

# **PROPOSAL FOR A PHYSICAL AGENTS (OPTICAL RADIATION) DIRECTIVE**

## **INITIAL REGULATORY IMPACT ASSESSMENT.**

### ***PURPOSE AND INTENDED EFFECT***

#### **Issue**

1. The Irish Presidency of the European Union developed a proposal for a Physical Agents (Optical Radiation) Directive that was subsequently presented to a European Council meeting by the Netherlands Presidency in July 2004. It is the fourth and last in a sequence of physical agents directives that amend the European Commission's original 1993 proposal for a Physical Agents Directive covering noise, vibration, electromagnetic fields and optical radiation.

#### **Objectives**

2. The proposal lays down minimum health and safety requirements regarding the exposure of workers to the risks arising from optical radiation. Optical radiation, which includes ultraviolet radiation (UV), infrared radiation, visible light and lasers, is a form of radiation that can interact with people in a way that varies according to the radiation wavelength. The objective of the proposal is to protect workers from the risks associated with this potential hazard and to achieve harmonisation of control regimes between Member States. It aims to achieve this by using the guidelines for restrictions on exposure that have been produced by the International Commission for Non-ionising Radiation Protection (ICNIRP). These scientifically based guidelines are designed to prevent the effects on health that can occur at high levels of exposure.

3. The proposal places a range of duties on employers. These include the requirements to assess and control exposure, reduce risk, and provide information and training to workers. There are also provisions on health surveillance.

#### **Risk assessment**

4. The risk from optical radiation depends on the type of radiation and the intensity and the part of the body that is exposed. The symptoms of excessive exposure are well defined and the areas of the body most at risk are the skin and the eyes. The effects on the eye include damage to the cornea and lens whilst the effects on the skin include redness, burning and blistering and an increased risk of skin cancer. As artificial sources of optical radiation are well controlled, adverse effects are rare. However, the main source of UV exposure is the sun. Whilst exposure to the sun is usually a matter of personal choice, it can be an issue for some people who work outside.

5. The ICNIRP guidelines upon which the Directive is based set out a series of exposure values – called exposure limit values (ELVs) in the Directive - that are designed to prevent adverse health effects.

6. Currently there is no UK legislation specific to optical radiation. The general duties to assess and control risks contained in the Health and Safety at Work Act 1974

and the Management of Health and Safety at Work Regulations 1999 apply. The proposal adds little to these existing requirements, but it does define more precisely what is expected. For example, it requires, for artificial sources, assessment of exposure as a means of assessing risk and compliance with ICNIRP guidelines and, for all sources, specific items of information and training. There are three broad types of optical radiation that need to be considered separately: solar exposure, lasers and broadband sources.

7. The National Radiological Protection Board (NRPB) has estimated that there are about 1 million outdoor workers who may be exposed to the sun. In the main little is done to protect them from UV exposure although both assessment of risk and control measures are very simple. HSE has published guidance in leaflets which, if followed, would ensure compliance with the Directive, but the guidance is not at present enforceable.

8. The NRPB has estimated that about 2.1 million people work in places where lasers are used, though probably few are likely to come into contact with lasers where there is a risk of exposure above the ELVs. There is a hazard-based classification system for lasers and a British Standard which covers their use. The classification defines those lasers which, if misused, could result in overexposures. In most industrial applications high-powered lasers are properly controlled, while in some other applications they are not. However, misuse of a laser would be an offence under existing legislation and the Directive proposal does not add to this.

9. The NRPB has also estimated that about 2.4 million people work in places where broadband sources are used, though only 400,000–1,300,000 of these are at any risk from possible inadequate control. Those who are actually likely to be exposed above the ELVs are considerably fewer. There are some industrial sectors and processes in which the emissions would immediately cause the ELVs to be exceeded, including those that generate or use an intense source of light such as in welding and glass manufacture, but these applications are almost universally controlled. Other applications, such as the use of high-powered lighting in entertainment, are rather less well controlled, though the risk of actual ill-health is very low.

### **Options considered**

10. It is the UK view that compliance with the ICNIRP guidelines affords sufficient protection and control to prevent ill health. We do not expect significant health and safety benefits from the proposal and it is important therefore that any costs to industry should be proportionate. We believe this can be achieved if the final negotiated Directive does little more than adopt the international guidelines for the control of exposure. We welcome the fact that, unlike the three previous Directives, there are no exposure action values, for which there is no scientific justification. In relation to outdoor workers, the ELVs do not apply but there is a requirement to assess the risk and take any appropriate measures.

11. The Government view is that negotiations should seek to prevent any strengthening of the proposal particularly in relation to outdoor workers and the provisions on health surveillance.

12. The “do nothing” option is not feasible because of the UK’s legal obligation to implement the Directive.

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

13. Most of the information used in this RIA was sourced from two NRPB reports commissioned by HSE<sup>1</sup>. Many assumptions have been based on judgements applied by HSE's technical experts. Costs have been discounted at an annual rate of 3.5% (in line with Treasury guidance) and earnings have been uprated by 1.8% to account for real annual increases. Prices are expressed in 2003 values.

14. In determining the correct level of resources to devote to promoting and enforcing the proposals, HSE must take a proportionate approach. In the great majority of cases, the risk to human health from optical radiation is low and so HSE has not attached a high priority to optical radiation and is unlikely to do so in the future. The number of employers who are likely fully to comply with current duties as expressed in the new proposals is assumed to rise by 10%<sup>2</sup>. The effect of varying this assumption is examined in the "uncertainties" section.

## ***BENEFITS***

### **Health and safety benefits**

15. At or below the limit values in the draft Directive, there will be no adverse health effects for workers. If workers were to be exposed at levels substantially in excess of these values, adverse health effects could well be observed either to the eye or the skin. For example, in the case of the eye, ultraviolet radiation can damage the cornea, infrared radiation can produce cataracts and laser radiation can cause severe damage that may result in blindness. In the case of the skin, UV radiation can produce a range of symptoms from reddening to burning and blistering and an increased risk of skin cancer. Powerful lasers can cause skin burns.

16. HSE has received few reports of ill-health or injury from exposure to optical radiation. Most reports of harm relate to the misuse of lasers, and these are occasionally serious. There will be benefits if such injuries are eliminated, but this is a function of compliance with existing law. Undue exposure of the general population to the sun has led to large numbers of skin cancers (many fatal) and to other skin damage, but it is not possible to identify the contribution to this of occupational exposure, since all outdoor workers will have substantial exposure during leisure activities. However, action to inform workers of the risks of solar exposure may have the effect of increasing awareness by both workers and their families of the risks of exposure at all times and this could lead to substantial but unquantifiable health and safety benefits.

17. In Article 4.4(c) the draft Directive calls for "particular attention, when carrying out the risk assessment, to... any effects concerning the health and safety of workers at particular risk". Although HSE has some broad information from NRPB

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<sup>1</sup> "Review of Occupational Exposure to Optical Radiation and Electric and Magnetic Fields with Regard to the Proposed CEC Physical Agents Directive" NRPB R265  
"Occupational exposure to optical radiation in the context of a possible EU Proposal for a Directive on optical radiation" NRPB-W35.

<sup>2</sup> Current levels of full compliance with the duties set out in the proposals is not known but is thought to be low.

reports on the number of workers that may be subject to any such risk, we lack accurate information on levels of exposure and dose response relationships. Consequently no attempt has been made to estimate the health benefit.

### **Other benefits**

18. There would be unquantifiable benefits to trade in providing a harmonised level of protection of workers to exposure to optical radiation across Europe. A harmonised level of protection would ensure that there was a 'level playing field' across the European Union.

## ***COSTS***

### **Business sectors affected**

19. The proposals would affect many sectors. Principal among these are; agriculture, forestry, horticulture, construction, leisure, outdoors maintenance, entertainments, research, medical, engineering, manufacturing and communication. NRPB has estimated that approximately a maximum of 5.7 million employees work in areas where there might be exposure to optical radiation, although few of these would be at risk of exceeding the ELVs (see paras 7-9 above<sup>3</sup>).

### **Total compliance costs to business**

#### *Familiarisation with the proposals*

20. The average length of time that employers spend familiarising themselves with the proposed regulatory changes is assumed to be thirty minutes. Unfortunately, HSE does not have any direct information on how many employers will be affected by the proposals. However given the estimate of 5.7 million affected employees, we can derive an estimate of how many firms will be affected by making assumptions about the average number of affected employees per firm. HSE assumes the latter figure lies between 7 and 20<sup>4</sup>. The labour cost per hour is assumed to be £23<sup>5</sup>. Under these assumptions, the one-off costs of familiarisation lie in the range of £0.32 million to £0.96 million.

#### *Determination and assessment of risk*

21. Employers of outdoor workers will not be expected to measure exposure to the sun. However they will required to assess the risks subjectively (and will be encouraged to use HSE guidance) and then record the result. NRPB report W35 suggests that approximately 1 million workers are exposed to high levels of optical

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<sup>3</sup> Note that the figures in para 7 to 9 do not exactly sum to 5.7 million due to rounding.

<sup>4</sup> The lower bound is the average firm size of all enterprises in Great Britain, while the upper bound is the average firm size of all enterprises that have employees (ie, the figure excludes enterprises with no employees). Figures were taken from Small Business Service statistics 2003.

<sup>5</sup> This is taken from NES 2003 and relates to a production manager (SOC 112) and includes a 30% for non-wage labour costs.

radiation from the sun<sup>6</sup>. HSE assumes that on average between 5 and 20 workers are included in one risk assessment, that the assessments take 20 minutes, and that the labour cost per hour is the same as for familiarisation. Under these assumptions<sup>7</sup> the first year costs are between £0.04 million and £0.15 million. These costs are assumed to recur on average every five years, which yields a ten-year present value of between £0.07 million and £0.29 million.

22. NRPB report W35 suggests that 3,484,000 workers are exposed to some risk from broadband and optical radiation. Of these, HSE judges that between 174,000 and 348,000 are exposed to high risk, and between 3,136,000 and 3,310,000 are exposed to low risk. Risk assessments do not have to be conducted on each worker and HSE assumes that on average a risk assessment covers between 10 and 15 workers. For high-risk environments, HSE assumes that a production manager (£23 an hour) must spend an extra 3 to 5 hours conducting proper assessments. For low-risk environments, the corresponding extra time spent on risk assessments is 0.5 to 1 hour. The estimated costs of laser and broadband risk assessments are between £0.64 million and £0.85 million. Assessments are assumed to recur on average every three years<sup>8</sup>. This yields ten-year present values of between £2.40 million and £3.14 million.

#### *Information and training for workers*

23. Outdoor workers are assumed to require an extra 20 minutes per year of instruction on avoiding risk from exposure to the sun. The labour cost is taken as the 2003 average UK rate of £15<sup>9</sup> an hour. The annual estimated cost is £0.76 million, which has a ten-year present value of £7.07 million.

24. The costs of providing information to workers who are exposed to low risks from laser and broadband optical radiation are assumed to be absorbed at insignificant cost within existing training procedures.

25. Workers at high risk from laser and broadband optical radiation are assumed to require an extra 90 minutes of instruction every year. This amounts to an annual cost of between £0.39 million and £0.78 million, which has a ten-year present value of between £3.62 million and £7.23 million.

#### *Health surveillance*

26. This Directive refers to duties in the Framework Directive that have already been transposed in the UK by the Management of Health and Safety at Work Regulations 1999. In addition, there is a requirement for the provision of appropriate health surveillance linked to the outcome of the risk assessment that can be

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<sup>6</sup> This estimate is based on 2001 Labour Force Survey figures. HSE assumes that the position has not changed significantly since then.

<sup>7</sup> And the assumption that the implementation of the Directive encourages an extra 10% of relevant employers to perform their duties under health and safety regulations.

<sup>8</sup> Risk assessments only need to be repeated when major changes are made to processes. The high-tech nature of lasers and some broadband optical radiation sources probably means that changes are relatively frequent.

<sup>9</sup> Information taken from the 2003 New Earnings Survey, with an allowance of 30% for non-wage labour costs.

accommodated under the existing national health structure. The Directive therefore places no new duties on industry.

#### *Action to reduce exposure*

27. The Directive requires that, for artificial sources, appropriate action should be taken and recorded if a risk assessment reveals the possibility of an ELV being exceeded, and that, for natural sources, risk should be reduced to a minimum.

28. For outdoor workers, the costs of taking action are assumed to be insignificant because protection is afforded by modest changes of behaviour, such as wearing a hat and a shirt. However, the action would still need to be recorded and this is assumed to take five minutes of a production manager's time. Only 1% to 10% of risk assessments are assumed to indicate the need for action. Under these assumptions, the estimated annual costs lie between £0.02 million and £0.19 million, which has a ten-year present value of between £0.07 million and £0.71 million.

29. HSE has assumed that insignificant costs will arise from action that has to be taken as a result of risk assessments for workers at low risk from laser and broadband optical radiation.

30. For laser and broadband optical radiation workers who are at a high risk of exceeding the ELVs (as determined by the risk assessment), the costs of developing an action plan are substantial because of the likely need to employ a consultant. HSE has assumed that between 5% and 20% of risk assessments (on high risk workers) would indicate the potential for ELVs to be exceeded, and that each action plan takes a consultant between 0.5 and 3 hours, and a production manager 1.5 hours to complete. The cost of a consultant is between £120 and £150 an hour<sup>10</sup>, while the production manager's time costs £23 (as described above). Action plans would have to be revised every three years. These assumptions yield a first year estimated cost of £0.01 million to £0.05 million, and a ten-year present value of between £0.02 million and £0.20 million.

31. The costs of implementing the action plans are difficult to assess. In some cases, the necessary action may simply be modifications to behaviour and better use of existing shields. In other cases investment in better protective equipment may be required. HSE has assumed that half of the action plans indicate the need for investment. Furthermore, we assume that the cost of additional equipment in each case lies between £300 and £1000<sup>11</sup>, and that the equipment must be replaced every three years. These assumptions yield a first year cost of between £0.01 million and £0.35 million, and a ten-year present value of between £0.03 million and £1.20 million.

#### **Costs to HSE**

32. Although enforcing the implementing Regulations will involve some cost, HSE anticipates that it would have to be absorbed within existing budgets. While this

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<sup>10</sup> Information provided by an HSE inspector.

<sup>11</sup> Although protection against broadband optical radiation would probably be cheaper, there are instances where this level of expenditure would not be sufficient to protect against lasers, and the costs would be significantly larger. £300 to £1000 is therefore taken as range that includes the true average.

would mean a re-allocation of resources, the subsequent opportunity costs are not readily quantifiable.

### **Environmental impacts**

33. No environmental costs have been identified

### **Total costs to society**

	First year costs £million	Ten year present value £million
<i>Implementation costs:</i>		
Familiarisation	0.32 to 0.96	0.32 to 0.96
Worker information	1.15 to 1.54	10.68 to 14.30
<i>Policy costs:</i>		
Risk assessment	0.68 to 1.00	2.47 to 3.44
Health surveillance	0.00 to 0.00	0.00 to 0.00
Action to reduce exposure	0.03 to 1.08	0.10 to 2.11
<b>Total</b>	<b>2.19 to 4.58</b>	<b>13.58 to 20.80</b>

*Note: Sub-totals may not sum to the totals because of rounding*

34. The estimated annualised cost<sup>12</sup> is between £1.47 million and £2.25 million.

### **Compliance cost for a typical business**

35. The cost of the proposals averaged across the assumed number of firms that operate in potentially high-risk environments is estimated to be between £70 and £99 in the first year, with a ten year present value of £317 to £614. However, the typical business in this category will not have to implement costly action plans, and hence the costs to such a firm will be somewhat lower.

### ***IMPACT ON SMALL FIRMS***

36. The impact of the Directive on firms is likely to be in proportion to the number of employees significantly exposed to optical radiation and the number of pieces of equipment that emit optical radiation. Assuming that employees in small firms are no more likely to be exposed to high risks than their counterparts in larger firms, and that small firms do not operate proportionately more pieces of high-risk equipment, there should be no disproportionate burden on small firms.

37. The fast pace at which the Directive has been negotiated has meant that there has been no time to consult British small firms. This will be corrected when the RIA for transposition into UK law is prepared.

<sup>12</sup> This is the constant annual figure that when applied and discounted over a ten-year period yields the ten-year present value.

## ***COMPETITION ASSESSMENT***

38. The proposals will affect a large number of industrial sectors and markets. In such cases, the Office of Fair Trading recommends that competition assessments are conducted on markets that exhibit a high degree of supplier concentration. These markets are at the greatest danger of suffering adverse impacts on competition from new interventions. However, in the case of the optical radiation Directive, there is no readily identifiable market that fits this description. Furthermore, compliance costs to individual companies are not only small but also, in the majority of cases, are incurred by all suppliers in the relevant markets, with new firms experiencing exactly the same set-up and on-going costs as existing firms. The only area of concern is that some markets are subject to high rates of technological change. However, this in itself does not present cause for concern over potential negative impacts on competition.

39. Overall, HSE does not expect negative competition effects when the proposals are transposed into UK law.

## ***BALANCE OF COSTS AND BENEFITS***

	First year £million	Ten year present value £million
Total Benefits	Unquantified	Unquantified
Total Costs	2.19 to 4.58	13.58 to 20.80

## **Uncertainties**

40. Although there are numerous uncertainties in the calculations, most have been made explicit by incorporating large ranges in key parameters. However this is not the case with the assumption on the number of extra employers that comply with the existing duties. This assumption has the greatest impact on the estimated compliance costs. Proportionate action on the part of HSE to enforce the proposals is assumed to encourage an extra 10% of relevant employers to comply. This is judged by HSE to be the likely maximum that will be attained. However, if this proved wrong and compliance with the duties increased by 50%, the first year costs would be between £10.88 million and £21.14 million, with a ten year present value of between £67.64 million and £105.21 million. Conversely, if extra compliance with the duties amounted to only 5%, first year costs would be between £1.10 million and £2.38 million, and the ten-year present value would be between £6.82 million and £10.70 million.

## ***ARRANGEMENTS FOR MONITORING AND EVALUATION***

41. The Directive, when adopted, would need to be implemented in the UK by regulations under the Health and Safety at Work etc. Act 1974. Monitoring of the impact will be on an ad-hoc basis by feedback and information received from HSE inspectors during the course of their routine inspections and from information provided by stakeholders.

## ***ENFORCEMENT AND SANCTIONS***

42. The proposed Directive uses existing international guidelines for the ELVs and the associated requirements for risk assessments and control of exposure are broadly identical to existing requirements under current health and safety legislation. This Directive when implemented will not generate specific enforcement action although appropriate action would be undertaken if a clear breach of health and safety responsibilities were identified.

43. We intend to issue guidance in due course that will allow employers to ascertain how they will achieve compliance with the Directive. We do not expect that the Directive will impose any significant additional burdens for those employers who are already assessing and controlling risks as part of existing duties.

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