

NEW CHEMICALS (HAZARD INFORMATION AND PACKAGING FOR SUPPLY) REGULATIONS ['CHIP 3'] : REGULATORY IMPACT ASSESSMENT (POST-CONSULTATION)

INTRODUCTION

1. This Regulatory Impact Assessment is a revised assessment of the costs and potential benefits of CHIP 3. It has been amended following comments received from industry during formal consultation.

PURPOSE AND INTENDED EFFECT

Issue

2. CHIP 3 will implement four directives:

- { the Dangerous Preparations Directive (1999/45/EC) (**DPD**);
- { the 1st Adaptation to the DPD.
- { the 2nd Amendment to the Safety Data Sheets Directive.
- { the 28th ATP (listing substances affected) to the Dangerous Substances Directive.

3. In addition, CHIP 3 will consolidate the existing law (i.e. replace the CHIP 2 Regulations and several sets of amending Regulations). The expected principal effects of the changes is described below.

Risk assessment

4. Exposure to or contact with harmful substances continues to present a significant health and safety risk in the workplace, responsible for around 5-10 fatal incidents each year. In addition, around 1,000 major injuries to employees and the self-employed are reported to HSE each year as a result of contact with harmful substances, and a further 4,000 incidents causing at least three days absence from work. Not all incidents involving harmful substances are in practice reported to HSE.

5. This Directive and implementing regulations form part of a series to ensure people (both at work and in the home) are properly informed about the dangers of chemicals, including any environmental risks associated with them. This greater awareness of environmental risk may prevent damage to the environment from the use/disposal of the chemical. The scale of environmental damage associated with lack of knowledge of hazardous chemicals is unknown. These Directives also facilitate the Single Market in international trade of chemicals by applying a single labelling system throughout the EU.

Options considered: transition period

6. Once Directives such as those listed above have been agreed they must be transposed into UK law by the dates specified. However, HSE's enforcement policy can allow some flexibility where companies have particular difficulties in fully implementing changes by a particular date, especially with respect to products already sold to retailers that may be difficult to recall and re-label. In this document,

costs are estimated given a three, six or twelve month transition period. Legally, the changes would have to be fully incorporated within three to four months. However, the length of time HSE considers it practical for many firms to comply with respect to products in the retail supply chain is an enforcement matter to be addressed at the time.

Sectors Affected and Consultation

7. We conducted an initial consultation with industry, who supplied us with some very provisional estimates of costs. This information has now been supplemented with further information supplied during formal consultation. It remains the case that all respondents reported the same broad effect in terms of the practicalities of the changes. We therefore believe that the costs below represent a reasonably accurate picture of the scale of the changes.

8. The main industry sectors manufacturing products affected by CHIP 3 are given in table 1 below. The total number of firms affected in some way by the changes will be around 3,800 - representing 267,000 employees. The majority of these, some 2,600, are small firms with nine or fewer employees.

9. Some sectors will be significantly affected. These are the manufacturers of paints, cleaning products, and other chemicals (but not pharmaceuticals or biocides). In addition to the firms shown at table 1, cement manufacturers and manufacturers of explosives and pyrotechnics will also be affected by the changes. There are some 75 companies involved in cement manufacture, employing an estimated 6,000 people. The number of explosive manufacturers affected by the changes is unknown at present.

10. In addition to the product manufacturers, large sections of industry will be affected by the classification of trichloroethylene (or 'trike') as a category II carcinogen, instead of category III. The cost implications of this change were examined during preparation of the UK's negotiating line, and these are reproduced below.

Table 1: Summary of UK industry most affected by CHIP 3 (figures relate to 1999)

Size of firm□	Number of businesses	Employment (000s)	Turnover (£m)
241 Manufacture of basic chemicals			
1-9	830	3	353
10-49	295	6	823
50-249	120	14	2,973
250+	70	66	16,728
1+ employees	1,315	88	20,878
242 Manufacture of pesticides and other agro-chemical products			
1-9	25	*	*
10-49	15	*	*
50-249	15	*	*
250+	5	*	*
1+ employees	55	4	735
243 Manufacture of paints, varnishes and similar coatings, and printing ink			
1-9	315	1	162
10-49	130	3	286
50-249	70	*	*
250+	25	*	*
1+ employees	535	29	4,093
244 Manufacture of pharmaceuticals and medicinal chemicals			
1-9	295	1	113
10-49	75	2	173
50-249	45	5	452
250+	50	58	9,510
1+ employees	460	66	10,248
245 Manufacture of soap and detergents, cleaning and polishing preparations			
1-9	425	1	158
10-49	130	3	289
50-249	60	7	558
250+	35	31	5,119
1+ employees	650	42	6,123
246 Manufacture of other chemical products			
1-9	490	2	206
10-49	165	4	428
50-249	80	9	1,390

250+	35	23	4,067
1+ employ- ees	770	38	6,091

Technical assumptions

11. Costs are in 2001 prices, as this is the date when the majority of information was supplied. Future costs and benefits are converted to present values in the base year of 2001 using the standard 6 per cent and 2 per cent discount rates, although no recurring costs are quantified, and these are expected to be very small.

COSTS TO INDUSTRY

12. Costs to each industry sector are detailed in turn below. The industry definitions are taken from the standard industrial classification, and turnover and employment figures will not necessarily be the same as the industries own classification.

Paint manufacturing industry (including varnishes, polishes, inks, and aerosol paints)

13. This industry will be particularly affected by the addition of three risk phrases to the majority of products. These are described first and then considered together.

Change of labelling - products newly placed on the market

14. The vast majority of solvent based paint (mostly decorative paint) and aerosol paints will now need to carry either the environmental or sensitiser risk phrases - or both. In addition, a substantial number of other coating products (for example varnishes, wood preservers etc.) will also need to carry one or both of these warnings. These products will usually have to include both risk phrases in their labelling. However, the costs of re-labelling will be similar if either or one of the phrases has to be included.

15. In addition, water based products will tend to contain the biocide Kathon to ensure preservation of the product (in the absence of a solvent, which would otherwise fulfill this role). The combination of these changes is therefore that the majority of paints will need new labelling, and a number of other coating products.

16. Paint manufacturers typically have many individually labelled products in several different ranges (the products varying in size and colour and sometimes composition). The total range of products will vary from around several hundred for a typical medium size manufacturer to several thousand for a large manufacturer. In addition, there are a number of small specialist suppliers who are likely to have a more restricted product range, and we assume an average product range of 50 (of all sizes) for this group (we apply this to firms with less than nine employees).

17. Several paint manufacturers, both large and medium size, reported that the cost of changing labelling templates would vary between £300 and £1,000 depending on the complexity of the label, with a typical cost of £500. On this basis, a medium size manufacturer reported changes to labelling would cost around £50,000 and the two largest manufacturers gave figures of £500,000 and £375,000 respec-

tively. For small specialist manufacturers we assume a cost of £10,000. We take these figures as roughly representative of the paint manufacture industry as a whole.

18. With respect to other coating products, the position is less clear, and further complicated by the fact that some larger manufacturers produce both paints and other coating products. A large coating manufacturer expected to have to include the environmental and/or sensitising phrase on between 10% and 20% of their products (up to half the solvent based ones). However, a number of water based products are also likely to be affected by the inclusion of Kathon in the approved supply list.

19. A maximum estimate of new labelling costs would be to apply the costs to typical firms above to all companies in this sector, as identified in table 1. However this is likely to be an overestimate, since the cost to the 25 large firms would be less than the cost to the large paint manufacturer. Instead we apply a cost of £200,000 as *an average* to 22 of the companies employing more than 250 workers in table 1, whilst acknowledging that costs to the three largest paint manufacturers will be far higher, and in the region of £500,000.

20. We also allow for a cost of £10,000 to the smallest firms. This would indicate total costs of £19 million in changing labels on the majority (probably around 75%) of all products supplied by this industry, calculated as follows:

$$315 * £10,000 + 200 * £50,000 + 22 * £200,000 + 3 * £500,000 = £19 \text{ million.}$$

21. Finally, manufacturers will hold redundant stocks of tin plate or empty tins. The extent of this stock will depend on the extent to which manufacturers have been able to anticipate the change. However, this anticipation will itself have a cost. Many manufacturers buy up to a years worth of tin plate as a bulk purchase.

22. One of the largest paint manufacturers has provided details of the further costs of redundant labels. Following a totally unanticipated change, they estimate that either disposing or washing off and remarking of existing tin plate would cost some £440,000. A further 36 million empty containers would be redundant. Economically, it is not worth remarking these, and the associated disposal cost would be some £1.6 million.

23. These are worst case costs, and they would be reduced to the extent that the changes are anticipated. Since this strategy also affects products already filled and placed on the market, these costs are carried forward to the next section and considered together.

Re-labelling or disposing of products already on the market

24. The above costs are those of making a one-off change to the labelling of products coming onto the market. However, products already placed on the market but not sold by the implementation date of the regulations will either have to be over labelled or disposed of. Some goods placed on the market will be relatively fast moving, with the majority passing fully through the supply chain within six months. However, other products may take two years on average to pass from manufacturer to end-user.

25. The extent to which re-labelling or disposal has to take place therefore depends crucially on the transition period. One large manufacturer of decorative paints provided the following estimate for the extent to which both pre-filled (empty), newly filled product, and product at the retailer would be affected, together with the costs incurred. These are reported in table 2 below. The costs for filled stock relates to disposal. Whether to re-label or dispose of filled stock is very much a logistic decision, and several commentators have said that the costs will be similar whichever strategy is adopted (this particular manufacturer thought that re-labelling would be more expensive) . Table 2 gives the amount of the total stock of each item affected and the associated cost.

Table 2: Example costs to a large paint manufacturer

	Pre-filled cans		Filled stock in warehouse		Filled stock with retailer	
	Amount	Cost	Amount	Cost	Amount	Cost
12 month transition	50%	£1.02m	25%	£3.37m	50%	£6.75m
6 month transition	100%	£2.04m	50%	£6.75m	100%	£13.5m

26. This company is a very large paint supplier, with almost all it's product affected. The amount of pre-labelled plate, unfilled cans or filled stock in the supply chain which is affected for smaller manufacturers may be below the figures indicated above, and (on the advice of the cleaning product industry association) could be as low as one-tenth the total amount, given a one year transition. It is therefore difficult to gross the figures in table 2 to the industry as a whole. However, an indicative figure - including coatings manufacturers as well as paint manufacturers - can be arrived at from the following assumptions which are based on the information supplied by the industry:

- { 75% of all industry product is affected. Of this 75%:
- { 10% to 20% of warehoused stock is affected given a 12 month transition, and 20% to 40% given a six-month transition.
- { 20% to 40% of both unfilled and retail stock is affected given a 12 month transition, and 60% to 80% given a six-month transition.

27. We can then gross down the costs in table 2 according to these assumptions, whilst again recognising that the costs in table 2 will be applicable to the three largest paint manufacturers. Since these costs relate to all large firms, we reduce the costs to smaller firms in line with our estimates of the costs of new labelling, which should give a good indication of production volume in different firm sizes. The company in table 2 estimated new labelling costs of £375,000. We have assumed £10,000 for the very small firms, £35,000 for medium size firms, and £110,000 for large firms - on average across the industry. We therefore gross the costs in table 2 down in the ratio 0.03 : 0.09 : 0.3 for small, medium and large firms respectively. Again, it should be emphasized that one reason for this reduction is that not all of these firms will be paint manufacturers.

28. This procedure leads to the following estimate for costs to a typical firm:

Table 3 : Costs of re-labelling etc given a 12 month transition: paint and coating industry

	Pre-filled cans/tinplate		Filled stock in warehouse		Filled stock with retailer	
	Amount	Cost £000s	Amount	Cost £000s	Amount	Cost £000s
Small	15%-30%	9-18	8%-15%	30-60	15%-30%	60-120
Medium	15%-30%	28-56	8%-15%	91-182	15%-30%	180-360
Large	15%-30%	92-184	8%-15%	300-600	15%-30%	600 - 1.2m

29. Following from table 2, costs given a six month transition period are simply double these estimates. Applying these estimates to the number of firms in the industry in table 1, by size band, indicates the following costs for a 12 month transition period:

Table 4: Total costs to paint and coating industry: 12 month transition (rounded to £10,000)

	Number	Cost to firm (table 3)	Total cost, £m
Small	315	£100,000 - 200,000	32 - 63
Medium	200	£300,000 - £600,000	60 - 120
Large	22	£1m to £2m	22 - 44
3 largest paint manufacturers	3	£11.2 million (from table 2)	34
TOTAL COST OF RE-LABELLING (ETC), £ millions			148 to 261

30. These costs are very approximate, but they indicate that the total cost to the industry could be in the order of two hundred million pounds. As an indication of the scale of these costs, table 1 reports total industry turnover as around £4 billion in 1998, which would uprate to around £5 billion in 2001 values. The costs of re-labelling etc would therefore be around 4% of industry turnover in that year.

31. These costs will roughly double given a six-month transition period, and double again given a three month transition - standing at around £400 million and £800 million respectively. However, this industry (as well as another industry) has advised that costs could be significantly mitigated by stock management. The effect of this is discussed below.

Administration costs

32. Manufacturers have not previously quantified administration costs associated with these changes, however one large coatings manufacturer reported that these are not insignificant, and gave a very rough figure of £50,000 in full economic cost time to everyone involved at the company. The estimate represented 40% of the costs of new labelling for this firm. Given that we have estimated new-labelling costs of around £19 million for the industry as a whole, this would indicate administrative costs on behalf of the manufacturers of around £8 million. It should be emphasized that these costs are very uncertain, and are probably large enough to also include the cost of familiarization with all elements of CHIP 3 across the industry.

Requirement for suppliers to provide safety data sheets (SDS) on request to professional users for non-classified preparations containing $\geq 1\%$ of substances hazardous to health or hazardous to the environment or assigned a Community Exposure Limit

33. With previous changes to CHIP, industry has indicated that the most significant cost is preparing or making changes to SDSs. Checking their own classification with that given by the ASL will be straightforward. Information previously collected from industry for the CBA of the Dangerous Preparations Directive (DPD) suggests that the cost of revising a SDS was between £100 and £230 in 1997, or about £130 to £300 in 01/02 prices.

34. The majority of solvent based products supplied by the paint and coating industry will already be classified. The majority of water based products will contain less than 1% of the hazardous substance and will not be affected by the requirement. . Manufacturers have commented that they already routinely supply safety data sheets where these are requested. However this is not a strict requirement in all cases of the Directive.

35. If 10% of all products in the industry fall under this new provision, this would range from several products (say 5) for a small specialist firm through to 20 to 30 for a medium size manufacturer, and perhaps 50 to 100 products for a large manufacturer. Given the number of firms in the industry at table 1, this would indicate costs of:

$\{ (315 * 5) + (200 * 20 \text{ to } 30) + (25 * 50 \text{ to } 100) \} * \text{£}130 \text{ to } \text{£}300 = \text{£}0.9 \text{ to } \text{£}2.5 \text{ million}$

36. This is a top estimate of the cost as the manufacturers may already be supplying data sheets to the end users of some of these products.

37. The Solvents Industry Association have pointed to the additional cost of sending the SDS to the end-users, at an estimated cost of £5 per copy. However, we expect these costs to be limited when the SDS is supplied at the same time as the product.

Manufacture of soap and detergents, cleaning and polishing preparations

38. This industry will be affected by the changes to phrases in exactly the same way as the paint etc manufacturing industry, however not to the same extent overall. The extent to which individual manufacturers are affected will vary greatly, since this industry is more diverse than the paint manufacture industry. Manufacturers of certain types of cleaning fluid (including aerosol sprays) may find that almost all of their products are affected. On the other hands, some manufacturers may not be affected at all.

Change of labelling - products newly placed on the market

39. As a very approximate estimate, the UK Cleaning Products Industry Association (UKCPI) have suggested that for a large manufacturer supplying a wide range of cleaning products, around 10% of these may be affected by one or more of the three new risk phrases. Changes to labelling will cost roughly the same for each product as that for the paint manufacture industry, in other words around £300 to as much as £2,000 for each item (the containers will typically be plastic, but this does not affect this element of the cost). However, unlike the paint industry, there would be an additional cost of £200 for the associated packaging (the vast majority of these products would be supplied to retailers in packages).

40. With respect to the cleaning product supply industry as a whole (see below), the UKCPI predicted average new labelling costs of £30,000 to £40,000 for a medium size company and £100,000 to £120,000 for a large company. These costs appear reasonable compared with information supplied by particular firms. Applying these costs to the number of firms in this industry at table 1, and allowing £10,000 for the smallest companies, this would suggest total costs of £14.75 million.

Re-labelling or disposing of products already on the market

41. As with the paint manufacture industry, recall costs would depend on how many products remain in the supply chain. Again, UKCPI have informed us that this is very variable depending on the product, and can be anything from one month to two years. However, UKCPI believe the majority of products will pass through the supply chain, and have suggested a figure of approximately 10% for those remaining on the shelf after one year. Given the fact that proportionately more products would be in the chain between 6 months and one year, we use a figure of 30% for products remaining on the shelf after 6 months.

42. Because of the diversity of products, costs are difficult to estimate. However, as with the paint manufacture industry, it is likely that logistic costs of recalling and re-labelling will in many cases be equal or greater than the costs of disposing of the product. In this case, we can use industry turnover as an approximate guide to the value of the product that would either be lost or recalled and re-labelled (strictly, we should exclude any profit margin, but in this competitive industry, this will be small compared to gross turnover).

43. From table 1, industry turnover was £6.1 billion in 1999, which would uprate to around £6.4 billion in 2001 prices. In order to estimate the proportion of products with longer shelf lives affected by CHIP3, we make the very broad assumption that the average time in the supply chain for all the industries products is six months. This means that products still remaining in the supply chain after one year contribute half the amount towards industry turnover than the average product would (since twice the amount of the average product will be sold during the year).

44. Following industry advice, we therefore predict that 0.5% of the industries production will be affected given a 12 month transition (10% of 10%, from above, and halving in line with the preceding paragraph). With a six month transition, however, the 'average' speed selling product is affected - if it is in scope. This means that around 2% of the industries production would be affected. However, proportionately more products are likely to be affected as the average shelf life is approached, so we use a figure of 3%. This would indicate re-labelling/disposal costs of £32 million for a 12 month transition and £192 million for a six month transition. The costs of further reducing the transition period to three months are difficult to estimate, but would be at least double that of a six month transition, or approximately £400 million. Costs could be higher than this, given a very short transition, as the average shelf life is actually exceeded.

45. We can compare this different method of estimating costs with those of the paint manufacture industry. Given a twelve month transition, total costs to the cleaning products manufacture industry are estimated to be 0.5% of turnover with 10% of all products affected. This compares with our 'bottom-up' estimate of the total costs to the paint manufacture industry of 4% of industry turnover with a total of 75% of all products affected. These costs are almost exactly comparable, and suggest that the detailed estimates given by the major paint manufacturer (and applied across the industry) are reasonable, and commensurate with industry turnover.

46. These are worst-case costs. The UKCPI have advised that costs could be significantly reduced by planning warehouse inventories of slow moving products, in partnership with retailers. In addition, there is the possibility that routine changes of artwork could be timed to coincide with the changes to risk phrases, although this cannot be guaranteed. Nevertheless, there is the possibility that costs could be reduced to as much as one-tenth of the worst-case level.

Administration costs and safety data sheets.

47. Working on the same basis as the paint manufacturing industry, we would expect administration (and familiarisation) costs of around £6 million across the industry as a whole, and also costs in compiling safety data sheets in the order of £1 million.

Manufacture of other chemical products

48. Several companies in this industry responded to our request for cost information. A major manufacturer of final products expected to need to conduct a review of all its 2,000+ product labels, and to change the classification and labelling of a significant number. They also pointed out the complex supply chain in their indus-

try. The British Aerosols Manufacturing Association pointed to re-labelling costs for a large number of final products as significant as those already identified, especially as they expected all product variants to have to have individual labelling for the first time. A major supply of laboratory chemicals has replied in detail to our request for information for the sector. We originally predicted similar costs to the cleaning product supply industry, since turnover is almost identical, and we thought a reasonable assumption was that around 10% of all products in this sector will be affected, as with the cleaning product supply industry.

49. However, the latter respondent reported that the work they had done so far indicated that some 20% of their chemical products would be affected. The company believes that labelling on all affected products will have to be altered, and all non-compliant stock will have to be re-labelled or disposed of. Significant labelling changes are expected to cost around £300, and minor changes around £50. The costs to this company of implementing the changes under a three to four month transition period are as follows:

Table 5 Costs to a typical large chemical product supplier

		Number of products affected * unit cost	Total cost
Changes to labelling, due to:	28th ATP	700 * £300	£210,000
	Environmental classification	500 * £300	£150,000
	R40/R68 changes	900 * £50	£45,000
	New SDS phrase	2000 * £50	£100,000
	New substances	300 * £50	£15,000
Changes to SDS software		2,100 * £130	£273,000
Changes to SDS			£24,000
Disposal/over-labelling			£750,000
Other costs			£5,000
TOTAL			£1,572,000

50. As noted by the respondent, the unit costs are at the lower end of the ranges supplied by other manufacturers. New labelling is estimated to cost just over £500,000, which comparable to the cost expected by the large paint manufacturers. However, disposal or over-labelling costs are much lower than those for paint manufacturers. This is because the inventories held by intermediate chemical manufacturers are typically far lower than those held by paint manufacturers. The new labelling costs are, however, higher than for those reported by the cleaning products industry. This may be due to the diversity of different products supplied by this firm, and the fact that more substances and preparations may be captured by the new risk phrases.

51. Since new labelling costs (at least to the larger manufacturers) appear similar in the paint and chemical product industries, we apply the same profile of costs reported by paint manufacturers to the chemical product industry, depending

on the number of companies in each size band in the chemical product industry given by table 1. This suggests new labelling costs of:

$$490 * £10,000 + 245 * £50,000 + 32 * £200,000 + 3 * £500,000 = £25 \text{ million}$$

52. We also vary the disposal or over-labelling costs in the same proportion as the new labelling costs, given the £750,000 cost reported by the company in this sector. This would suggest costs of :

$$490 * £15,000 + 245 * £75,000 + 32 * £300,000 + 3 * £750,000 = £37.5 \text{ million}$$

53. Finally, the changes to the SDS for newly affected products and corresponding changes in the associated software was predicted by the respondent in this sector to lead to costs of just under £300,000. Grossing this cost to the whole industry using the same method as above would indicate further costs of £15 million.

54. These costs can only be taken as approximate estimates since we are grossing information supplied by one company to the whole industry. We have not been advised about costs for smaller manufacturers, which make up a significant element of the total. Disposal or over-labelling costs in this sector are predicted by these estimates to be far lower than in the paint manufacture or cleaning products sector. This seems reasonable because of the far larger volume of product supplied by the latter two sectors. Moreover, the respondent in this industry advised that they would be able to sell significant amounts of the most valuable stock under a short transition period, and we assume this is also the case in the rest of the industry. The total quantified costs in the chemical product manufacturing sector, of just under £80 million, are therefore significantly lower than the two other sectors looked at so far.

55. These total costs relate to a short (3 or 4 month transition). With respect to the costs of over-labelling or disposal, we assume these are halved for a six-month transition period and halved again for a twelve month transition.

Other costs in this sector

56. Where a company proposes to self-classify a substance as a category 3 carcinogen, a dossier of the relevant information will be required to be sent to HSE. The respondent in this industry has already identified some 50 substances to which this requirement will apply, and thought that other companies in the industry would have many more. The costs of dealing with these substances are included above, however the respondent anticipated that compiling the information would typically take some time, as would analysis by HSE, but was unable to quantify this in advance of details on what is required.

Manufacture of basic chemicals

57. We are not expecting any significant costs to this industry, which (in general) supplies those industries above with raw materials. The majority of products supplied will be substances rather than mixtures. Basic chemicals will normally be supplied in bulk containers and are highly unlikely to remain in secondary manufacturers inventories for long periods of time. Even if some containers are affected, these will be far larger than the individual end products associated with them, and so the relative costs of re-labelling compared to value of the product will be far lower

than for manufacturers of consumer products. No basic chemical manufacturers notified us about significant costs during the consultation period.

58. As with the chemical product industry, at least some basic chemical manufacturers will be affected by the requirement to label all Category III carcinogens as “Limited evidence of a carcinogenic effect” (currently labelled with “Possible risk of irreversible effects”). There are approximately 90 such substances listed in the ASL. The numbers of self-classified substances and affected preparations are not known. We previously predicted that some 10,000 final products would be affected by this change in labelling, which is consistent with the information supplied by the respondent in the chemical product industry above (grossing this latter information across the industry gives a figure of 7,500). The costs relating to final products are therefore as given above. Costs relating to bulk substances will be far lower than this, but remain unquantified.

59. Finally, a major part of U.K. industry as a whole will be affected by the reclassification of trichloroethylene. This is discussed separately below.

Manufacturers of pharmaceuticals, agricultural products, and explosives

60. We initially expected the impact of both the new risk phrases and other industry specific changes to be far more limited in these industries compared to other chemical product suppliers. Final pharmaceutical products are exempt CHIP requirements since they are subject to specific medical legislation. Nevertheless, the Association of the British Pharmaceutical Industry have advised that CHIP3 will affect many pharmaceutical manufacturers, since intermediate mixtures may be moved between companies or sites. The industry will therefore face additional labelling costs, however these will tend to be smaller than for final products both because of the volume of mixtures moved, and the fact labelling can be amended at lower cost than with products for final consumption. Intermediate products in manufacture will tend to be used far more quickly than consumer products, and the industry is not expecting any significant over-labelling or disposal costs.

61. We have no specific cost information for the agricultural products supply industry or explosives industries, and we continue to assume that costs in these sectors will be limited.

Cement manufacturers

62. Cement manufacturers are likely to be affected by a requirement for suppliers to label cement or cement preparations containing $\geq 0.0002\%$ of chromium (VI) of the total dry weight of the cement with the phrase “Contains chromium (VI) May produce an allergic reaction” unless the preparation is already classified and labelled as a sensitiser with the phrase “May cause sensitisation by skin contact”. The British Cement Association (BCA) was contacted but was unable to supply cost estimates. The BCA did, however, note that its members were aware of the changes.

Reclassification of trichloroethylene

63. The cost implications to UK industry of the reclassification of trichloroethylene ('trike') as a category 2 carcinogen were examined at the time of the developments of the UK's negotiating line, and were found to be substantial. The main elements of the cost assessment are reproduced here. The original impact assessment was done in consultation with industry, and no further work has been undertaken. No further comments were obtained during formal consultation.

64. Trichloroethylene is manufactured by several companies throughout the world. Its principal use is as a solvent and cleaning agent for industry, and is widely used in engineering applications where metal degreasing is needed prior to painting - for example, in the aerospace industry and in the manufacturing of automotive components and a variety of precision instruments. 'Trike' is used (with less technical justification) for cleaning prior to wet processes including electroplating, anodising and passivation. It is also used in adhesives and to make replacement products for ozone-depleting substances, CFCs and HCFCs, that are being phased out under international treaty agreements.

65. As a result of the reclassification of trichloroethylene, there will be three main effects:

- a. Firstly, the labels and safety data sheets for trichloroethylene will have to make its status clear by labels "May cause cancer";
- b. Secondly, users of trichloroethylene will have to take extra precautions to ensure workers are protected. Trichloroethylene will be subject to the special provisions of COSHH dealing with carcinogens of categories 1 and 2; and
- c. Thirdly, trichloroethylene will be subject to specific requirements under the Solvents Emissions Directive (VOC) when this comes into force in April 2001. This Directive is administered by the Department of the Environment, Transport and Regions (DETR) who have commissioned their own cost benefit analysis as part of the transposition of the VOC Directive.

66. The main effect of the change in classification for trichloroethylene will be change of practice in the engineering industry where trichloroethylene is widely used for degreasing. Current control measures will not be adequate so there will be costs to users in either upgrading equipment or changing to alternative substances or processes.

67. There are currently around 4,000 degreasing plants across the UK, using up to a total of 14,000 tonnes of trichloroethylene per year. Of these plants, it is estimated that less than 100 are using modern, fully enclosed systems and are currently meeting the Volatile Organic Compounds (VOC) Directive emission standard. This means that up to 3,900 plants may face costs to either upgrade their equipment or switch to alternative substances or processes.

Cost of alternative substances

68. There are alternative substances and processes to trichloroethylene. However, in many cases these alternatives may not be suitable for all uses, and it is necessary for each user to find which processes can be substituted, and with what.

69. Table 5 summarises some of the alternatives for all sorts of surface treatment. It should be borne in mind that some treatments presently require rust and scale removal as a separate treatment to any solvent degreasing, and that the need for routine degreasing is questionable. Several firms requiring degreasing have tried brominated alternatives to trichloroethylene and examined aqueous cleaning systems but have found no safer and economically viable alternatives. Others have been entirely happy with the change to non-solvent methods. The choice factors are different if a new installation is being considered, rather than replacement of a working system.

Table 5: Alternatives to the use of trichloroethylene

Alternative substance/ Processes	Characteristics (compared with trichloroethylene)
1. Aqueous cleaning processes	Highly suitable for wet destination processes such as electroplating. For some non electroplating processes there are significant increases in energy requirement (8-10 times) leading to corresponding increases in CO ₂ (green house gas) emission. Increased potential for water borne pollution. Vast decrease in the cost of waste solvent disposal Cleaning not as effective. Cost of equipment approximately £103,400 (1999/00 prices), includes plant equipment and drying oven. This compares favourably with the cost of a new vapour degreasing system if the old system is incapable of upgrading.
2. Non halogenated processes	Large increase in the potential for low level ozone formation. Health concerns (e.g. respiratory problems) Most of the solvents are flammable/ combustible.
3. Brominated solvents □	Possible ozone depleters. Toxicological concerns not fully examined.
4. Other chlorine based solvents	Energy expensive (high boiling points) Volatile and difficult to control in standard equipment.
5. Dry blasting cleaning (eg limestone, bicarbonate, mica, glass bead),	Cost of new blasting equipment (very variable with size) Very low waste disposal costs Costs of blast medium and carriage

	Advantage:removes dirt and light rust also
6. High pressure water blasting	Cost of blasting equipment Moderate waste disposal costs Removes substantial amount of rust and old paint also
7. Other non-solvent methods	Depends on the necessity to remove dirt and grease Sometimes no treatment at all is required Large cost advantage
8. Detergent and light oil ('Gunk' - type) with water rinse	Increased manual work Product finishes wet with water or with oil Higher materials cost as fresh used for each item High waste water disposal costs

70. As mentioned above, the health and safety of these substitutes to humans and the environment have not necessarily been evaluated to the same level as trichloroethylene, so there may be health, safety and environmental costs associated with the use of these substances. These are unquantifiable. In some cases, the alternatives are of lower health risk.

71. It is accepted that some product processes will continue to require solvent vapour degreasing. It is not known how many existing vapour degreasing activities fall into this class.

72. Once trichloroethylene has been reclassified, it is understood from industry sources that about 3,500 plants could be modified to use less than 1 tonne per annum (TPA) by 2007. However, many of these plants will require considerable investment to do so as none of the 'traditional' open topped degreasing baths, even the very new ones, could meet the more stringent VOC emission standard (see below).

73. It is assumed that for those plants involved in the cleaning of medium and small parts, changing to enclosed systems or improving the operating practices of their existing systems may be sufficient to reduce their emissions to below the 1 TPA threshold. This is approximately 3198 plants¹.

74. It is also assumed that for those plants involved in the cleaning of parts requiring large baths (e.g 60 feet long), the option to install an enclosed system is not available This is approximately 702 firms². These firms' only option is to switch to an alternative substance or process. The decision on which substitute would be based on the local factors, ie. what are the parts that need cleaning and the machin-

¹ 82% of 3,900 plants. See assumptions p6

² 18% of the 3,900 firms. See assumptions p7.

ery available etc. According to some industry contacts, significant costs will be incurred in making these changes³.

75. Furthermore, COSHH requires employers to conduct a comprehensive risk assessment of any potential substitute prior to use. On the basis of the information currently available, it has not been possible to value the cost of some firms switching from trichloroethylene to another substance/process.

76. The maximum time-scale for equipment replacement under the VOC Directive for category 2 and 3 carcinogens is 30 October 2007. However, the substitution of carcinogens mutagens and reprotoxins (CMRs) is encouraged in 'the shortest possible time'. At present DETR have not provided advice on how this will be interpreted but it implies that the cost of switching to alternative substances/processes is incurred more immediately.

Cost of upgrading equipment

At the moment, over 70% of the UK industry uses open degreasing baths. One problem with the traditional style equipment is that they are not correctly maintained and, as operators are not adequately trained, the risks are not properly managed. Modern, fully enclosed degreasing baths are now available where the operator has far less direct contact with the solvent.

The cost of these enclosed systems varies depending on the size of the parts requiring cleaning. Table 6 below outlines these costs.

Table 6: Unit costs of upgrading equipment

Enclosed System Costs:	1999/00 prices
Small-medium parts	£20,000 - £25,000
Large Parts	Up to £100,000

VOC Directive requirements

77. This Directive restricts the use of solvents in certain industrial processes in order to reduce low level ozone production. It includes the use of solvents in surface cleaning ie degreasing. If trichloroethylene is classified as a category 2 carcinogen then for degreasing uses substitution is promoted and environmental levels of trichloroethylene must be reduced to a very low level.

78. The threshold limit, above which the VOC Directive applies, is one tonne per year. The use of enclosed systems can reduce the amount of solvent required to do the cleaning by up to 80%⁴. If trichloroethylene were to be reclassified, the relevant stack emission limit would change from 20 mg/m³ (3 ppm for trichloroethylene) to a limit of 2 mg/m³ (0.3 ppm for trichloroethylene). Industry representa-

³ As trichloroethylene is part of the specification for the manufacture of precision stainless steel and Titanium Alloy steel for the aerospace industry, this sector will incur several thousands of pounds on approvals and testing to confirm that the new degreasing techniques are satisfactory for the high specification required.

⁴ Evidence from 4 companies who have switched from using open-topped degreasing units to enclosed systems, cited in HSE's 'Good Health is Good Business Campaign' literature on the use of solvents.

tives have indicated that this level will be impossible to achieve for some plants (for example, the aerospace industry), even when allowing for the upgrade of equipment.

79. To calculate the cost to industry of upgrading equipment, a number of assumptions were made:

- a. It was assumed that of the 3,900 degreasing plants not currently meeting VOC standards, 17% of these plants handle small components, 65% intermediate components and 18% large components.
- b. Only those plants handling small or intermediate parts (82%) will be able to meet the standard (post reclassification) by installing enclosed cleaning systems or improving their operating practices.
- c. The remaining 18% are assumed to adopt aqueous cleaning systems.
- d. Between 50% and 80% of these plants are assumed to be small businesses (SMEs).
- e. The cost of annual maintenance is 5% of the cost of the upgraded equipment.

80. Of the 3,900 plants, therefore, 3,198 may upgrade their equipment and be able to meet the VOC stack emission limit. This produces a one-off cost of £77 million for machinery. The annual costs⁵ would be approximately £4 million and the 10 year net present value⁶ of these costs would be equal to £108 million.

81. The remaining plants (702) face the option of switching to using alternative chemicals and/or processes, as discussed above. If we assume that 50% of these plants switch to using an aqueous cleaning system, this would produce a one-off cost of £28 million⁷.

Training costs

82. Both equipment upgrading and chemical/process substitution would require workers to be given some form of training. It is known that some of those plants who have already installed enclosed degreasing systems have expended considerable resources in providing their staff with awareness and training programmes. This was to ensure that their entire workforce had a better understanding of the issues surrounding the use of chlorinated solvents for cleaning and degreasing applications as well as promoting safe working practices.

83. For training, we assume £150 a day for costs of the instructor, plus the daily wage of the replacement worker(s). We assume that the number of trainees be-

⁵These are the costs to maintain the equipment.

⁶See footnote 1.

⁷The capital cost, for firms cleaning large parts, of switching to an aqueous cleaning system is assumed to be £80,000 from the figures used in the DETR Regulatory and Environmental Impact Assessment for the Implementation of the EC Solvent Emissions Directive, Entec, 1999.

ing trained at any one time per plant is between 1 and 5. Assuming that training can take between 1 and 5 days, there is an estimated one-off total training cost of between approximately £0.5 million and £12 million⁸.

Total costs to industry (end-users) : trichloroethylene

84. Table 4 below summarises the total one-off and 10 year Present Value costs.

	One-off Costs (£m)	10 Year Present Value (one off plus recurring) (£m)
Equipment upgrade	77	108
Process/chemical substitution	28	28
Training	0.5 - 12.0	0.5 - 12.0
Total	105.5 - 117	136.5 - 148

Effect of CHIP on other legislation

85. Several pieces of legislation either refer to, or rely upon, CHIP (or its underlying directives) in order to determine whether any particular substance or preparation comes within their scope. A previous review of the relevant legislation suggests that, in practice, the substances affected by these proposed changes are unlikely to have any effect, with the following exceptions:

- a. The Control of Substances Hazardous to Health Regulations 1999 (No. 437) (COSHH). The new classifications will need to be taken into account when compiling any assessment as required under COSHH.
- b. Special Waste Regulations 1996 (No. 972). Newly classified, or re-classified substances, may become classed as 'special waste'.
- c. The Control of Major Accident Hazards Regulations 1999 (No. 743) (COMAH). Newly classified substances could bring a previously non-classified site under one of the COMAH tiers of classification.

86. With respect to COSHH, the most important effect is the reclassification of trichloroethylene. For a chemical with a MEL, employers are required to reduce exposure to as low as reasonably practicable below the MEL. Assuming employers are already complying with the MEL, a change to the category classification for trichloroethylene should not impose any additional cost on industry. A category 2 classification may, however, provide added impetus for employers to lower exposure even further.

87. Costs may be incurred if substances become classed as special waste for the first time. It is very difficult to estimate the scale of these additional costs (if any), since whether a substance is classified as special waste depends on the exact nature of the relationship between the special waste regulations and these propos-

⁸ Assuming a minimum of 1 person per plant trained for 1 day, the cost equals (£150+ £123x3,900) and a maximum of 5 workers per plant being trained for 5 days, the cost equals 5x(£150+£123x19500).

als. It is possible that these costs could be significant, but there is insufficient information to be able to make any assessment. We specifically asked for information in this regard, but no organisations notified us of additional costs during the formal consultation.

88. Finally, the new Approved Supply List (ASL) will bring into scope as major hazards many sites which currently hold or manufacture quantities of petroleum preparations at a much lower threshold than amounts currently specified under COMAH. However, when the forthcoming 'Seveso II' amendments are put in place, new proposed thresholds (currently 2,500 and 25,000 tonnes - and not expected to change) will apply to these "petroleum products". The majority of sites brought in to COMAH under CHIP would then 'drop out' of COMAH in 2004.

89. Several consultees referred to this issue. To resolve this situation, HSE is proposing to effect an interim arrangement which will mean that the sites below the Seveso II threshold, but currently affected by the ASL, will not be included in COMAH. There will still be an increase in the number of COMAH sites as a result of Seveso II, and this is now being examined as part of HSE's response to the Directive.

BENEFITS

Health and Safety Benefits

Safety benefits

90. It is difficult to assess the safety benefit that will be gained from these amendments alone, rather than from the existence of the CHIP regulatory framework as a whole. Indeed, with regard to actual incidents, it is generally difficult to disentangle the role played by CHIP in mitigating or preventing incidents from other factors (including other regulations) that would have also played a part.

91. However, we can attach a value to all the reported incidents as noted in the risk assessment, following the DETR approach to valuing the reduction in risk associated with road traffic fatalities. The value of fatal risk reduction (VFR) attached to a future fatality in year 2001 values is around £1.2 million. It should be noted that this is the value attached to a small reduction in what is already a small risk, and HSE has traditionally assumed that this figure would also be applicable to risks in the workplace (or from hazardous substances more generally). We can also value injury prevention using a 'weighted average' approach that has been applied in other industries and in previous HSE research on the costs of accidents. This would suggest that 1 future fatality and around 10-20 future serious injuries has a VFR equivalent to around 1.2 fatalities. However, it is well established that there is under-reporting of injuries (compared to an effective 100% reporting of fatalities) in all HSE enforced sectors. To allow for this, and also the effect of non-reportable injuries, we therefore assume that 1 future fatality prevented corresponds to 1.5 "equivalent" fatalities prevented.

92. Given the scale of the safety risk from hazardous substances described above, this leads to an annual valuation of:

5-10 fatalities * 1.5 * £1.2 million = £9 million to £18 million.

93. This is equivalent to a present value of between £80 million and £160 million over ten years, and is the safety risk relating to all incidents, whether affected by the CHIP regime or not. We would only expect the CHIP regime as a whole to be able to have a marginal future impact on this total risk, and the actual changes brought about by CHIP3 only relate to a small proportion of the risk that CHIP could mitigate in the future.

Health Benefits

94. The major health benefit will be in alerting both workers and consumers to products that may cause an allergic reaction. The proposals will not prevent new cases of asthma and dermatitis but will prevent those who already suffer from these conditions from experiencing attacks. The number of people suffering from dermatitis caused by hazardous substances is unknown. The number of people suffering from asthma in the U.K. is estimated at 3.4 million⁹, of which 1.5 million are children and 1.9 million adults. While the benefits of alerting these people to hazardous substances likely to exacerbate their conditions could be considerable, they are unquantifiable.

95. In addition, there may be some health benefit from the reclassification of trichloroethylene as a category 2 carcinogen, although the health effects in humans of this substance is disputed, and has been the subject of considerable debate. However, controlling exposure to this substance will also reduce the risk of vapour inhalation, which can result in unconsciousness.

Other Benefits

96. The disruption to work activity and mitigation costs associated with exposure to a harmful substance have not been costed but could be considerable. Previous work in other industries has shown that this cost can exceed the safety benefit valuation by two or three times. Whilst there is less likely to be equipment damage associated with hazardous substances, there is more likely to be time lost in mitigating any spillage. It would not be unreasonable to assume that these additional costs are at least as significant as the value attached to direct safety benefits, ie equivalent to a present value of around £100 million over ten years. Again, the specific changes brought about by CHIP3 could only be expected to prevent a small proportion of this future risk.

97. Changes to the ASL should result in more and better information to users of dangerous substances. Hazards and risks can be more easily identified and appropriate actions taken. This should lead to improvements in health and safety, and perhaps greater protection of the environment. Responding to the CHIP 99 consultation, the Trades Union Congress (TUC) contended that amending the Regulations present an opportunity for suppliers to review and improve SDSs. We might expect a tangible benefit if this is the case, given the scale of the risks already noted. However, these effects cannot be quantified, and one industry association has noted

⁹Asthma.org.uk - website of the national asthma campaign

that is seen as confusing users, and that the numerous changes can sometimes result in confusion to many 'downstream' users (despite the best efforts by suppliers to explain the changes).

Total benefits

98. We estimate the total cost of accidents involving harmful substances are in the order of £200 million in present terms over ten years. However CHIP 3 would only impact on a very small, and unknown, proportion of this risk, and we cannot separately estimate the contribution that these current amendments will make in reducing these costs. We would also expect further health benefits from reductions in other illnesses.

ENVIRONMENTAL IMPACTS

99. The proposals will inform the public of the environmental risks associated with hazardous substances, this will have two positive effects. Firstly it will reduce the risk of misuse or disposal of the substance that would cause causing environmental damage. It will also enable the public to make an informed choice between products containing substances damaging to the environment and any environmentally friendly alternatives. This may cause consumers to move towards the use of products less likely to damage the environment and place economic pressure on firms to reformulate their products to reduce or remove the substance that causes the environmental damage.

BALANCE OF COSTS AND BENEFITS

100. Total one-off quantified costs of CHIP3, if no action was taken by industry to mitigate these costs by stock management, are detailed in the table below. These are one-off costs. Recurring costs have not generally been quantified at this stage and are expected to be very small in comparison (and zero for the changes in phrases, which is the majority of the cost).

Table 7: Summary of one-off costs (rounded to reflect uncertainty) : assuming no inventory management is undertaken.

	3 month transition	6 month transition	12 month transition
Paint manufacture□	At least £800 million	£400 million	£200 million
Cleaning products etc manufacture	At least £400 million	£200 million	£50 million
Other chemical prod-	£80 million	£60 million	£50 million

ucts			
Basic chemicals□	Unquantified, but thought to be relatively modest		
Other industries (medicines, cement, agro-products and ex- plosives)	Unquantified, but thought to be relatively modest		
Reclassification of Tri- chloroethylene	£110 million		
TOTAL	£1,400 million	£800 million	£400 million

101. These are worst-case costs, and suggest that the total cost of the proposals - if no mitigating action is taken by industry - would be around £400 million given a 12 month transition, but increasing to around £800 million given a 6 month transition, and increasing further to some £1,400 million given a three month transition.

102. However, industry has advised that the costs relating to re-labelling could be significantly reduced by stock management, at the extreme to around one-tenth of the worst-case costs. However, successful inventory management will be *proportionately* far more difficult under a six-month transition than a twelve month transition, and even more so under a three month transition. In addition, routine new labelling will be twice as likely to occur in any event given the longer period. Firms may also have more opportunity to reformulate some of their products to remove the hazardous substances and remove the requirement for labelling given a longer period.

103. In order to compare costs with benefits, we assume that at least some successful inventory management and reformulation will reduce new and re-labelling costs to one-fifth of their apparent totals given a twelve month transition, and one-half their apparent totals given a six month and three month transition. Total costs of the proposals given these 'best-case' assumptions are therefore £200 million for a twelve month transition, £400 million for a six month transition period, and around £700 million for a three month transition.

104. These total costs compare to potential safety benefits of reducing incidents relating to dangerous chemicals as a whole (not just the part of the risk that can be addressed by the CHIP regime) of around £200 million, and unquantified health benefits of probably the same order of magnitude (this is based on previous published work by HSE on the costs of accidents, which found that the costs of all injuries and all ill health were of approximately the same order of magnitude).

105. Even if these amendments were effective in preventing or mitigating 10% of all incidents to do with chemical exposure, this suggests that the costs of the CHIP 3 regulations are likely to outweigh the potential health and safety benefits by at least an order of magnitude. There is also the unquantifiable benefit of additional information improving consumer choice and health, the proposals are also likely to have a positive environmental impact. All of the benefits are recurring in nature

where as the costs are largely one-off, incurred when the proposals are first introduced.

106. This assessment suggests how crucial an adequate transition period is in limiting costs to industry. The effect of shortening the transition period from 12 to 6 months results in costs to industry that would outweigh the potential safety and health benefits of the entire CHIP classification regime for a period of around five to ten years - even given the best case assumptions.

Impact on Small and Medium Sized Establishments (SMEs)

107. We expect a disproportionate impact on SMEs, who are less likely to be able to manage their product supplies to minimise costs, spread the costs of labelling over many products, and (crucially) put logistic operations in place to recall or dispose of products already supplied to retailers.

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