IMPLEMENTATION OF THE 3RD INDICATIVE OCCUPATIONAL EXPOSURE LIMIT VALUES (IOELV) DIRECTIVE (2009/161/EU)

Impact Assessment

An Impact Assessment (IA) is a tool, which informs policy decisions. All NI Government Departments must comply with the impact assessment process when considering any new, or amendments to, existing policy proposals. Where regulations or alternative measures are introduced an IA should be used to make informed decisions. The IA is an assessment of the impact of policy options in terms of the costs, benefits and risks of the proposal. New regulations should only be introduced when other alternatives have been considered and rejected and where the benefits justify the costs.

The IA process is not specific to the UK Civil Service or the NI Civil Service – many countries use a similar analysis to assess their proposed regulations and large organisations appraise their investment decisions in similar ways too.

Please find enclosed a final IA in respect of the implementation in Northern Ireland of the 3rd Indicative Occupational Exposure Limit Values (IOELV) Directive (2009/161/EU**)**.

Contact: Julie Gillespie
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E-mail: Julie.gillespie@hseni.gov.uk

IMPLEMENTATION IN NORTHERN IRELAND OF THE 3RD INDICATIVE OCCUPATIONAL EXPOSURE LIMIT VALUES (IOELV) DIRECTIVE (2009/161/EU)

NOTE ON COSTS AND BENEFITS

1. I declare that:

    a. the purpose of the revision of the HSE publication entitled “EH40 Workplace Exposure Limits”, to include new and revised Workplace Exposure Limits (WELs) for the nineteen substances listed in the 3rd Indicative Occupational Exposure Limit Values (IOELV) Directive (2009/161/EU) (“the Directive”), together with the publication of related notices on the HSENI website and in the Belfast Gazette, is to fully implement the Directive in Northern Ireland; and

    b. I am satisfied that the costs and benefits assessment, prepared in association with the measures to implement the Directive in Great Britain, may be applied, with modifications to the Northern Ireland measures.

2. An estimate of the costs and benefits associated with the measures to implement the Directive in GB, together with the effect on the Northern Ireland costs and benefits is appended to this Note.

3. There is no impact on charities, social enterprise or voluntary bodies.

D Breen
Health and Safety Executive for Northern Ireland

March 2012

PART I

GREAT BRITAIN IMPACT ASSESSMENT

(Prepared by the Health and Safety Executive)

IMPLEMENTATION OF THE 3RD INDICATIVE OCCUPATIONAL EXPOSURE LIMIT VALUES (IOELV) DIRECTIVE (2009/161/EU)

1. The following pages contain a copy of the Impact Assessment, prepared by the Great Britain Health and Safety Executive, in respect of the implementation measures in GB.

2. The overall assessment shows that there are no costs that can be monetised. Familiarisation and compliance costs are not expected to be significant. Costs associated with checking compliance with the proposed Workplace Exposure Limits, and resulting from implementation of control measures where compliance is not already achieved, are possible. Such costs are however not expected to be significant.

Title:

3rd Indicative Occupational Exposure Limit Values Directive

Lead department or agency:
Health and Safety Executive
Other departments or agencies:

Impact Assessment (IA)

IA No:

Date: 23/03/2011

Stage: Consultation

Source of intervention: EU

Type of measure: Primary Legislation

Contact for enquiries:
Tim Harris

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

Indicative Occupational Exposure Limit Values (IOELVs) are indications of safe levels of workplace exposure at which ill-health effects are unlikely to occur for hazardous substances. From time to time the European Commission, with the agreement of Member States, introduces a new list of IOELVs in the form of a Directive.
The 3rd IOELV Directive was adopted on 17th December 2009. Member States have to implement the Directive by establishing national limits taking into account the IOELVs. The final date for implementation is 18th December 2011.
Separate implementation is required in Northern Ireland and in Gibraltar.

What are the policy objectives and the intended effects?

Member States are required by Treaty commitments to establish in national law limits for all substances subject to IOELVs, taking the IOELV into account. In Great Britain, this is achieved by establishing or revising Workplace Exposure Limits (WELs), which are established within the framework of the Control of Substances Hazardous to Health Regulations 2002 (as amended). No changes to legislation are needed. The objective is to publish 5 new and 12 revised WELs, bringing these into effect on 18 December 2011.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Policy option 1: Do nothing.

Policy option 2: Implement the Directive by establishing and revising limits in line with the new IOELVs, except where a limit other than the IOELV is robustly justified.

Policy option 2 is the preferred option.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year

What is the basis for this review? Not applicable **If applicable, set sunset clause date:** Month/Year

Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Not applicable

Ministerial Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: _____ Date: _____

Summary: Analysis and Evidence

Policy Option 1

Description:

Do Nothing

Price Base Year N/A	PV Base Year N/A	Time Period Years N/A	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** Nil

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	Nil		Nil	**Nil**

Description and scale of key monetised costs by 'main affected groups'

This option continues with the status quo and therefore has no costs.

Other key non-monetised costs by 'main affected groups'

By failing to implement the proposed IOELVs, the UK Government would be in breach of Treaty obligations, with the associated risk of infraction proceedings for under-implementation.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	Nil		Nil	**Nil**

Description and scale of key monetised benefits by 'main affected groups'

This option maintains the status quo and therefore has no benefits.

Other key non-monetised benefits by 'main affected groups'

N/A

Key assumptions/sensitivities/risks **Discount rate (%)** N/A

N/A

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: Nil	**Benefits:** Nil	**Net:** Nil	No	NA

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Great Britain		
From what date will the policy be implemented?			N/A		
Which organisation(s) will enforce the policy?			N/A		
What is the annual change in enforcement cost (£m)?			Nil		
Does enforcement comply with Hampton principles?			N/A		
Does implementation go beyond minimum EU requirements?			N/A		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** Nil		**Non-traded:** Nil
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** Nil		**Benefits:** Nil
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro** N/A	**< 20** N/A	**Small** N/A	**Medium** N/A	**Large** N/A
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	N/A
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	N/A
Small firms Small Firms Impact Test guidance	No	N/A
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	N/A
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	N/A
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	N/A
Human rights Human Rights Impact Test guidance	No	N/A
Justice system Justice Impact Test guidance	No	N/A
Rural proofing Rural Proofing Impact Test guidance	No	N/A
Sustainable development Sustainable Development Impact Test guidance	No	N/A

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 2

Description:

Implement new IOELVs in line with EU Directive

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
	2010	10	**Low:** Optional	**High:** Optional	**Best Estimate: Minimal**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	Minimal		Minimal	**Minimal**

Description and scale of key monetised costs by 'main affected groups'

There are no costs that can be monetised. Familiarisation and compliance costs are not expected to be significant. HSE has conducted an early informal consultation with industry and received no responses indicating concern over the Directive. The formal consultation is being used to ensure the costs presented are as accurate as possible, as well as to gather information on four substances where impacts cannot be identified.

Other key non-monetised costs by 'main affected groups'

Costs associated with checking compliance with the proposed Workplace Exposure Limits, and resulting from implementation of control measures where compliance is not already achieved, are possible. Such costs are however not expected to be significant, as set out in the evidence base.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	Nil		Nil	**Nil**

Description and scale of key monetised benefits by 'main affected groups'

There are no benefits identified that can be monetised.

Other key non-monetised benefits by 'main affected groups'

There may be an improvement in protection of human health in the workplace as the new Workplace Exposure Limits result in improved exposure controls to levels where no adverse health effects will occur. These are not expected to be significant, as set out in the evidence base.

Key assumptions/sensitivities/risks

None

Discount rate (%) 3.5

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: Minimal	**Benefits:** Nil	**Net:** Minimal	No	N/A

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Great Britain		
From what date will the policy be implemented?			18/12/2011		
Which organisation(s) will enforce the policy?			HSE		
What is the annual change in enforcement cost (£m)?			Nil		
Does enforcement comply with Hampton principles?			NoYes		
Does implementation go beyond minimum EU requirements?					
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** Nil	**Non-traded:** Nil	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** Nil	**Benefits:** Nil	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro** N/A	**< 20** N/A	**Small** N/A	**Medium** N/A	**Large** N/A
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	12
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	12
Small firms Small Firms Impact Test guidance	No	12
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	12
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	12
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	12
Human rights Human Rights Impact Test guidance	No	12
Justice system Justice Impact Test guidance	No	12
Rural proofing Rural Proofing Impact Test guidance	No	12
Sustainable development Sustainable Development Impact Test guidance	No	12

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in References **section.**

References

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures**.**

No.	Legislation or publication
1	
2	
3	
4	

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the Annual profile of monetised costs and benefits **(transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).**

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	Min**	Min	Min	Min	Min	Min	Min	Min	Min	Min
Annual recurring cost	Min	Min	Min	Min	Min	Min	Min	Min	Min	Min
Total annual costs	Min	Min	Min	Min	Min	Min	Min	Min	Min	Min
Transition benefits	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Annual recurring benefits	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
Total annual benefits	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil

*** For non-monetised benefits please see summary pages and main evidence base section**

**** Minimal costs**

Microsoft Office
Excel Worksheet

Evidence Base (for summary sheets)

Problem under consideration

1. Indicative Occupational Exposure Limit Values (IOELVs) are concentration limits for hazardous substances present in a workplace atmosphere, where ill-health effects are unlikely to occur.

2. From time to time the European Commission, with the agreement of Member States, introduces a new list of IOELVs in the form of a Directive. The 3rd IOELV Directive was adopted on 17th December 2009, listing 19 substance IOELVs. Limits are proposed substance-by-substance and each has been subject to a 6-month public consultation at EU level.

3. Member States have to implement the Directive by establishing national limits in law, taking into account the IOELVs. The final date for implementation is 18 December 2011.

Rationale for intervention

4. Member States are required by Treaty commitments to set legally binding national limits for all 19 substances, taking into account the level of the IOELV.

5. The hazards to human health of each substance in the Directive, and the level of exposure at which each could cause harm to health, have been examined by the European Commission's Scientific Committee on Occupational Exposure Limits (SCOEL), a body of experts drawn from throughout the European Union, including from the UK. IOELVs, proposed by SCOEL, are scientific limits set at a level at which, as a result of repeated exposure throughout their working lifetime, no harmful effects would be predicted to occur to workers or to their progeny. Implementation of the limits can therefore be deemed protective of the health of British workers.

Policy objective

6. The objective is to implement the 3rd IOELV Directive in line with Treaty obligations, in order to establish science-based limits for workplace exposure to the hazardous substances concerned, with a view to protecting the health of British workers whilst minimising impacts on business.

Description of options considered (including do nothing)

7. Policy Option 1 is to do nothing.

8. Policy Option 2 is to implement the Directive by establishing and revising limits in line with the new IOELVs, except where a limit lower than the IOELV is robustly justified (which is not the case in this Directive).

9. This is achieved by establishing a Workplace Exposure Limit (WEL) at the same value as each IOELV. The Control of Substances Hazardous to Health Regulations 2002 (as amended) – known as the COSHH Regulations or simply COSHH – refer to the list *Workplace Exposure Limits*, giving statutory effect to the limits listed there, which are set and published by HSE.

Background Information

10. Exposure to hazardous substances at work can have a wide range of damaging effects on human health. There are many ways that humans can be exposed to hazardous

substances at work, which are influenced by the physical form of the substances themselves, whether they readily evaporate or create dust, how they are used, and a number of other factors.

11. Great Britain – and the rest of the United Kingdom – has a well established regulatory environment for the control of workplace risks associated with use of hazardous substances in the system of Workplace Exposure Limits (WELs) and the COSHH Regulations. A WEL is a limit on the concentration of a hazardous substance present in the air that people breathe, averaged over a specified reference period referred to as a 'time-weighted average' (TWA). Two periods are used: long-term exposure limit (8 hours) and short-term exposure limit (STEL).

12. In parallel with the development of the COSHH/WEL system over the last decade, policy shifted from domestic limit setting to adoption of European limits. This reflecting increasing efforts at the European level to develop and apply similar levels of control across the EU, avoided duplication of that risk assessment work at the domestic level, and helps ensure that British business benefits from a level playing field with other EU member states.

13. Limits are usually established for specific substances, but generic controls have also been applied based on hazards relating to the physical form of a substance, rather than its chemical composition – for example dusts where, regardless of what the dust is actually composed of, at certain concentrations, particle sizes, and exposures, any dust can cause ill-health when inhaled.

14. There are only a limited number of ways that exposure to substance hazards can be controlled, namely: elimination of the substance from the workplace; changing the physical form of the substance (e.g., fine powder converted to granules), dilution of the substance to lower the effect of concentrated exposure; extraction of the hazardous substance from the workplace atmosphere, for example ventilation hoods; containment of the hazardous substance; and use of personal protection, such as appropriate protective gloves and/or respiratory equipment.

15. Small changes in a WEL are unlikely to lead to a new control measure being necessary, as the same method of exposure control is likely to be already providing the necessary protection.

16. Other factors such as customer pressure, developing technologies, and shifting market forces - as well as a general drive on the part of industry to move away from use of hazardous substances - result in changing use patterns for these substances. In several cases, such as the glycol ethers, use has largely been phased out either because of safer or cheaper alternatives becoming available or in response to international agreements like the Rotterdam and Stockholm Conventions.

Substances overview

17. The 3rd IOELV Directive establishes nineteen IOELVs.

18. No change to the WEL is proposed for two of the substances, because the new recommended limit values are identical to the current WEL. These substances are hydrogen sulphide and methyl methacrylate.

19. There are currently no WELs for five of the substances listed. In order to implement the Directive, HSE proposes to establish a WEL for each of these substances, in line with the IOELV. The substances are: bisphenol-A, mercury and divalent inorganic mercury compounds, methyl acrylate, sulphuric acid (mist), and vinyl acetate.

20. For one further substance, phenol, the Directive requires the establishment of a Short-Term Exposure Limit (STEL), where currently there is only an 8-hour time-weighted

average (TWA) WEL. HSE therefore proposes to establish a STEL for this substance in line with the IOELV.

21. A reduction of the current WEL – decreasing the limit of workplace exposure – is required for ten substances, to comply with the Directive. These are: carbon disulphide, N,N-dimethylformamide, 1,4-dioxane, 2-ethoxyethanol, 2-ethoxyethyl acetate, ethyl acrylate, 2-methoxyethanol, 2-methoxyethyl acetate, methyl isocyanate and n-methyl-2-pyrrolidone.

22. For one further substance, tertiary-butyl methyl ether, HSE propose to align the GB WEL with the new IOELV, which is slightly higher than the existing WEL. For 1,4-dioxane HSE also propose removal of the existing short-term WEL, because no short-term limit is required by the Directive. The advice of the SCOEL is that the new IOELVs are levels at which ill-health effects are unlikely to occur.

23. Other than where no change to the existing WEL is proposed, the substances listed in the 3rd IOELV Directive, along with usage and other relevant data, are set out below.

24. When compiling this assessment, details of manufacturers, importers, formulators, and other users, for all the substances in question were obtained from literature and internet sources, and from relevant trade associations. Details of the trade organisations contacted by HSE are presented after the summary section at the end of this assessment.

25. Additionally, for methyl isocyanate and sulphuric acid, exposure data were available from the Health and Safety Executive's National Exposure Database (NEDB) and were also obtained from companies manufacturing, formulating and using these substances.

26. For further information regarding the substance usage overview, please refer to Appendix 1 – Substance usage overview.

Calculation of Costs and Benefits

27. *Policy option 1* is to do nothing

28. Failure to establish exposure limits in national law which take the new IOELVs into account would be a breach of Treaty obligations, with the resulting likelihood of infraction proceedings being brought against the Government by the European Commission.

29. Failure to implement these limits could further result in a lower level of health protection comparative to the rest of the EU, and therefore negative outcomes for British workers, as employers would not benefit from the clarity and certainty of widely-recognised formal limits published as WELs.

30. *Policy Option 2* is to implement the Directive by establishing a WEL at the same value as each IOELV, except where a limit other than the IOELV is robustly justified.

31. This policy option satisfies the requirement that new legally binding limits be established in UK law for each substance for which an IOELV is listed in the 3rd IOELV Directive.

32. An assessment of the costs that each new WEL would impose on both business and the taxpayer is presented below. Each assessment of cost is based upon evidence supplied both by industry (through an early initial consultation), HSE's Occupational Hygienists and Economists. The information on costs presented reflect our best possible estimates given the information that is currently available, and will be subject to further revision following the receipt of information to be gained during consultation.

33. The proposed WEL for bisphenol-A (inhalable dust) is identical to the existing WEL for inhalable dust of any kind, with which industry is already required to comply. As a result, compliance with the new WEL should not result in further costs to industry.

34. As a known carcinogen, COSHH already requires that exposure to 1,4-dioxane be controlled to a level as low as reasonably practicable (ALARP). In addition, GB already has an equivalent WEL that is very similar to the proposed revised limit (only 5 parts per million higher). Existing control measures should therefore be sufficient for compliance with the new WEL. HSE therefore does not expect the proposal to introduce an additional burden on industry.

35. For mercury and divalent inorganic mercury compounds, an exposure limit which was in use until 2005 is very similar to the proposed new WEL. We would expect the vast majority of companies to have kept existing control measures in place despite this WEL being removed. Additionally, COSHH requires that the control of workplace exposure is proportionate to the health risk and so, given the known hazards of mercury, the controls currently in place should be at least equivalent to those that achieved compliance with the previous limit anyway. The introduction of the new WEL is therefore not expected to increase burdens on industry.

36. Four of the substances (2-ethoxyethanol; 2-ethoxyethyl acetate; 2-methoxyethanol; and 2-methoxyethyl acetate) are what are known as 'glycol ethers'. Glycol ethers are most commonly used in coatings products, and HSE has been advised by the British Coatings Federation that none are used in coatings products in the UK. Therefore, industry should not bear additional costs resulting from the introduction of the new WELs.

37. There is no known British manufacturer of carbon disulphide. The one identified British user of carbon disulphide (this substance is used predominantly in the manufacture of viscose fibre and cellulose film) believes that the change to the WEL will have no cost implications for them.

38. Ethyl acrylate is used largely in closed systems, which isolate the substance from workers - and as such exposure is already very well controlled. The new WEL should not impose significant additional burdens on British industry.

39. The new IOELV for phenol only introduces a short term exposure limit (STEL) in addition to the existing WEL (which is unchanged). Workplace exposure to phenol is already controlled to a very low level by users (rarely exceeding 1 ppm) and there are no British manufacturers. Consequently, the new STEL is not expected to impose any additional costs on British industry.

40. The main British manufacturer of vinyl acetate has indicated that they do not expect the new WEL to impose any additional cost on their operations, and the British Coatings Federation has indicated that their members should be able to comply with the proposed new limit without incurring any significant cost.

41. As a very corrosive chemical and a suspected carcinogen, exposure to sulphuric acid (mist) is already well controlled under the COSHH Regulations. Hence, HSE do not expect industry to bear additional costs associated with the proposed WEL, which is specifically limited in application to the 'thoracic fraction' as a result of industry submissions during SCOEL considerations. Further information may be gained from consultation.

42. For four of the substances, N,N-dimethylformamide, N-methyl-2-pyrrolidone, methyl acrylate and methyl isocyanate, it has not been possible for HSE to obtain specific information on the likely costs of the proposed WELs. Relevant industry organisations and contacts were asked to comment on the implications for each of these substances, and no concerns have been raised, from which we conclude that the proposed changes are not of significant concern, and that they will impose minimal or close to zero cost on British industry. For these four substances and sulphuric acid (mist), further information is sought during consultation in order to confirm the potential impact as well as gather

information on existing control measures. Information is also being sought to confirm that the costs identified for all other substances in this impact assessment are as accurate as possible.

43. Overall costs of option 2 are expected to be close to zero. Whilst there are expected to be health and safety benefits, it is not possible to quantify these.

44. This policy option does not preclude maintaining more restrictive standards than the new IOELVs where these are sufficiently more protective of health to justify any increased burden on business. However, where existing limits need to be relaxed to align them with the IOELVs in the present Directive, the advice of the SCOEL is that the new IOELVs are comparable to the existing limits under which ill-health effects are unlikely to occur, and so costs associated with negative health impacts from any revision of the WELs is not expected to occur.

45. Familiarisation costs are expected to be negligible. An amendment of the HSE publication *Workplace Exposure Limits* is normally launched with a press release, notifications to trade press, and an announcement on the HSE website. Companies affected by the proposed changes are not expected to spend much time familiarising themselves with the WEL system which is already well-established, and especially given the minimal expected costs of the Directive. There may be a small cost as managers check that they are compliant with the proposed WELs, although we are not able to quantify this. We expect that overall familiarisation costs are minimal and close to zero.

46. While there may be health benefits as a result of reduced exposure where WELs are new or are revised downwards, these are unlikely to be readily quantifiable. Definitive information regarding ill health resulting from present exposure levels is generally not available, and consequently it is difficult to quantify or monetise the benefits of controlling exposure to a comparatively lower level. Where employers are not expected to have to take additional action in order to comply with a new limit - for instance where existing measures already achieve compliance - a practical effect on ill-health levels would not be expected.

47. Whilst a specific estimate of the costs to industry is not possible, the substance by substance assessment indicates that the burden is expected to be minimal.

Specific Impact Tests

Statutory Equalities Duties Impact Test

48. A separate equalities impact assessment is to be conducted prior to implementation of the Directive. However, early consideration has not identified any potential areas for concern.

Competition Assessment Impact Test

49. The proposed WEL changes shall not impact on competition within the economy. They apply equally to all firms in the EU and impose minimal costs to those in the UK.

Small Firms Impact Test

50. As costs resulting from the proposed changes are minimal, there will not be an impact on small firms.

Greenhouse Gas Assessment Impact Test

51. There are no implications for greenhouse gas emissions from the proposal

Wider Environmental Issues Impact Test

52. There will be no wider environmental impacts resulting from the proposed changes

Health and Well-being Impact Test

53. The proposed WEL changes will not have any implications on health and well-being, apart from the possible effects mentioned in the main body of the evidence base resulting from decreased exposure to hazardous chemicals.

Human Rights Impact Test

54. The proposal will not have any implications for human rights.

Justice Impact Test

55. There will be no justice implications because of the proposal.

Rural Proofing Impact Test

56. There are no specific impacts on rural communities as a result of the proposal.

Sustainable Development Impact Test

57. There is no impact on sustainable development from the proposal.

Summary and preferred option with description of implementation plan

58. Policy option 1 would result in a breach of Treaty obligations, with the potential for infraction, and could result in a lower level of health protection for British workers.

59. Policy option 2 is the preferred option. Amending the list Workplace Exposure Limits to include 5 new and 12 revised WELs and publishing this to take effect on 18 December 2011 provides both legally robust implementation of the Directive and protection of the health of British workers, while avoiding unnecessary burdens on British business.

APPENDIX - Substance Overview

Bisphenol-A (inhalable dust)

60. Bisphenol-A is used predominantly as a chemical intermediate in the manufacture of resins, flame-retardants and rubber chemicals. Four companies within the EU manufacture bisphenol-A, none in the UK.

61. The total amount of bisphenol-A manufactured within the EU, based upon submissions to CEFIC by the manufacturers, is estimated to be around 700,000 tonnes per year. According to EU statistics in 1997 the total imports of bisphenol-A into the EU were 8,010 tonnes/year.

62. A WEL already exists for dust of any kind which is regarded as a substance hazardous to health, which is set at the same level as the proposed new WEL for bisphenol-A.

63. Separately from the new IOELV, which relates to workplace exposures to the inhalable dust, bisphenol-A has recently been linked in the media to ill-health effects in humans arising from the presence of the substance in some food-contact plastics, and a new control on use of the substance in infant feeding bottles has been enacted at the European level. The IOELV and the proposed WEL relate are however not specifically related to these concerns.

Carbon disulphide

64. Carbon disulphide is a dense, highly volatile and refractive clear liquid, which yellows on exposure to air and light and usually has an offensive odour due to minor impurities such as mercaptans.

65. It is highly flammable, and its vapours can auto-ignite at temperatures above 102 oC. It is slightly soluble in water, miscible in many organic solvents and is a good solvent for a wide range of organic substances, sulphur and phosphorus. Carbon disulphide can be found in natural sources such as salt marshes and volcanic plume and ash. Traces also occur in crude oil and coal tars.

66. It is principally used in making viscose rayon fibre, cellulose film and other viscose products. It is also used in the production of carbon tetrachloride and for the manufacture of other chemicals, pesticides, dyes, drugs, and in rubber curing. Its use as a laboratory agent is becoming more restricted due to its high reactivity, flammability and toxicity.

67. There is no known UK manufacturer of carbon disulphide. The one identified British manufacturer of viscose fibre/cellulose film believes that the change to the WEL will have no cost implications for them.

N,N-Dimethylformamide

68. Dimethylformamide is a colourless, high-boiling, strongly polar, hygroscopic liquid with a faint amine odour. It is a flammable liquid with an acrid odour and infinitely miscible with water and with many lipophilic solvents.

69. Dimethylformamide is predominately used as a solvent in the synthesis of fine chemicals, in polyacrylonitrile fibre production, polyurethane coating and in the electronics industry. The remaining use is split into various applications such as varnishing, surface coating, polyamide coating, absorbents, cleaners, and extractants. In addition, dimethylformamide is used as a solvent in crop protection agents.

70. In the year 2000 the total production volume in the EU was in the range of 50,000 to 100, 000 tonnes/year.

71. No comments were received from British industry about the proposed change to the WEL.

1,4-Dioxane

72. 1,4-Dioxane is a highly flammable liquid with a melting point of 12 °C and a boiling point of 101 °C. Its odour is ether-like. The substance is miscible in water and in the most organic solvents.

73. In Great Britain it is used primarily as a solvent in the manufacture of chemicals and as a laboratory reagent.

74. 1,4-Dioxane is not manufactured in the UK. In Europe, it is currently only produced at one production site at a volume estimated in 1997 to be 2,000-2,500 tonnes, with an export outside the European Union of 575 tonnes. In 1995 the production capacity of known producers, and the worldwide production volume, was estimated at 8,000 tonnes/year and 10,000 tonnes/year, respectively.

75. In general the world-wide production of 1,4-dioxane is decreasing because of changing use patterns.

76. As a carcinogen, COSHH already requires that exposure to 1,4-dioxane be controlled to as low as is reasonably practicable and that additional control measures be put in place where process and handling is not totally enclosed.

Glycol ethers: 2-Ethoxyethanol, 2-Ethoxyethyl acetate, 2-Methoxyethanol, 2-Methoxyethyl acetate

77. 2-Ethoxyethanol was used as a chemical intermediate for ethoxyethyl acetate and as a solvent, particularly for epoxy coatings, nitrocellulose, natural and synthetic resins, lacquers, dopes, printing inks, and adhesives.

78. World-wide reported uses for the glycol ethers in general are in paints and enamels; printer's ink; plastic packaging for foodstuffs; pigments for silk-screen printing; photographic and photolithographic processes; CDs, circuit boards and integrated circuits; cleaners for household and industrial use; and antifreeze in hydraulic fluids and aircraft fuel.

79. Exposure has been reported from semiconductor and circuit board manufacture, printing, painting (especially automobile and ship painting), furniture finishing, paint production and automobile repair.

80. In 1994 2-methoxyethanol and 2-methoxyethyl acetate were classified by the EU as toxic for reproduction and their use in consumer products was prohibited. The usage has declined significantly.

81. All four glycol ethers (ethoxyethanol, ethoxyethyl acetate, methoxyethanol, and methoxyethyl acetate) have been largely superseded and, as far as HSE is aware, are not present in any current coating products.

Ethyl acrylate

82. Ethyl acrylate is a colourless, flammable liquid with an acrid, penetrating odour and a low odour threshold.

83. The production volume of ethyl acrylate is estimated to be 50-100,000 tonnes per year in Europe. Ethyl acrylate is used in various industries as an intermediate in the production of emulsion-based polymers, which are then used in paint formulations, industrial coatings and latex products.

84. Due to the disagreeable odour it is manufactured and used mainly in closed systems and exposure is already well controlled.

Mercury and divalent inorganic mercury compounds, including mercuric oxide and mercuric chloride (measured as mercury)

85. Elemental mercury is a heavy, silvery white liquid with melting point of -39 oC and boiling point 356 oC. It readily forms amalgams with most metals.

86. Mercury occurs naturally as sulphide. It is produced from the roasting of cinnabar ore, which contains about 0.5% mercury. The only EU producer is the Almadén mercury mine in Spain. Other sources of mercury include Russia and China. The largest-scale use of mercury is in the chlor-alkali industry; elemental mercury forms a flowing cathode in cells used for the electrolysis of brine.

87. An exposure limit in use until 2005 was very similar to the proposed new WEL.

88. Metallic mercury is used for a small number of purposes, including electrical equipment such as batteries and semi-conductors, dentistry amalgams, barometers and paper manufacturing. However, a recent European directive has prohibited the sale to the general public of clinical thermometers and new mercury measuring devices (such as barometers), implemented via the EU REACH Regulation.

89. In the EU, only the chlor-alkali industry remains a significant industrial user of mercury, and it is progressively phasing out the use of mercury-containing cells for production of chlorine. There is only one British site still using mercury technology to produce chlorine but the company anticipates no cost implications in complying with the new WEL.

90. A typical 1.2 metre fluorescent tube will contain between 15 and 20 mg of mercury. Recycling of mercury-containing fluorescent lamps is increasing, with between 20 to 40% of the mercury present in the bulbs being released into the air during the two-week period following their initial breakage. COSHH requires that suitable measures are in place to control workplace exposure to mercury, and the proposed new WEL is very similar to the previous limit.

91. Additionally, mercury and a number of related compounds have been made subject to controls under the United Nations Environment Programme, including a ban on export which has already been enacted in the EU, which came into effect on 15 March 2011. Mercury is also the subject of further proposed United Nations controls on trade and use.

Methyl acrylate

92. Methyl acrylate is a colourless volatile, flammable liquid with an acrid odour.

93. Methyl acrylate is used primarily as a co-monomer with acrylonitrile in the preparation of acrylic and methacrylic fibres, which are used in clothing and furnishings. It is also used in the production of coatings, adhesives, elastomers, super absorbent polymers, flocculants, as well as fibres and plastics when other co-monomers are used. The production rate in the EU is in excess of 10,000 tonnes per year.

94. No comments on the proposed new WEL were received from British industry in preliminary consultations.

Methyl isocyanate

95. Methyl isocyanate (MIC) is a clear liquid at room temperature. It is sparingly soluble in water, although on contact with water it reacts violently, producing a large amount of heat. It has a sharp odour.

96. MIC occurs primarily as an intermediate in the production of carbamate pesticides, and was the chemical involved in the Bhopal major accident. It has also been used in the production of polymers and is found in tobacco smoke.

97. MIC has also been identified in emissions from heating of core sand and mineral wool, where it results from breakdown or chemical transformation of the carbamide resin binder. Exposure measurements made in foundries indicate that MIC occurs primarily where 'hot box' cores are used in the industrial process known as chill casting. It also occurs in the isocyanate mixture created by the thermal breakdown of certain polyurethane lacquers during welding, cutting and grinding operations in automobile repair shops.

98. Isocyanates are already subject to a generic WEL, and are subject to monitoring and control measures.

99. No comments on the proposed new WEL were received from British industry in preliminary consultation.

N-Methyl-2-pyrrolidone

100. N-Methyl-2-pyrrolidone (NMP) is a water-miscible colourless liquid with a characteristic amine odour.

101. The primary use of NMP is as a solvent in a wide range of applications including the paints and petrochemical industries, for stripping and cleaning applications in the microelectronics industry, for the removal of graffiti, as a paint stripper and as a substitute for chlorinated solvents.

102. It is also used as an intermediate in the pharmaceutical, polymer and other chemical industries and as a formulating agent for plant protection and biocidal actives, and as a solvent for pigments, dyes and inks. Further uses include as a penetration enhancer for topically applied pharmaceuticals and as a vehicle in the cosmetics industry. It is increasingly used as a replacement for chlorinated solvents because of concern about the toxicological profile of some of the latter, e.g. it has been used to replace dichloromethane as a solvent in paint strippers.

103. Although NMP does not have a high vapour pressure, the pattern and wide range of uses results in some potential for occupational exposure by inhalation. Dermal exposure to NMP in the occupational setting is also likely, given the pattern and wide range of uses. NMP is readily absorbed through the skin, and dermal exposure is thus considered to contribute significantly to the internal NMP dose.

104. No comments on the proposed new WEL were received from British industry in preliminary consultations.

Phenol

105. Phenol is a white crystalline mass which occurs naturally in coal tar and is produced synthetically from benzene, with production levels in the EU in excess of 1,000,000 tonnes per annum.

106. Phenol is not manufactured in Great Britain but it is imported and used primarily in the production of phenolic resins, with lesser amounts used for manufacture of caprolactam, alkyl phenol and as a disinfectant and antiseptic.

107. Up to 25,000 people may be exposed to phenol from the use of resins as sand binders in foundries. Occupational exposure levels are generally reported to be less than 1 ppm (4 mg.m-3), although levels up to 4.4 ppm (17 mg.m-3) have been reported in a plant manufacturing synthetic fibres.

108. Monitoring and control measures should already be in place for phenol as appropriate, reflecting the existing 8-hour time-weighted average (TWA) WEL.

Sulphuric acid (mist)

109. Sulphuric acid is a dense, oily, colourless and odourless liquid with low vapour pressure. Impurities tend to produce a brown discolouration. It is hygroscopic and soluble in water although the addition of water can produce a violent, exothermic reaction. Concentrated sulphuric acid is corrosive to metals but non-flammable.

110. There is currently only one manufacturer of sulphuric acid in Great Britain. Potential exposure in the manufacturing plant is likely to be low, owing to the enclosed production process. Respiratory protective equipment is used during maintenance, and sampling operations take place inside ventilated booths.

111. About 75% of the downstream uses of sulphuric acid, in a wide range of major chemical manufacturing companies, are in enclosed processes and exposures are likely to be relatively low. However, the other 25% of uses have the potential for higher exposures.

112. The largest single use of sulphuric acid is as a reagent with phosphate rock in the production of phosphate fertilisers, with lesser uses in the production of ammonium and potassium sulphate. Sulphuric acid is used as an acidic dehydrating agent in organic chemical and petrochemical processes, as well as in oil refining. In the inorganic chemical industry, it is used most notably in the production of titanium dioxide and to make hydrochloric and hydrofluoric acids, aluminium and copper sulphate and chromium compounds. Sulphuric acid is widely used to chemically remove oxides and scale from the surface of steel and iron (acid-pickling) before further processing, for the extraction of metals such as copper, uranium and vanadium from ores, and in non-ferrous metal purification and plating. Other uses include the manufacture of plasticisers, dyestuffs, explosives, silicate for toothpaste, adhesives, rubbers, edible oils, lubricants, the production of food acids such as citric or lactic acid and to directly control pH during the processing of some foods and beverages.

113. Concern about the toxicity of sulphuric acid in the workplace atmosphere is focussed on its potential, as an inhaled aerosol, to exert local effects on the respiratory tract, as a consequence of low pH. Such effects can be manifested as sensory irritation of nerve endings, acute or longer term inflammation at various sites along the length of the respiratory tract epithelium, and ultimately the possibility of tumour formation in the respiratory tract, believed to be a consequence of sustained tissue inflammation and repair processes. Human carcinogenicity data and other research suggest that the larynx is a site of particular concern, in relation to epithelial inflammation, damage and ultimately cancer.

114. Because the proposed new WEL will be based on the thoracic fraction only, in line with industry proposals during SCOEL consideration of sulphuric acid (mist), and taking into account existing COSHH requirements to control exposure, HSE expect that any increased costs for compliance will be minimal. However to measure the thoracic fraction for enforcement purposes will require a validated method, which is currently not available. There are candidate methods, but further assessment and possibly development of new methods will be needed before a method suitable for enforcement purposes is available.

Tertiary-butyl-methyl ether

115. Pure tertiary-butyl-methyl ether is a colourless volatile liquid with a terpene-like odour. It is soluble in most organic solvents and it is also quite soluble in water. Tertiary-butyl-methyl ether is flammable and combustible. The unpleasant odour and the low odour thresholds have a premonitory effect, whereby inividuals are readily able to detect exposures.

116. The annual production volume of tertiary-butyl-methyl ether in 1997 in the EU was 3,030,000 tonnes. About 187,000 tonnes was imported and about 904,000 tonnes was

exported outside the EU in 1997. The annual consumption of tertiary-butyl-methyl ether within the EU was hence 2,313,000 tonnes in 1997.

117. Tertiary-butyl-methyl ether is typically manufactured in petroleum refineries but also in plants manufacturing industrial organic chemicals. The main use is as an oxygenated additive/component in petrol, which accounts for more than 98% of the total quantity produced in the EU. Only a minor amount is used for other purposes, such as use as a solvent instead of diethyl ether in the chemical and pharmaceutical industries, and in laboratories.

118. Enquiries with the petroleum industry have revealed that protective measures for gasoline blends are primarily aimed at benzene exposure rather than at any tertiary-butyl-methyl ether that may be present, and consequently a relaxation of the WEL is not likely to have any direct impact in Great Britain.

Vinyl acetate

119. Vinyl acetate is a colourless, volatile and flammable liquid with an odour described as either sweet and 'ether-like', or sharp and sour. It usually contains an inhibitor, hydroquinone, for storage of the chemical. Vinyl acetate polymerises when exposed to light.

120. Vinyl acetate is not known to occur naturally. It is a key intermediate in the production of a number of polymers and resins for adhesives, coatings, paints, films, textiles, and other end products. The largest derivative is polyvinyl acetate (PVA), mainly used for adhesives, but also paper coatings and paints and industrial coatings. PVA is also used to make polyvinyl alcohol, used for textiles, adhesives, packaging, films, thickeners and photosensitive coatings, and also for the production of polyvinyl butyral - a resin with strong adhesion, used in laminated glass and commercial buildings.

121. Europe is a net importer of around 150,000 tonnes annually, mostly sourced from the USA.

122. The main British manufacturer believes that the new proposed WEL will not cause any extra costs for their operations, and the British Coatings Federation believes that its members could comply with the proposed new limit without significant cost.

Trade Associations, organisations and consultants contacted

Aluminium Federation Ltd

BP

British Adhesives and Sealants Association

British Association of Chemical Specialities

British Coatings Federation (BCF)

British Occupational Hygiene Society (Global Occupational Hygienist List)

British Plastics Federation

Cast Metal Federation

Chemical Industries Association

CJH Consult Associates

Confederation of British Metalforming

Construction Products Association (CPA)

Cristal Global

Crop Protection Association

European Sulphuric Acid Association

Eurisol (UK Mineral Wool Insulation Association).

Food and Drink Federation.

Ineos Enterprises Ltd

Institution of Cast Metals Engineers

Institute of Materials, Metals and Mining

Institute of Metal Finishing.

National Association of Agricultural Contractors

National Sulphuric Acid Association

Paint Research Association

Shell (UK) Ltd

Surface Engineering Association

UK Petroleum Industry Association

Additional contributions were obtained from HSE/HSL inspectors and occupational hygienists.

In addition, a wide range of British companies were contacted by HSE for information, with seven companies and two trade associations being visited by HSE's occupational hygienists.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)];
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here] WELs will be amended as a matter of course if IOELV Directive requirements change. Where Directive requirements have not changed, Treaty obligations (and the associated risk of infraction) would prevent the UK Government from altering our implementation of the relevant Directives, regardless of the findings of a PIR. With this taken into account, a PIR does not represent an efficient use of administrative resource where implementation requirements have not changed. Review of WELs will be undertaken as a matter of course during the next round of IOELV discussions, which are in their very early stages.

PART II

NORTHERN IRELAND COSTS AND BENEFITS

IMPLEMENTATION IN NORTHERN IRELAND OF THE 3RD INDICATIVE OCCUPATIONAL EXPOSURE LIMIT VALUES (IOELV) DIRECTIVE (2009/161/EU)

Costs

1. The impact assessment prepared in respect of the implementation measures in Great Britain showed that there are no costs which can be monetised. Familiarisation and compliance costs are not expected to be significant. Costs associated with checking compliance with the proposed Workplace Exposure Limits, and resulting from implementation of control measures where compliance is not already achieved, are possible. Such costs are however not expected to be significant.

Benefits

2. Implementation of the Directive is necessary to comply with EU treaty obligations and will avoid the risk of infraction proceedings for under-implementation.

3. There may be an improvement in protection of human health in the workplace as the new Workplace Exposure Limits result in improved exposure controls to levels where no adverse health effects will occur. These are not expected to be significant.

Summary

4. Overall it is considered that there will be no significant impact on NI business.