possible extra costs incurred by FOD we assume that during the first year of the Amended Regulations, FOD inspectors will take about an extra 15 minutes on each inspection at premises where TGIC is being used to check compliance with the Regulations. After a year 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 inspectors will spend an extra 5 hours (based on 10% of the 200 'significant user' premises being inspected) on their health-related inspections in the first year of the amended Regulations. This translates to an annual cost of £215<sup>2</sup>.

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<sup>2</sup> Based on hourly cost of a band 3 inspector of £43.

## **Total costs**

29. The Annex provides a summary of overall costs. Over a ten-year period, total quantified costs are estimated at around £7.6 million in present value terms. The most significant quantified cost is that of regular cleaning of walls and surfaces (regulation 7(5)(c)).

30. Although these quantified costs are themselves subject to considerable uncertainty, they should best be interpreted as an indicator of the minimum overall cost for three reasons:

- (a) there are unquantifiable potential costs associated with substitution though these are likely to be much less significant (at least in terms of cost per firm) than those which have been quantified;
- (b) there are unquantified costs associated with designating areas and installations; and
- (c) they do not include costs to small-scale applicators of TGIC-based powder coatings (see 'Appraisal of Uncertainty').

31. Undiscounted annual costs are presented in the table below.

**Table**

	Yr1	Yr2	Yr3	Yr4	Yr5	Yr6	Yr7	Yr8	Yr9	Yr10
Cost (£'000)	903	899	915	931	948	965	982	1,000	1,018	1,036

32. Total policy costs are equal to about £7.6 million.

33. Total implementation costs are equal to about £40,000<sup>3</sup>

## **BENEFITS**

### **Health and safety benefits**

34. There are no data from humans or from animal studies on the carcinogenic potential of TGIC. However, in animal studies, TGIC has been demonstrated to be a somatic cell mutagen and therefore, in HSE's view, has the potential to lead to the induction of cancer. TGIC has also been shown to induce genetic damage in germ cells and thus there may be the potential for the transmission of heritable mutations via these cells into offspring, which theoretically could lead or contribute to the development of cancer in offspring. There are no data on dose-response relationships. Overall, reducing exposure may reduce the risk of developing both somatic and/or germ cell mutations and thus may reduce the risk of developing cancer. It is not possible to quantify any such reduction in risk.

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3 These are the costs associated with familiarisation with the Regulations.

35. As a germ-cell mutagen TGIC also has the potential to lead or contribute to the development of other (non-cancer) inheritable genetic-related disease in offspring. TGIC is a severe eye irritant and a mild skin and nasal irritant. It also has the potential to cause skin sensitisation that can lead to severe skin rashes (allergic contact dermatitis). Recently, at least one report of respiratory sensitisation associated with TGIC has been received, but as yet there is insufficient evidence to reclassify TGIC as a respiratory sensitiser.

36. However, the measures that firms may need to take to comply with the additional requirements for carcinogens under COSHH (over and above those already implied by the MEL) are unlikely to result in any significant reduction in exposure to TGIC. Areas away from the process plant (where we assume improved cleaning practices) are not areas where there is significant exposure to TGIC. There may be some health and safety benefits resulting from a general improvement in hygiene but these are unlikely to be significant.

37. TGIC containing inks are used in screen-printing, curtain coating or electrostatic spraying. It is used least in electrostatic spraying and then probably in a booth. Screen-printing and curtain coating do generate aerosol, but as the vapour pressure of TGIC is extremely low, there is unlikely to be any significant exposure. The number of workers exposed during these application activities is likely to be low.

38. To summarise, it is not expected that there will be significant health and safety benefits, although there may be some increase in standards following the publicity associated with the designation of TGIC as a mutagen. This is because there is already a MEL for TGIC which not only requires employers to ensure exposure does not exceed  $0.1 \text{ mg/m}^3$  (8-hour time-weighted average) but that they reduce exposure so far as is reasonably practicable below the MEL.

#### **Other benefits**

39. There may be some operational benefits resulting from improved cleaning practices but these are unlikely to be significant.

#### **IMPACT ON SMALL AND MEDIUM SIZED BUSINESSES**

40. The large majority of applicators are likely to be (very) small firms, although many will use only very small quantities of TGIC powder coating. For the small firms litmus test, ten small firms were contacted. Responses were received from two. A further one applicator firm had been contacted earlier. The responses from these firms indicated that they would not incur any costs due to changes in the Regulations. They also indicated that they could use substitute products with no additional cost. They agreed that there is generally good compliance with the existing provisions in COSHH with regard to TGIC.

41. To summarise, many small and medium sized businesses are affected by the proposal but the evidence we have indicates that small firms may not incur much cost. Furthermore, they would not be disproportionately affected more or less than a larger firm.

#### **ATYPICAL WORKERS**

42. There are no groups of atypical workers in the industry sectors examined.

## ENVIRONMENTAL IMPACTS

43. There will be no significant environmental impact from extending the scope of the Carcinogens Directive to include mutagen TGIC.

## COMPETITION ASSESSMENT

44. The industry that will face costs as a result of this amendment is coating powder manufacturing. This industry has a fragmented market structure, with a fair number of small and medium-sized firms. Large differential effects on firms within the industry are unlikely, as the costs themselves are linked to better ways of working with existing plant (improving spraying and cleaning techniques etc), that affect all firms. The amendment will not raise significant barriers to entry to newcomers, particularly because entrants may find it slightly easier than incumbents to start using new products without TGIC. No other competition implications have been identified.

## BALANCE OF COSTS AND BENEFITS

45. Quantified and unquantified costs and benefits are summarised in the table. The largest element of the costs which firms are likely to face is for improved cleaning services, but overall costs are potentially modest. There are not expected to be any significant benefits, since there is already an MEL for TGIC. Therefore, costs will exceed benefits and possibly by a large amount.

## SUMMARY OF COSTS AND BENEFITS - MUTAGENS

£ thousands, 2001 prices

<b>A: QUANTIFIED COSTS AND BENEFITS</b>	One-off costs/benefits	Recurring costs/benefits	Present value over ten years
<b>COSTS</b>			
Familiarisation	40 (min)		40 (min)
Reg 7(5)(b) prohibition of eating etc.	nil	nil	nil
Reg 7(5)(c) cleaning	nil	883 (min)	7,601 (min)
Reg 7(5)(d) designating areas and installations	unquantified	unquantified	unquantified
Reg 7(5)(e) safe storage and disposal	nil	nil	nil
<b>Total costs to industry</b>	40 (min)	883 (min)	7,641 (min)
<b>Total costs to HSE</b>	Negligible to be contained within existing resources		
<b>Total quantified costs</b>	40 (min)	883 (min)	7,641 (min)
<b>BENEFITS</b>			
<b>Total quantified benefits</b>	unquantified	unquantified	unquantified

## APPRAISAL OF UNCERTAINTIES

46. The quantified cost of extra cleaning is based upon a number of assumptions and therefore subject to considerable uncertainty.

47. None of the quantified costs include costs to small-scale applicators of TGIC-based powder coating as it was not possible to quantify these costs (see paragraph 9). It was noted earlier that these could amount to a further 800 to 1467 firms (after deducting our estimated 200 'significant' users). If so, this could mean that the cost to industry as a whole is considerably higher than that indicated above.

48. For these 800 to 1467 firms, familiarisation is likely to take considerably less time, perhaps an hour. If so, this would give a further cost of about £17,000 to £31,000.

49. For cleaning, we assume that two-thirds of these firms spend an average of an extra hour per week and half a day every three months. This would give an extra 8.5 days per firm per year. Applying the same monetary values for staff time used earlier, this would cost £760 per firm. Applied to the number of firms assumed to be affected (0.67 x 800 to 1467) gives a further cost of £405,000 to £743,000 per year. Over a ten-year period additional costs would be £3.5m to £6.4m in present value terms.

50. We have less knowledge of exposure patterns at these firms and therefore there is more uncertainty over the benefits that the action taken by employers would bring. However, it is likely that any overall reductions in exposure would be small.

51. To summarise, the uncertainties affect both costs and benefits and so it is impossible to estimate how those uncertainties affect the balance between the costs and benefits.

## ARRANGEMENTS FOR MONITORING AND EVALUATION

52. Compliance by TGIC users with the additional requirements in COSHH which apply to carcinogens and which will be extended to Category 1 and 2 mutagens will be monitored by HSE's FOD inspectors during their planned and preventive visits to workplaces, and through any feedback received from the industry.

## PART 2 – ADDING DIOXINS TO SCHEDULE 1 OF COSHH

### PURPOSE AND INTENDED EFFECT

#### Issue and Objectives

53. The term 'dioxins' refers to a group of 75 polychlorinated dibenzo-p-dioxins (PCDDs) and 135 polychlorinated dibenzofurans (PCDFs) of which 17 are considered to be biologically active (all those chlorinated at the 2, 3, 7 and 8 positions). Each of these 17 congeners has similar health effects but the potency within the group varies widely. The most extensively studied and most toxic of the congeners is 2,3,7,8-tetrachlorodibenzo *para* dioxin (TCDD).

54. PCDDs and PCDFs are not intentionally manufactured or supplied within the UK, but are generated as unwanted by-products in the combustion of organic material. The feedstock and conditions of combustion determine the range of congeners that form. This means that the mixture of dioxins generated in a combustion process could vary from day to day. Since the potency of individual congeners varies, the overall potency of mixtures of different composition will vary. In order to assess the overall potency of any given mixture, toxic equivalency factors (TEFs) have been assigned to each of the 17 biologically active congeners. These TEFs express the potency of each congener relative to the potency of TCDD and enable the overall potency of any mixture to be expressed as an equivalent dose of TCDD (TEQ). Within the UK it is the scheme put forward by the World Health Organisation (WHO) in 1997 (WHO-TEFs) that is now used.

55. As part of a UK Government position paper on PCDDs, PCDFs and polychlorinated biphenyls (PCBs) that exhibit “dioxin-like” activity, an Interdepartmental Group was asked to provide information on the nature and extent of dioxin exposures and intakes of the UK population. In order to provide up-to-date information on work-related exposures, HSE surveyed the potential for dioxin exposure and commissioned a sampling exercise in certain industry sectors. “Dioxin-like” PCBs have a different source to the PCDDs and PCDFs and their TEFs are much lower, so we considered only the dioxin and furan congeners and grouped them under the heading “dioxins”.

56. As a result of this survey and sampling exercise, ACTS recommended that a Chemical Hazard Alert Notice (CHAN) be issued giving generic guidance to industry on the potential for dioxin formation and that specific guidance be issued to the aluminium recycling industry. The third action recommended was that dioxins (the seventeen dioxin and furan congeners mentioned earlier) be added to Schedule 1 of COSHH. This RIA is in response to that recommendation and seeks to estimate the costs and benefits to UK industry of that action.

### **Risk assessment**

57. Table 1 summarises the known dioxin exposures in UK industry. All the data was obtained over the last two years from a sampling exercise sponsored by HSE and conducted by HSL and Lancaster University.

**Table 1 Dioxin in air levels - personal samples**

Industry sector	Number of samples	Range (pg WHO-TEQ/m <sup>3</sup> )
Aluminium recyclers	19	1.3 - 54.9
Other metal recyclers	4	<Level of detection - 9
Municipal Waste Incinerators	2	0.2 - 0.3
Landfill	1	1.7

**Table 2 Dioxin in air levels - static samples**

Industry sector	Number of samples	Range (pg WHO-TEQ/m <sup>3</sup> )
Aluminium recyclers	12	2.0 - 72.7
Other metal recyclers	10	0.1 - 24.0
Municipal Waste Incinerators	4	0.1 0.3
Landfill	2	0.1 - 0.2
Cement manufacture	4	All <Level of detection

## **OPTIONS**

58. The other options considered were:

- (a) doing nothing; or
- (b) setting an OEL for dioxins.

59. Option (a) was rejected because the sampling exercise indicated that certain industries would continue to be exposed to dioxin levels that could easily be reduced by provision of information and simple guidance.

60. Option (b) was deemed unacceptable for several reasons. There is no currently validated method for personal sampling for dioxins. The method used in the HSE sampling exercise was an adapted method from a published paper and was based on the static method. Also, the laboratory analysis of dioxins is extremely time-consuming and expensive, and is restricted to a very few laboratories in the UK. Dioxin exposure will vary widely in some industries from day to day as the production is crucially dependent on several factors. UK industry would find it difficult to measure dioxin exposure routinely and be able to assess their current situation.

## **INFORMATION SOURCES AND BACKGROUND ASSUMPTIONS**

61. During 2002, the following sources were consulted.

- (a) ALFED Aluminium Federation;
- (b) British Cement Association;
- (c) British Metals Recycling Association;
- (d) British Non-Ferrous Metals Federation;
- (e) S. Grundon (Waste) Ltd.

62. Costs are expressed in net present terms for a ten-year appraisal period. In arriving at a ten-year cost figure, the Treasury recommended discount rate of 3.5% is used. All costs are in 2001 prices. Earnings are assumed to increase by 1.8% per year in real terms which is the observed increase for the whole economy over the last 25 years or so.

## **BENEFITS**

### **Health and safety benefits**

63. The toxicology of dioxins has not been formally reviewed by HSE/WATCH (Working Group for the Assessment of Toxic Chemicals). Within the UK it is the Food Standards Agency (FSA) that has overall responsibility for deciding the official view on the health effects of dioxins. In October 2001, the FSA Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) published its statement on the tolerable daily intake (TDI) for dioxins and dioxin-like PCBs (COT, 2001, see ACTS/03/2002). In this statement, the COT recommended that the TDI for the UK should be reduced to 2 pg WHO-TEQ/kg bw. Above this exposure level there would be concerns for adverse health effects, in particular for reproductive health effects and cancer. However, there is no clear data on the precise risks associated with particular exposure levels.

### **Health effects**

64. The toxicology of dioxins is complex. Dioxins are ubiquitous in the environment and the main source of human exposure is via the diet. However, there is concern about additional occupational exposure. Occupational inhalational and dermal exposure to dioxins will typically occur through contact with surface contaminated particulates.

65. Much of the data on dioxins is derived from oral dosing studies, which show that dioxins are readily absorbed from the gastrointestinal tract. Very few studies have been conducted to examine percentage uptake from inhalation or dermal exposure. Based on the limited data available, for occupational exposure scenarios it seems reasonable to assume 100% systemic intake of inhaled dioxins and 1% systemic intake across the skin. Once absorbed, dioxins distribute throughout the body, including the brain and reproductive organs. Dioxins are not readily removed from the body and will accumulate on repeated exposure. A half-life of TCDD in humans of 6-11 years has been reported.

66. There is a wide variation in animal susceptibility to single exposures to dioxins depending on species and strain. Deaths following exposure to TCDD generally occur weeks rather than days after exposure. Humans seem to be among the less susceptible species. Deaths have not been reported following incidents in which exposure to dioxins occurred. The most clearly linked effect is the development of a skin condition termed chloracne. This takes several months to develop following exposure and can persist for several years. However, it is not possible to derive a dose-response relationship from the available data.

67. There is no evidence to suggest that dioxins are skin or eye irritants. There have been case reports of individuals who received intense acute exposure to TCDD experiencing temporary respiratory irritation (EPA, 2000). There is no evidence to suggest that dioxins are skin sensitisers or asthmagens.

68. Most concerns for dioxins centre on the effects of long-term exposure. A range of effects has been demonstrated in laboratory animals. However, there is no consistent evidence that these effects also occur in humans. There is evidence from studies in laboratory rodents that TCDD has adverse effects on the immune system, but there is no clear evidence for this effect in humans. In other reports TCDD exposure has been related to decreased testosterone levels and possible effects on thyroid hormone uptake, but the results from different studies are inconsistent. There have also been reports of a positive association between human exposure to dioxins and the incidence of ischaemic heart disease but the studies in which this association was reported did not adequately account for potential confounding factors, hence the association remains uncertain.

69. There is no evidence to suggest that dioxins are genotoxic. The UK Committee on Mutagenicity (COM) has discussed this aspect of the toxicology of dioxins, most recently in 1999, and concluded that “the weight of evidence from the large amount of data indicated that TCDD was not genotoxic”.

70. The UK Committee on Carcinogenicity (COC) has given a view on the carcinogenic potential of dioxins. It concluded that based on all the available evidence TCDD should be regarded as a “probable human carcinogen” but noted that the excess of cancer mortality reported in the heavily exposed industrial cohorts was small and commented that any increased risk of cancer at background levels of exposure is likely to be extremely small and not detectable by current epidemiological methods. The COC also stated that although a precise mechanism for carcinogenesis in laboratory animals or humans could not be elucidated from the available information, the data suggested that a threshold approach to risk assessment was likely to be appropriate. This means that there is a level of exposure below which there would be no concerns for cancer but it is not possible to determine what this level of exposure is.

71. There are several concerns in relation to the potential reproductive effects of dioxins. One study has shown a decrease in the proportion of male children born to fathers exposed to TCDD as a result of the Seveso incident. However, it is not clear if these findings from a peak exposure incident are relevant to individuals who receive steady exposure to background levels. A separate study, the Seveso Women’s Health Study, to evaluate possible links between exposure to dioxins and endometriosis and other reproductive endpoints is ongoing and the COT considered that insufficient data were available at present to draw any conclusions. Studies in animals have also shown adverse effects linked to pre-natal exposure to TCDD. The most sensitive effects were on the developing male reproductive system and reflected adverse effects on reproductive performance seen in studies with adult animals. The COT considered that these findings were relevant for humans and based its recommendation for a TDI of 2 pg WHO-TEQ/kg bw on this data.

72. There are also reports that dioxins can cause developmental effects. Studies conducted on cohorts in Rotterdam, Gronigen and Amsterdam suggested an effect of pre-natal dioxin exposure to background levels on cognitive development. However, several confounding factors such as breast-feeding, smoking and maternal education have been identified and it is not clear if these were adequately accounted for in the analyses of these studies. Overall, the COT concluded that no clear conclusions could be drawn on the relationship between pre-natal dioxin exposure and cognitive development until follow up studies could be performed with these children at later stages in life.

73. To summarise, there is concern about the adverse health effects of exposure to dioxins above the recommended TDI of 2 pg WHO-TEQ/kg bw. Exposure above this level is associated with an increased risk of adverse reproductive effects and of cancer. However, there is no clear data linking particular exposure levels to particular risk levels. Since there is no clear quantitative evidence on the health effects of dioxins in humans, health benefits cannot be estimated.

## **COSTS**

### **Business sectors affected**

74. 15-20 sites in the following business sectors were investigated:

- (a) Metal recycling;
- (b) Cement manufacture;
- (c) Municipal Waste incineration;
- (d) Landfilling of APC (Authorised Pollution Control) ash.

75. The addition of dioxins to Schedule 1 of COSHH affects all business sectors whose activities involve temperatures exceeding 250°C, and where organic material, chlorine or metal is used for catalysis. However, the four sectors above are the most likely ones to incur additional costs. In the other business sectors, costs are likely to be low or insignificant because the majority should be complying with the COSHH Regulations and their supporting ACoP. The main requirement resulting from this amendment to COSHH is essentially to clean the workplace regularly and whenever necessary, and this should simply require more thorough cleaning by these firms.

76. For instance, non-ferrous metal processes have limited scope for dioxin-related risk. The existing guidelines for the aluminium recycling industry do not impose costs beyond a requirement to clean premises regularly. Dioxins emissions in steel production are high, and as such are dealt with as an environmental hazard by the Environment Agency. The steel industry is well informed about the COSHH Regulations and their supporting ACoP and carcinogen-related risks are small in other parts of the steel industry.

77. Moreover, other measures to reduce and control exposure to ‘as low as is reasonably practicable’ will also be ‘cost-neutral’ in that they will mostly require reinforcement of existing good practice. For instance, the new guidelines for dealing with dust or wearing protective clothing are generally already followed. Greater awareness of the guidelines would ensure that these practices continue, or perhaps highlight a cheaper alternative (e.g. cheaper protective clothing that is as effective). For these reasons, costs to businesses are expected to be low or insignificant.

### **Compliance costs to business**

78. Some costs will be common to all sectors and are listed below.

**(a) Familiarisation with the duties under regulation 7(5)(a) to 7(5)(e) of the proposed COSHH 2002 and consideration of the implications.** This is assumed to take a half day's time of a manager or equivalent. Based upon earnings data plus an allowance for non-wage labour costs the hourly cost is about £21 per site.

**(b) Compliance with Regulation 7(5)(c) - cleaning floors, walls and other surfaces at regular intervals and whenever necessary.** There is a wide variation in current cleaning practices between different sectors and within sectors, but we have assumed a general cost.

**(c) Compliance with Regulation 7(5)(d) - the designating of those areas and installations which may be contaminated by carcinogens, and using suitable and sufficient warning signs.** No industry sector currently designates areas where there is potential exposure to dioxins. It is difficult to assess what firms might have to do to comply until their risk assessments are complete but the cost per firm is unlikely to be large.

**(d) Extra monitoring as a result of the risk assessment.** Although the decision will be based on the risk assessment findings, we have assumed that there will be no sampling exercises undertaken as a result, because of the cost and complexity of the analysis and the small number of laboratories equipped for the analysis.

#### Metal recycling

79. Recent changes in environmental legislation have drastically reduced the total number of sites that melt scrap metal. There are about 4,000 sites with waste management licenses, of which about 2,000 are car breakers, about 300 are ferrous scrap dealers (with no furnace capability), and about 500 are non-ferrous merchants. It is believed that in this latter group, no more than 50 sites use furnaces to melt the scrap.

80. These fifty sites will need to include dioxins specifically in their risk assessment. As a result, it is anticipated that some simple actions to reduce exposure will be taken at some sites. We estimate that some of these actions will be cost-neutral; examples include further emphasis on the need to eliminate eating and drinking in the workplace and some better separation of non-metallic scrap.

81. At fifty sites, the cost of familiarisation with the duties under regulation 7(5)(a) to 7(5)(e) of the proposed COSHH 2002 and consideration of the implications will be £21 x 4 x 50 = £4,200. This will be a one-off cost.

82. The cost of compliance with Regulation 7(5)(c) - cleaning floors, walls and other surfaces at regular intervals and whenever necessary – is fraught with uncertainty. There is a wide variation in sites but we have assumed that there will be a need for extra cleaning amounting to around two days per month and an extra three days at six month intervals for high-level surface cleaning. This amounts to an average of thirty days annually per site. At an average cost of £90 per man day, the total cost will be £90 x 30 x 50 = £135,000. This will be an annual cost.

83. Total costs for metal recycling will be £139,200 in the first year and £135,000 in subsequent years. Thus, total costs over ten years in present value terms are £1,254,000 (rounded).

#### Cement manufacture

84. There are four UK cement manufacturers, and between them they have fourteen sites. Our single sampling exercise at one site showed no detectable dioxin exposure to the workforce, so it is unlikely that there will be any change in the cleaning regime. As a result of the change in legislation, there will be small costs from the need for familiarisation with the duties under regulation 7(5)(a) to 7(5)(e) of the proposed COSHH 2002 and consideration of the implications. For fourteen sites, this will amount to  $£21 \times 14 \times 4 = £1176$ , which will be a one-off cost.

85. We believe that this represents the total cost to this industry sector.

#### Municipal Waste Incineration

86. Following the implementation of the Waste Incineration Directives in 1996 (89/369/EEC and 89/429/EEC), the majority of old UK MWIs closed, leaving only eleven with improved air pollution abatement equipment.

87. Overall, we believe that there will be no extra cost to this industry. Because of sensitive local issues over dioxins, this sector routinely analyses stack emissions and dioxin air levels at the boundary of the sites. The change to legislation will be cost-neutral because the industry already has a very high awareness of the dioxin problem.

#### Landfills

88. There are currently twelve UK landfill sites that take authorised pollution control (APC) ash from the incinerators and this accounts for 88% of the ash. Six waste treatment plants treat APC ash prior to landfill by mixing with non-volatile organic liquids and sludges such as emulsion paint residues, latex, waxes and greases; the solidified waste is then landfilled at a further six landfill sites. Overall, there are six treatment sites and eighteen landfill sites that accept APC ash in treated or untreated form. A sampling survey at one site that accepts "fresh" APC ash shows that background dioxin levels were low but that the one personal sample showed a level of  $1.7 \text{ pg/m}^3$ .

89. Although only one sample, we believe that this means all sites will need to familiarise themselves with the duties under regulation 7(5)(a) to 7(5)(e) of the proposed COSHH 2002 and consider the implications. This will result in a one-off cost of  $£21 \times 4 \times 18 = £1512$ .

90. Landfill sites have a rigorous cleaning regime already, but we believe there will be a need for extra precautions around the ash silos to prevent buildup of dioxin-containing ash in dry weather. Assuming that all twentyfour landfill sites and treatment plants instigate an average extra man-day's cleaning per month, this will result in an annual cost of  $£90 \times 12 \times 24 = £25,920$ .

91. Total costs to the APC landfill will be £27,432 in the first year and £25,920 in subsequent years. Thus total costs over ten years, in present value terms, are £241,000 (rounded).

### Costs to HSE

92. The main cost implications will be divided between Health Directorate's Chemical Policy Division and FOD's Central Specialist Division (i.e. occupational hygienists). However, costs will be small and will be contained within existing resources. Any extra costs incurred by FOD inspectors in enforcing the proposal are also likely to be small and will be contained within existing budgets.

### Other costs

93. There should be no other costs.

### Total costs to society

£thousands, 2001 prices

Industry	One-off costs	Annual recurring costs	Total ten-year discounted costs
Metal-recycling industry	4.2	135.0	1 258.7
Cement manufacture	1.2	0	1.2
Municipal Waste Incineration	0	0	0
APC Landfill	1.5	25.9	242.4
<b>Total*</b>	6.9	160.9	1 502.3

- Rounded to the nearest hundred. Totals may not add up due to rounding.
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### Total Annual Costs

**Table :** Total undiscounted annual costs over ten years.

£thousands, 2001 prices

Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10
167.8	163.8	166.8	169.8	172.8	175.9	179.1	182.3	185.6	188.9

### Policy Costs

94. All costs are policy costs.

### **Implementation costs**

95. There are no implementation costs; familiarisation is part of policy costs. In this case, familiarisation of managers with the requirements for dioxins is considered an essential aspect of the policy.

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

96. There will be no disproportionate costs to small businesses, charities or voluntary organisations.

### **Atypical workers**

97. We believe there are no groups of atypical workers in the industry sectors examined. All the workers concerned are typical employees working five eight-hour shifts a week.

### **Environmental impacts**

98. There will be no significant environmental impact from the addition of the 17 key dioxins to Schedule 1 of COSHH.

### **Competition Assessment**

99. Of the industries that will face costs as a result of the dioxins amendment, metal recycling and landfills have a fairly fragmented market structure, with many medium-sized firms. The cement market is controlled by four very large producers. Large differential effects on firms within each industry are unlikely, as costs should fall on firms in proportion to their size. The proposal to add the 17 dioxins to schedule 1 of COSHH will not raise significant barriers to entry to newcomers, and no other competition implications have been identified.

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

100. Quantified costs and benefits are summarised in the table. The largest element of the costs which firms are likely to face is for improved cleaning services, but overall costs are potentially modest. The 10-year net present value of total costs incurred is £1,502,200 (rounded to the nearest hundred). Many sectors of industry will be affected by the addition of the dioxins to Schedule 1 of COSHH, but this RIA details the impact on only four sectors. These sectors, however, are those most likely to produce levels of dioxins posing the greatest risk, and HSE judges that costs incurred in other sectors are likely to be much lower or insignificant. Total benefits cannot be quantified because of a lack of firm data.

## SUMMARY OF COSTS AND BENEFITS - DIOXINS

£thousands, 2001 prices

QUANTIFIED COSTS AND BENEFITS	ONE-OFF COSTS/BENEFITS	RECURRING COSTS/BENEFITS	10-YEAR PRESENT VALUE
<b>COSTS</b>			
Familiarisation	6.9	nil	6.9
Reg 7(5)(c) cleaning	nil	160.9	1 495.3
TOTAL COSTS TO INDUSTRY	6.9	160.9	1 502.2
TOTAL COSTS TO HSE	nil	nil	nil
TOTAL QUANTIFIED COSTS*	6.9	160.9	1 502.2
TOTAL QUANTIFIED BENEFITS	Unquantifiable	unquantifiable	unquantifiable

\* Costs are rounded to the nearest hundred. Total costs may not add up due to rounding.

### Uncertainties

101. There are large uncertainties. The perceived risk is based on a small and selective sampling exercise. The actions required are then averaged over a range of heterogeneous sites.

102. The actions required depend on the risk and the regulatory changes required being known and acted upon. The extra risk assessments required are likely to be included in present risk assessment systems, but some sites may need extra resources. In practice, action taken (cleaning etc) will depend crucially on the results of the risk assessments, and is therefore difficult to forecast. Some costs are therefore unquantifiable, and cleaning costs are subject to considerable uncertainty. Perhaps most crucially, the benefits are unquantifiable.

### Arrangements for monitoring and evaluation

103. Compliance by these industry sectors will be monitored by HSE's FOD and HID Inspectors during their planned and preventative visits to workplaces, and through any feedback received from the industry.

## OVERALL COSTS AND BENEFITS – CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH (AMENDMENT) REGULATIONS 2003

104. The old Treasury Green Book (guidance on appraisal) required costs to be discounted at the rate of 6.0%, and health benefits at 2%. Under the new revised Green Book a lower discount rate of 3.5% will apply to both costs and benefits. However, RIA's completed under the old discounting regime will continue to use the old rates for comparison with previous RIA's. We show the balance of costs and benefits according to both discounting regimes in the tables below. Discounting costs at the new, lower rate increases the 10-year net present value of costs by about £350,000.

£thousands, 2001 prices, rounded to the nearest hundred. Discount rate **3.5%**

AMENDMENT	TOTAL QUANTIFIED COSTS (10 YEAR NPV)	TOTAL QUANTIFIED BENEFITS (10 YEAR NPV)
MUTAGENS	7 641	Unquantifiable
DIOXINS	1 502.2	unquantifiable
<b>TOTALS</b>	<b>9 143.2</b>	<b>unquantifiable</b>

£thousands, 2001 prices, rounded to the nearest hundred. Discount rate **6%**

AMENDMENT	TOTAL QUANTIFIED COSTS (10-YEAR NPV)	TOTAL QUANTIFIED BENEFITS (10-YEAR NPV)
MUTAGENS	7 430	unquantifiable
DIOXINS	1 357.5	Unquantifiable
<b>TOTAL</b>	<b>8 787.5</b>	<b>Unquantifiable</b>

## 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.....

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