

MAXIMUM EXPOSURE LIMIT FOR CHLOROETHANE

REGULATORY IMPACT ASSESSMENT

PURPOSE AND INTENDED EFFECT

Issue and Objectives

1. Chloroethane is a colourless flammable vapour under normal conditions. It has a boiling point of 12°C and vapour pressure of 133 kPa at 25°C. It has an ethereal odour with a threshold around 4 ppm.

2. Chloroethane was included in a proposal for a first European Commission Directive on Indicative Occupational Exposure Limit Values (IOELV) in 1999. However, the first IOELV Directive, as adopted, did not include chloroethane, but chloroethane has been included in a proposal for a second IOELV Directive. The proposed IOELV is 100 ppm as an 8-hour time weighted average (TWA). No short-term exposure limit (STEL) is proposed. If the proposed IOELV for chloroethane is adopted, member states will be required to set a national occupational exposure limit for chloroethane that takes into account the IOELV.

3. Because of the discrepancy between the IOELV proposal and the existing OES for chloroethane (1000 ppm 8-hour TWA and 1250 ppm STEL), HSE asked WATCH in 2000 to consider the available health and exposure information relating to chloroethane and make recommendations. WATCH, at the meeting in January 2000, concluded that the criteria for an Occupational Exposure Standard were not satisfied, and considered that the setting of a MEL would be justified. ACTS agreed that the OESs should be withdrawn, and a proposal to this effect was included in a Consultative Document, CD157, issued in May 2000. After considering consultees' comments ACTS recommended and HSC approved the withdrawal of the OESs with effect from 14 May 2001. A Chemical Hazard Alert Notice (CHAN 17) has been issued by HSE to offer guidance on control of exposure while the occupational exposure limit is under review. The ultimate objective is to replace the OES with a Maximum Exposure Limit (MEL). This document addresses the financial consequences of this action. The costs quoted in the document are (unless otherwise stated) those that were current at the time this RIA was written (2000).

Risk assessment

4. The carcinogenicity of chloroethane has been subject to limited investigation, with only one study in rats and mice using a single high exposure. There is unequivocal evidence that chloroethane is carcinogenic in mice with a pronounced increase in the incidence of uterine tumours at 15,000 ppm. The mechanism of carcinogenicity is unknown and the possibility of a genotoxic mechanism cannot be discounted. There is no information on the dose-response relationship. However, the structural analogue bromoethane has also been shown to cause uterine tumours at considerably lower concentrations than that tested with chloroethane and no threshold concentration for tumour induction has been identified. The similarity in tumour findings for these two structurally related chemicals suggests a common

mechanism of action and provides some evidence to suggest that chloroethane could cause tumours at lower concentrations. There are no relevant human data. Given the absence of information on mechanism and dose-response, the relevance of the animal carcinogenicity to humans cannot be discounted.

5. The available data suggest that dermal absorption of chloroethane is minimal and that it does not have sensitising properties. WATCH decided, at its January 2000 meeting, that 'Skin' and 'Sen' notations would not be appropriate.

OPTIONS CONSIDERED

Substitution

6. The use of alternative substances or techniques is not considered in this paper for the following reasons. In the Health Services sector the product use is agreed with the Medicines Control Agency and consideration of substitutes would have to be reviewed with that Agency, the practitioners and the Health Service. In the manufacturing industry substitution would not be practical at present. However, developing technology and use patterns may see future uses reducing significantly and possibly disappearing.

7. HSE has undertaken a Regulatory Impact Assessment for a MEL at various levels of exposure.

8-hour TWA

8. The following levels for a potential MEL were chosen for comparison.

- a level of 10 ppm 8-hour TWA.
- a level of 50 ppm 8-hour TWA.
- a level of 100 ppm 8-hour TWA (equal to the proposed IOELV).

Short-term exposure limit

9. As the principal health concern leading to a proposal for a MEL is possible carcinogenicity, there is no justification for a short-term exposure limit in addition to an 8-hour TWA, and one has not been considered in this paper.

INFORMATION SOURCES

10. Information for this RIA was collected by consultation with the industry and services sectors affected. Questionnaires, asking for information on processes, exposure patterns and potential costings for implementing the MEL at the levels suggested above, were sent to the following three sectors.

(a) Import and distribution

11. Only one company was identified as being involved in the importation and distribution of pre-packaged vials of chloroethane liquid. Its use was solely as a local anaesthetic. Deliveries of the cases of vials are made routinely to a supplier who supplies distributors who, in turn supply local health service outlets. For this use of the substance a pharmacy-only licence has been granted by the Medicines Control Agency.

12. No occupational exposure data for the company employees or distributor staff were available as no repackaging or handling of the substance was involved.

13. The industry assessed that the costs of implementing controls to comply with any of the proposed maximum exposure limits indicated were negligible.

(b) Health services and related users

14. Chloroethane is commonly used as a local anaesthetic. It is used on an intermittent basis. It is applied to skin directly by spraying small quantities of liquid e.g. 2 ml, or in the case of dentistry by application to a small cotton swab and then direct contact with skin or tooth. It quickly evaporates and causes local cooling. Applications will be of brief duration of the order of a few seconds or a minute. Health service contacts indicated exposures would be less than 10 ppm 8-hour TWA during typical use. It has been assumed that uses and hence exposures in related users, e.g. veterinary surgeons, chiropodists, is similar. It is used by tattooists and body piercers, against advice from Environmental Health Officers, but no further investigations were made for this application.

15. No quantitative measurements of exposures to chloroethane vapour were available but calculations from the use of 2 ml of spray in an unventilated consulting room of assumed volume of 20 m³ were made. This suggests that short-term concentrations of around 30 ppm might arise from a single application in small, unventilated consulting rooms. However, if 6 ml were applied then around 90 ppm would arise under the same circumstances. It is assumed that there would be rarely more than three such uses per day. In hospital surgeries, which are generally larger and more commonly fitted with ventilation, concentrations would generally not exceed 10 ppm.

(c) Chemical manufacturing

16. Only one plant in the UK was found to be using chloroethane as a chemical precursor. The chloroethane is imported, mainly by ship to this company, but there are some road tanker deliveries. The chloroethane is held in closed systems and used for the production of alkyl lead compounds. Systems are in place to minimise vapour release from loading and production operations. It was indicated that quality control operatives would not be exposed to vapour because of closed-loop sampling and currently applied control techniques.

17. Some exposure may occur from emergency maintenance operations or plant failure, but these require the use of suitable breathing apparatus as standard practice and personal exposure will be minimal.

18. No occupational exposure data were available which quantified employee exposures but industry assumes occupational exposures are minimal. No exposure data for use of chloroethane were available on the National Exposure Database.

19. Potential exposures to the highly volatile vapour under local exhaust control were modeled using EASE. This predicts that during breaches of containment short-term peaks of 100-200 ppm are possible. In this situation it is assumed that the peaks are of 1 minute duration and are performed up to twice per shift. Time-weighted average exposures are predicted to be less than 10 ppm 8-hour TWA.

Technical assumptions

20. All costs are calculated in 2000/2001 prices over a ten-year period¹. The base year for appraisal is year 2000/2001. Details of the actual costings are described below.

HEALTH AND SAFETY BENEFITS

21. The industry/services sectors that returned their questionnaires and were using chloroethane at the time of the survey reported that there had been no cases of ill-health that they associated with exposure to chloroethane.

22. If chloroethane is carcinogenic in humans, reductions in exposure should be connected with a reduced incidence of ill-health. However, the evidence is not available to quantify the benefits of this proposed reduction in the OEL.

23. Furthermore the information provided by the industry and services sectors suggests that exposures are generally lower than 10 ppm 8-hour TWA with the potential for some local anaesthetic uses to result in concentrations of 30 ppm for brief periods. Exposures to vapour during maintenance or repair activities in chemical manufacturing are assumed to be high and suitable breathing apparatus is used as the protective measure.

COSTS

Business sectors affected

24. There is very limited use of chloroethane in the UK. Three main sectors are involved.

1. 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.

(a) Import and distribution

25. Only one company was found that is involved in the importation of prepackaged product and supply to wholesale distributors. These groups, in turn, supply health services (including dental and veterinary) practices. Prepackaged containers are not opened before redistribution and so there is unlikely to be any exposure in this sector.

(b) Health Services and related users

26. The use of the substance as a local anaesthetic is widespread within hospitals (various specialist departments), dentistry, general practice and limited use in veterinary practices. The use is regulated by a licence system, administered by the Medicines Control Agency. Estimates of the numbers of people exposed were not provided but it is anticipated that up to 7000 health service and related services staff will be potentially exposed. Calculated exposures were estimated to be less than 10 ppm 8-hour TWA but under adverse conditions short-term peak concentrations could be up to 30 ppm for a single application of 2 ml and 90 ppm for use of 6 ml.

(c) Chemical manufacturing

27. The one chemical manufacturing company, which uses the substance as a feedstock, estimates that between 50 and 100 people could be exposed to the vapour/liquid. The plant used for storage and production, operate as closed systems and exposures were estimated from the EASE model at 0.0-0.1 ppm. Exposures estimated from the EASE model for tanker coupling activities, i.e. breaches of vented discharge systems indicated short-term concentrations of 100-200 ppm but of brief duration and less than 10 ppm 8-hour TWA.

Nature of compliance costs to charities and voluntary organisations

28. There are no anticipated costs for charities and voluntary organisations. Discussions with charitable veterinary practice representatives suggest little use by their profession.

Compliance costs for each sector of industry

29. It is assumed that, irrespective of the MEL value adopted, each business sector will undertake an initial risk assessment review and associated air sampling. Where additional control measures may be necessary, the extra control and monitoring costs will be considered for each potential MEL value. It is unlikely that companies would increase health surveillance, as there are no validated health surveillance methods available. In addition, there is unlikely to be the need for additional training on exposure control strategies.

Risk review and air sampling

30. Employers should undertake a review of the exposure risks where there is a potential of exceeding the MEL. Some users that have not quantified exposures will carry out initial air sampling to measure effectiveness of controls in relation to the

new MEL. As most current users indicate that exposures are likely to be below 10 ppm 8-hour TWA they are unlikely to instigate a routine monitoring programme.

31. For the review of assessment of risks and air sampling programme for chloroethane we can calculate some typical costs. A day's time for a consultant is estimated to cost between £500 and £600. A day's time for a technician is estimated to cost between £200 and £300 and the cost of each chloroethane analysis is assumed to be £20. A small business might require one day of a consultant's time with up to 10 samples collected, making a total of between £700 and £800. Larger businesses might require longer involvement of the consultant and technician with a variable number of samples. The charge per day would be £800-900 plus the cost of analysis of collected samples.

(a) Import and distribution

32. For a MEL of 10 ppm or 50 ppm, additional sampling might be undertaken to confirm that exposures are minimal. Over a ten-year period, if it is assumed that 5 such sampling exercises are undertaken, along with assessment review, the costs would be between £3,000 and £4,000². For a MEL of 100 ppm it is unlikely that any sampling will be necessary.

33. No additional costs for controls were indicated for any of the limits.

(b) Health Services and related users

34. For a MEL of 10 ppm and 50 ppm, initial sampling costs would involve an unknown number of premises. However, if we assume 30 practices (GPs, dentists and vets) costs will be between £22,000 and £28,000 in year 1 only³.

35. For a MEL of 100 ppm, the costs to achieve 100 ppm 8-hour TWA are assumed to be low with all businesses indicating compliance currently. Some air sampling may be carried out to confirm compliance with the MEL. It is assumed that 10 such sampling exercises would be conducted at a cost of between £7,000 and £9,000 in year 1 only⁴.

(c) Chemical manufacturing

36. Costs are estimated to be similar for a MEL of 10 ppm, 50 ppm or 100 ppm. The use of chloroethane in the manufacture of alkyl lead compounds has decreased significantly due to a downturn in the relevant market. Exposures of the 50-100 persons at the site who are potentially exposed can occur during emergency repair, maintenance or during work that requires breaching of the closed systems. Personal protective equipment is used as the control measure. Exposures to other persons at the production site were reported to be negligible. Some costs would be associated with adoption of a MEL at 10, 50 or 100 ppm 8-hour TWA. It is assumed that this

2.Includes: a day's time for a technician, a consultant and the cost of one sample in years 1,3,5,7 and 9. (min cost: Y1:£500+£200+£20=£720).

3.Min one-off cost of reviewing (£500+£200+£20) times 30 practices sampling= £21,600.

4.Min one-off cost of reviewing (£500+£200+£20) times 10 practices sampling = £7,200.

would be related to increased air sampling during typical potential exposure activities, and dependent on the results, routine monitoring to indicate continued effectiveness of controls. Estimates of these suggest that between £17,000 and £22,000 would be required for the assessment review, sampling, monitoring and analysis over a ten-year period. This is based on the requirement for a consultant hygienist and a technician spending 30 days over ten years reviewing activities, measuring exposures and analysis of collected samples.

37. Despite earlier indications from European and US industries that this substance may be used in other industrial sectors no evidence for the use of chloroethane in other chemical manufacturing processes in the UK was indicated.

Exposure control

(a) Import and distribution

38. For a MEL of 10 ppm, 50 ppm or 100 ppm, no additional control measures or monitoring are considered necessary.

(b) Health Services and related users

39. The costs of implementing control measures and additional monitoring could be significant where more ventilation (and hence heating) in consulting rooms was required to dilute vapours to maintain exposure levels at less than 10 ppm 8-hour TWA. There would be minimal additional costs if the limit was set at 50 ppm 8-hour TWA and no additional control and monitoring costs if the limit was set to 100ppm.

40. The additional costs for controls to achieve 10 ppm 8-hour TWA could be significant, particularly in general practice, and dentistry. If some of these premises were shown to be contaminated with excessive concentrations of chloroethane above 10ppm 8-hour TWA, the provision of improved ventilation or local extraction in consulting rooms would be necessary. Assuming an estimated cost of £200 per installation and approximately 5,000 premises⁵ requiring improved ventilation, the total one-off cost would be about £1 million. In addition, air monitoring/evaluation, running and maintenance costs are estimated to cost a further £1.4 million over 10 years⁶.

41. Costs to control exposure to 50 ppm 8-hour TWA are estimated to be significantly lower. The predicted use and conditions of use were calculated to lead to potential concentrations of 30 ppm of chloroethane under some adverse conditions although concentrations would be unlikely to exceed 50 ppm. There would be some costs associated with initial sampling to confirm exposures below 50 ppm 8-hour TWA under representative conditions. The costs for these are assumed to be between £22,000 and £28,000 with samples collected from 30 representative

5. Figure based on HSE judgment of the number of premises that will require ventilation installation.

6. Assumes 5,000 premises annually checking extraction performance and 30 premises additionally carrying out air monitoring at a cost of about £30 (£150,000 in year 1). Plus additional annual monitoring of air quality at a cost of £500+£200+£20 times 30 premises per year = £22,000.

small/medium services over ten years. Costs for additional controls are assumed to be negligible under these conditions.

42. For a MEL of 100 ppm, no additional control measures or monitoring are considered necessary.

(c) Chemical manufacturing

43. No additional expenditure on controls to maintain exposures at any of the MEL values was considered necessary.

(d) All sectors - short term exposure limit

44. There is no proposal to introduce a short-term exposure limit.

TOTAL COMPLIANCE COSTS

45. The information provided by the various sectors is limited. The quantifiable total costs to industry and services if the limit was set at 10 ppm 8-hour TWA would be around £2.4 million over 10 years, in present value terms; the bulk of that expenditure would be borne by the health services and related users. If the level were set at 50 ppm 8-hour TWA or greater, then costs would amount to between approximately £61,000 and £78,000, largely as a result of initial assessment review and sampling requirements to determine compliance with MEL. If the level were set at 100 ppm 8-hour TWA or greater, then costs would amount to between approximately £24,000 and £31,000, largely as a result of annual monitoring by chemical manufacturers.

46. Comparison with limits set in Europe and USA suggest the most common limit is currently 100 ppm 8-hour TWA but there appears to have been little consideration of the potential human carcinogenic effects of this substance in setting that limit.

47. The total costs for all the affected business sectors are summarised in Table 1 below.

Policy costs

48. Total policy costs will equal the total costs of the proposal.

Implementation costs⁷.

49. There are no implementation costs.

⁷Implementation costs are those associated with implementation of the measure, sometimes called the red-tape burden, as opposed to policy costs, which are those associated with achieving the policy objective.

Table 1: Summary of costs to comply with a variety of MELs, 8-hour TWA
(present values over ten years (£)).

Business sector	Cost for a MEL of 10 ppm (£)	Cost for a MEL of 50 ppm (£)	Cost for a MEL of 100 ppm (£)
Assessment review Costs to: 1) Supply/distribution 2) Health Services etc 3)Chemicals manufacture	1) £3,000-£4,000 2)£22,000-£28,000 3)£17,000-£22,000	1)£3,000-£4,000 2)£22,000-£28,000 3)£17,000-£22,000	1)None necessary 2)£7,000-£9,000 3)£17,000-£22,000
Additional costs for control Supply and distribution <input type="checkbox"/>	None considered necessary	None considered necessary	None considered necessary
Health Services etc <input type="checkbox"/>	£2.4 million is estimated	£22,000-£28,000 is anticipated	None considered necessary
Chemical Manufacturing <input type="checkbox"/>	None considered necessary	None considered necessary	None considered necessary
Total present value (ten years, £)	Around £2.4 million.	Around £61,000-£78,000	Around £24,000-£31,000

NB Totals may not add due to rounding

Impact on small businesses, “Litmus test”

51. As part of a regulatory impact assessment small-sized businesses are contacted to determine the impact for this sector. However, some of the businesses and services indicated above would be classified as small businesses and no impact would be anticipated at 50 and 100 ppm. At 10 ppm 8-hour TWA the cost might be over £1 million, e.g. dental practices and veterinary surgeries⁸.

Costs to HSE

52. Because of the proposed change to a MEL, there will be an increased emphasis on chloroethane exposure at all premises during inspection visits. However, since there are only a few companies handling chloroethane, any increased workload for inspectors, in HSE or the local authority enforced areas, are likely to be minimal. Hence it is estimated that additional enforcement costs should also be low.

8.As dental and veterinary practices make up approximately half of the health services staff we have assumed half the costs of review, control and monitoring measures.

Total costs to society

53. The vast majority of the societal cost is borne by health services and related users sector and industry. This is detailed above.

ENVIRONMENTAL IMPACTS

54. There are no environmental impacts other than the health effects already discussed. In industry, no additional external discharges of chloroethane are anticipated, as no further workplace controls are envisaged. The quantities emitted from the clinical uses would be very small, whether or not local ventilation was installed.

BALANCE OF COSTS AND BENEFITS

55. Since long-term benefits are unquantifiable, it is not possible to compare total costs and total benefits. We believe, though, that there might be up to 10,000 workers exposed to chloroethane, and that total quantifiable costs are variable dependent on the MEL set e.g. for 10 ppm 8-hour TWA these could be around £2.4m over a period of ten years, in present value terms.

56. It is useful to consider what the costs per worker exposed are from setting a MEL for chloroethane, and how these costs compare with past MELs set for substances with genotoxic concerns. The RIA for phenol listed examples of costs per worker for some recent MELs in its Table 4 (ACTS/20/2000). These were around £500 for alkyl sulphates, £400-1300 for hydrazine, and £14 for phenol; and for vanadium pentoxide are £550-1800 for an engineering control strategy and £1100-2700 for an RPE control strategy. The costs per worker for hydroquinone are currently under estimation. Given the total compliance costs and the number of workers exposed, the cost per employee exposed with setting a MEL for chloroethane at 10 ppm 8-hour TWA is of the order of £240-480 per worker assuming between 5000 and 10,000 exposed workers. This is at the lower end of the range of costs per employee exposed obtained for MELs set for several other substances of genotoxic concern. However as dental and veterinary practices would generally fall within the definition of small- and medium-sized enterprises, within this group the cost burdens may be high. The estimated costs per employee (for employee numbers in the range 5000-10000) are significantly lower for the other options, being £6-16 at 50 ppm, and £2-6 at 100 ppm

57. Taking account of total expenditure of all these sectors, total quantifiable costs and the cost per worker exposed appear to be fairly low.

SUMMARY AND RECOMMENDATIONS

58. On the basis of the information obtained from industry and services sectors it is reasonable to conclude that control of chloroethane is currently being achieved in the UK to less than 50 ppm 8-hour TWA. However, it is considered that the costs of control to 10 ppm 8-hour TWA would be disproportionately high for SMEs. There is some concern that exposures at 100 ppm 8-hour TWA, accepted by several other authorities in the world, might still have some residual risk that is unacceptable.

59. In view of the information collected to date, HSE recommends external consultation on a MEL at 50 ppm, 8-hour TWA.

UNCERTAINTIES

60. The information received from industry/services is scarce, thus many of the assumptions are based on limited replies to our questionnaire and HSE's best judgment. There is uncertainty over the number of premises in the health services and related users sector that would incur initial risk review and sampling costs. The costs will vary considerably depending on the exact number of premises. The uncertainties of the assumptions made are reflected in the use of ranges.

RESULTS OF CONSULTATION

61. The questionnaire and limit value options were sent to those services and companies identified as either supplying or using chloroethane. The arrangements for consulting in the health services sector were by way of specialists representing hospital trusts. The cover letter stated that current investigations suggested that there would be little impact if the limit were set at 50 ppm 8-hour TWA.

62. A further wide public consultation was held between March and June 2002. All respondents who replied on this issue agreed with the establishment of a MEL of 50 ppm (8-hour TWA). The MEL set at this level came into force in May 2003.

ARRANGEMENTS FOR MONITORING AND EVALUATION

63. The proposed MEL will be enforced by HSE at the premises where it is the enforcing agency and by the Local Authority at premises where it is the enforcing authority. Because of the proposed change to a MEL, there will be an increase in the emphasis inspectors attach to chloroethane exposure. However, since there are only a few companies handling chloroethane any increased workload for inspectors is likely to be minimal. Even in clinics, additional work might include enquiries about use of chloroethane as part of the general enquiries related to compliance with the COSHH Regulations. The MEL will be reassessed if significant new information becomes available which places doubt on the current assessment of the health risks.

CONTACT POINT AND DATE

Richard Pedersen
Health and Safety Executive, Chemicals and Flammables Policy Division
International Chemicals Unit
7NW Rose Court, 2 Southwark Bridge, London SE1 9HS
Tel: 020 7717 6216
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