

EXPLANATORY MEMORANDUM TO
THE SUPPLY OF MACHINERY (SAFTEY) REGULATIONS 2008

2008 No. 1597

1. This explanatory memorandum has been prepared by the Department for Business, Enterprise & Regulatory Reform and is laid before Parliament by Command of Her Majesty. It includes information for the Joint Committee on Statutory Instruments.

2. Description

This statutory instrument revokes and replaces the Supply of Machinery (Safety) Regulations 1992 (S.I.1992 No 3073, as amended by the Supply of Machinery (Safety) (Amendment) Regulations 1994, (S.I.1994 No 2063) and the Supply of Machinery (Safety) (Amendment) Regulations 1995 (S.I. 2005 No 831)), which transposed the requirements of Directive 98/37/EC (consolidated) on the approximation of the laws of the Member States relating to machinery.

3. Matters of special interest to the Joint Committee on Statutory Instruments

None.

4. Legislative Background

4.1 These Regulations implement Directive 2006/42/EC of the European Parliament and of the Council on machinery and amending 95/16/EC (recast) ("the Machinery Directive"), which revokes and replaces Directive 98/37/EC. A Transposition Note has been prepared and is attached as Annex 1 to this Explanatory Memorandum.

4.2 The scrutiny history of the Machinery Directive is as follows. The Commons European Scrutiny Committee considered it politically important and cleared it (Report 2, Item 22113, Session 01/02). The Lords Select Committee on the EU did not report on it (Progress of Scrutiny, 29/10/01, Session 01/02).

4.3 There were further update letters from the Minister to the Scrutiny Committees relating to EM 5557/01 on 13/9/04, letter of 2/8/05 (Pro-forma letter on political agreement), a letter of adoption circa 22/1/06, and also letters of 30/1/06 and 31/7/06. As the proposal cleared scrutiny in 2001, the ensuing update letters were not subject to scrutiny by the Committees.

4.4 The most recent EM on "Machinery" was EM 7030/03, submitted on 21/3/2003 on an "Amended Proposal for a Directive of the EP & of the Council on machinery and amending Directive 95/16/EC". The Commons European Scrutiny Committee considered it not legally or politically important and cleared it (Report 16, Item 24342, Session 02/03). The Lords Select Committee on the EU did not report on it (Progress of Scrutiny, 31/3/03, Session 02/03).

4.5 There were also update letters to the Scrutiny Committees from Ministers: letters of 13/9/04 and 21/10/04 and notification of common position July 2006. As the EM was cleared straight away in 2003 these letters were not subject to scrutiny by the Committees.

5. Extent

This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The Machinery Directive is a New Approach directive. New Approach directives remove technical barriers to trade by harmonising national health and safety provisions in a number of product areas. Products which comply with their requirements are CE marked and can be placed on the market and put into service throughout the EU. The original Machinery Directive removed technical barriers to trade within the Single Market Area for a vast range of products from certain domestic appliances through to heavy industrial plant such as diggers and cranes. A new EU Machinery Directive to replace the existing one, that had first been adopted in 1989 and ultimately consolidated as 98/37/EU, was adopted and published on 9 June 2006.

7.2 The background to the revision of the directive is briefly as follows. The new directive does not make fundamental changes to the existing directive. It is a case, rather, of tidying it up and addressing certain problems encountered in the past in administering it. Thus, important parts of the text have been re-worded to make clear exactly what products are included in the scope and what the various players then need to do to bring them into conformity with the essential health and safety requirements of the directive. Examples include the interface with the Low Voltage and Lifts Directives and a new concept of "partly completed machinery" to deal with uncertainties inherent in the old directive down the supply chain. The new directive also includes a modernising element. Full quality assurance, a method for conformity assessment that has only been developed since the original directive was adopted, is now introduced as an option. This will allow many manufacturers to CE mark their product ranges more efficiently than hitherto – with reference being made to their overall design and manufacturing systems rather than the individual type testing of products. There are also some minor additions to the scope to cover products, such as builders' hoists, which, it is widely acknowledged, should have been covered by the original directive.

7.3 The Directive primarily affects the manufacturers of 'machinery', "lifting accessories" and, to a lesser extent, 'partly completed machinery' as defined by the directive, and component suppliers, but it also has an impact upon those who import these goods into the European Union, those who export to other Member States, and those who re-brand other manufacturers' equipment as their own.

7.4 BERR, and previously DTI, has been in regular contact with the main affected industries and stakeholders both throughout the negotiating period for the Directive and since the Directive was agreed and published in June 2006. This date establishes the timetable for transposition and then enforcement of the directive – Member States must adopt and publish the necessary provisions in their own legislation for transposing the directive by 29 June 2008 so that these can come into force on 29 December 2009. BERR therefore launched a public consultation on the basis of a draft Statutory Instrument for 12 weeks from the end of September 2007 to meet this deadline. The consultation included a partial regulatory impact assessment. It was issued directly to the approximately 200 contacts on our Machinery stakeholders' list and would, no

doubt, have been further disseminated by these recipients.

7.5 There is limited scope in a transposition exercise of this sort to depart from the text of the directive when drafting the UK regulations. However, within these parameters, the consultation document did offer some re-wordings of certain core definitions for comment. Consultees were also asked whether it was clear how the regulations would affect them in a practical way, for example whether they would need to assess the conformity of their products in conjunction with a third party (a so-called ‘notified body’).

7.6 The consultation attracted a small response – approximately a dozen replies were received - which is probably a reflection of the point made above about the limitations of this sort of exercise. In addition the directive itself made only relatively minor changes to the original one and these were backed up in almost every instance by a strong consensus in their favour.

7.7 There was, nevertheless, much of value to emerge and the replies that were received generally welcomed the draft regulations as a package. There was a general preference for *maintaining* the text of the directive in the core definitions since these would be need to be analysed *at European level* to produce guidance and it would be best if this were done on entirely consistent texts. The one exception to this was the re-drafting of the directive’s definition of ‘partly completed machinery’ which *was* welcomed and is therefore present in this SI, although in this instance it was largely a question of separating out, and thus making more digestible, a rather dense paragraph of directive text.

7.8 In addition the consultation brought to light at least one error, that has now been rectified. A full analysis of the results of the consultation can be found in the attached BERR response that was issued on 25 April attached as Annex 2.

7.9 Once the SI is in place BERR will be refreshing its standing guidance booklets. Whilst useful, especially for those manufacturers approaching the regulations for the first time, these booklets simply reproduce, in a concise and user friendly fashion, the text of the regulations. In certain respects the most important guidance about the directive, and thus, by extension, the UK regulations, is the interpretative analysis performed at European level under the supervision of the European Commission and involving all Member States’ governments and pan-European representative organisations, amongst others. The process of producing this guidance is already well underway and BERR is active in bringing to the forefront particular areas of interest to UK stakeholders and arguing for the most positive interpretations of the legal texts from a UK perspective. The consultation exercise was useful too in bringing some of these issues to the fore.

7.10 Further information on the policy background to the Regulations is set out in the Impact Assessment.

8. Impact

8.1 An Impact Assessment is attached to this memorandum.

8.2 The Regulations will bring benefits from greater protection and promotion of the European Internal Market in machinery, greater health and safety protection for those using, or coming into contact with, machinery, and environmental and animal welfare benefits where machinery is involved. These benefits are difficult to quantify precisely, but are estimated to be in the range of £2-11 million per annum, excluding environmental and animal welfare benefits. There will be one-off costs to businesses from familiarising themselves with the Regulations, estimated to be in the region of £4 million in 2009. Annual costs from training of staff and from adapting machinery to meet the requirements of the Regulations are estimated to be in the region of £1 million per annum.

9. Contact

Mike Dodds at the Department for Business, Enterprise & Regulatory Reform (e-mail: mike.dodds@berr.gsi.gov.uk , tel. 020 7215 1339) can answer queries regarding the instrument.

Summary: Intervention & Options

Department /Agency: Department for Business, Enterprise and Regulatory Reform	Title: Impact Assessment of The Supply of Machinery (Safety) Regulations 2008	
Stage: Final	Version: One	Date: 29 May 2008
Related Publications: Implementing the new Machinery Directive in the UK - A Consultation Document		

Available to view or download at:

<http://www.berr.gov.uk>

Contact for enquiries: Trevor Reid

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

There are two main problems under consideration. The first relates to the placing of machinery on the EU market, and the second relates to the appropriate level of health and safety protection for those using, or coming into contact with, machinery. Government intervention is necessary to establish the legal framework for the 'internal market' in machinery, and it is necessary because the 'full' social costs of injuries from machinery are estimated to exceed the private costs and this can lead to health and safety protection which is too low from the viewpoint of society as a whole.

What are the policy objectives and the intended effects?

The policy objective is to transpose the new European Machinery Directive to protect and promote the 'internal' market' in machinery, and to provide the appropriate level of health and safety protection for those using, or coming into contact with, machinery. The intended effects are that manufacturers and/or importers of machinery only place machinery on the EU market which meets relevant essential health and safety requirements.

What policy options have been considered? Please justify any preferred option.

The main policy options considered were those in negotiation of the new European Machinery Directive. The Government supports the EU's 'New Approach' to regulation on which the new Directive is based, and negotiated the new Directive to achieve improvements and a modernisation of the existing Directive. The new Machinery Directive is a harmonisation measure based on Article 95 of the Treaty establishing the Community. It allows the UK some latitude regarding procedural matters, such as details of enforcement, but gives few options as regards its substantive requirements.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The policy will be reviewed by BERR three years after the provisions of the SI come into effect.

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:

Gareth Thomas

..... Date: 19th June 2008

Summary: Analysis & Evidence

Policy Option:
Transposition of
Machinery Dir

Description: UK Regulations transposing the new European Machinery Directive.

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups' Costs will be incurred by manufacturers and professional importers of machinery placing machinery on the EU market. Main costs are familiarisation and training costs, with some design and build costs.
	One-off (Transition)	Yrs	
	£ 4 million	1	
	Average Annual Cost (excluding one-off)		
	£ 1 million		Total Cost (PV) £ 15-17 million
Other key non-monetised costs by 'main affected groups' None.			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups' Protection and enhancement of the 'internal market' in machinery should lead to greater competition and innovation, and the removal of non-compliant machinery - to benefit of UK businesses and consumers. Also benefits to UK users, and those coming into contact with machinery, from enhanced health and safety protection.
	One-off	Yrs	
	£		
	Average Annual Benefit (excluding one-off)		
	£ 2-11 million		Total Benefit (PV) £ 16-105 million
Other key non-monetised benefits by 'main affected groups' Protection of environment and enhancement of animal welfare, where machinery is involved and where animals come into contact with machinery.			

Key Assumptions/Sensitivities/Risks Existing Machinery Directive has had 10-20 per cent positive impact on 'machinery sector' and on health and safety; New Directive is 5-10 per cent improvement over existing Directive.

Price Base Year 2008	Time Period Years 12	Net Benefit Range (NPV) £ 1-88 million	NET BENEFIT (NPV Best estimate) £ 45 million
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What is the geographic coverage of the policy/option?		UK		
On what date will the policy be implemented?		29/12/2009		
Which organisation(s) will enforce the policy?		HSE/ORR/LAs		
What is the total annual cost of enforcement for these organisations?		£ No additional		
Does enforcement comply with Hampton principles?		Yes		
Will implementation go beyond minimum EU requirements?		No		
What is the value of the proposed offsetting measure per year?		£ None		
What is the value of changes in greenhouse gas emissions?		£ Zero		
Will the proposal have a significant impact on competition?		No		
Annual cost (£-£) per organisation (excluding one-off)	Micro 108	Small 108	Medium 108	Large 108
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)

(Increase - Decrease)

Increase of £ 0.1-0.3mn Decrease £ **Net Impact** £ 0.1-0.3 mn

Key:

Annual costs and benefits: Constant Prices

(Net) Present Value

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Purpose and intended effect

Objective

1. The Department for Business, Enterprise and Regulatory Reform (BERR) Statutory Instrument (SI), *The Supply of Machinery (Safety) Regulations 2008*, transposes into UK law Directive 2006/42/EC of the European Parliament and of the Council on Machinery.¹
2. Directive 2006/42/EC updates and replaces the existing European Directive on Machinery (Directive 98/37/EC). BERR's SI simplifies UK law in relation to the Machinery Directive.
3. The new Machinery Directive has, like the existing Machinery Directive, the following main objectives:
 - To ensure the free movement of machinery falling within its scope across the member States of the European Union (an 'internal market objective').
 - To provide for the appropriate level of health and safety for persons in the European Union using and coming into contact with machinery (a 'health and safety objective').
 - To provide for the appropriate level of environmental protection, and protection of domestic animals, in situations where machinery is involved (an 'environmental and animal protection objective').
4. BERR's SI implements the new Machinery Directive in the UK to achieve these objectives.

Background

5. Directive 2006/42/EC, the new Machinery Directive, aims to rationalise and modernise the existing Machinery Directive (98/37/EC) and to bring greater clarity to the legislative framework applying to the production and use of machinery. This is in terms of, for example, re-drafting the scope and applications of machinery covered by the Directive, and in terms of making a clearer distinction between the Machinery Directive and other relevant legislation, in particular, the Lifts Directive, the Low Voltage Directive (LVD), and the Tractors Directive.
6. The Machinery Directive is based on the principles of the European Union's 'New Approach'.
7. The 'New Approach' aims to maximise the free movement of goods within the Internal Market of the European Union by removing barriers to trade resulting from the adoption of diverging national technical standards and regulations between member States.
8. The 'New Approach' introduces 'harmonised legislation' limited to the essential requirements that products must meet to be placed on the EU market, and to benefit from free movement within the Community. 'New Approach' Directives are based on Article 95 of the Treaty establishing the Community.
9. The first Directive in relation to machinery entered into force on 1 January 1993. This Directive has been amended three times and was consolidated into the existing Directive on machinery (Directive 98/37/EC).
10. In 2001, the European Commission proposed a new Machinery Directive with the aim of modernising, clarifying and simplifying the text of the existing Directive.
11. The resulting new Machinery Directive was adopted on 17 May 2006, and member States are required to transpose its requirements into national law by 29 June 2008, with the provisions of the Directive being applicable in member States from 29 December 2009.

¹ This Directive also amends Directive 95/16/EC which is concerned with Lifts.

Rationale for Government Intervention

12. Potential barriers to trade caused by adoption of diverging national technical standards and regulations are often considered in terms of, so-called, 'non-tariff trade barriers'. In attempting to remove such barriers, so as to obtain the benefits from trade liberalisation,² Government plays an important role in establishing the legislative framework in which businesses and consumers can conduct their transactions on a 'level playing field' within transparent and predictable rules.

13. In terms of health and safety, the 'full' economic, or social, costs of injuries are estimated, generally, to exceed the private costs. The costs of health and safety impacts are usually considered in terms of 'direct' costs such as the costs of using health care resources, and 'indirect' costs such as negative impacts on the quality of life. The fact that indirect costs may not be taken into account by, for example, businesses when they establish their own health and safety standards means that from the viewpoint of society, these health and safety standards may be too low. Government may be able to establish the appropriate levels of health and safety for society as a whole, which more closely reflect the 'full' costs and benefits of health and safety impacts.

Consultation

14. BERR played an active role in negotiations for the new Machinery Directive at European level. In this role BERR was supported by the UK's Health and Safety Executive (HSE).

15. BERR maintained links with key representatives of the main industrial sectors affected by the Machinery Directive throughout the negotiation of the new Directive.

16. The partial IA of this final IA formed part of BERR's public consultation (25/09/2007–18/12/2007) on draft Regulations to implement the new Machinery Directive in the UK. The consultation asked two questions on the partial IA, one relating to the estimated benefits and the other to the estimated costs.

17. There were four responses to the question related to benefits, two of which supported the estimates outlined in the partial IA, and two of which disagreed with the estimates. One representative organization, whilst not questioning the estimates of the level of potential benefits, did question whether these benefits would materialize in the absence of pro-active enforcement action, in particular with reference to non-compliant lifting equipment. One representative organization said that the costs in the IA were under-estimates because of the inclusion in the new Machinery Directive of certain risks relating to tractors.

18. Enforcement of the Machinery Directive across the Internal Market is ultimately a European-wide issue. At this level the UK enforcement bodies play an active role in engaging with enforcement bodies in other member States to highlight best practices, exchange information, and develop systems to reduce the level of non-compliant machinery placed on the European market.

19. With regard to lifting equipment, enforcement should be significantly improved by the new Machinery Directive. Currently there are problems dealing with equipment that is claimed not to be a 'lift' in the sense of the 'Lifts Directive' but which includes enough of the features of a 'classic lift' that it ought to be governed by the more stringent essential requirements of that Directive rather than by the Machinery Directive. The new Machinery Directive addresses this problem directly, introducing a clear demarcation between the two Directives, and it also has more detailed essential requirements for lifts/lifting equipment that remain in its scope – these changes will enable more effective enforcement to take place.

20. Concerning tractors the (partial) inclusion under the new Machinery Directive was only, at worst, to be a stop-gap measure for a very limited period. The European Commission has said that the revision of the Tractors Directive is on timetable. This will mean that by the time the new Machinery Directive comes into force all risks relating to tractors will be covered by the new Tractors Directive.

21. There were five responses to the question related to costs, three of which supported the estimates of the potential costs outlined in the partial IA, and two of which disagreed with the estimates.

² The removal of such 'non-tariff trade barriers' can result in greater competition and increased innovation for the benefit of both business and consumers alike.

22. One representative organization questioned the estimates of the potential costs of implementing the new Directive, and said they could be several times higher than those in the partial IA due to additional requirements for documentation and testing of products. One representative organization questioned the cost estimates on the grounds that costs occurred largely as a result of 'cutting corners' or 'work stress' rather than because of the machinery itself.

23. In terms of the costs of additional requirements for documentation and testing of products, there is no requirement to test every product which falls under the new Machinery Directive. Testing can be undertaken by, for example, sampling from production runs. The UK Government will explain in its own Guidance Notes to the new Machinery Directive how testing can best be undertaken to ensure compliance with the new Directive at least cost to businesses.

24. In relation to documentation, it is not obvious that the new Machinery Directive will require any significant increase in the volume of documentation needed for machinery over and above what is produced currently.

25. The requirements of the new Directive in relation to lifting machinery and accessories have not changed significantly from the present Directive. To explain this, guidance on the application of the new Directive is in the process of being produced by the European Commission with input from both member State industries and national authorities, including from the UK. This guidance will, in particular, explain that component parts supplied for the manufacture of complete lifting accessories, whose parts cannot be disassembled and used in different configurations, will not be 'lifting accessories' in the terminology of the new Directive but will rather be 'components'. Guidance will also address the matter of the testing and use of quality control systems for series produced lifting machinery and accessories.

Options

26. During negotiations on the new Machinery Directive the UK had three main options. These were: to seek to get the existing Machinery Directive removed from the EU statute book; to seek to obtain no revisions to the existing Machinery Directive and its amendments; or to seek revisions to the existing Machinery Directive.

27. The UK Government supports the aims of the Machinery Directive and the principles of the 'New Approach' which underpin the Machinery Directive, and thus the first of these options is not considered further in this final IA. This final IA outlines the costs and benefits of the new Machinery Directive compared to the existing Machinery Directive.

28. The new Machinery Directive is a harmonisation measure based on Article 95 of the Treaty establishing the Community. It allows member States some latitude as regards procedural matters such as the details of enforcement at the national level, but gives them very few options as regards the substantive requirements to be introduced. For example, it does not permit member States to impose more stringent health and safety requirements for machinery than are provided for in the Directive, and it has very few derogation provisions.

Costs and Benefits

29. The new Machinery Directive takes its scope from the existing Machinery Directive and applies to the following products:

- (a) Machinery;
- (b) Interchangeable equipment;
- (c) Safety components;
- (d) Lifting accessories;
- (e) Chains, ropes and webbing;
- (f) Removable mechanical transmission devices;
- (g) Partly completed machinery.

30. The range of products outside of the scope of the new Machinery Directive, largely because they are covered by other legislation, includes:

- (a) Safety components intended to be used as spare parts;
- (b) Specific equipment for fairgrounds/amusement parks;
- (c) Machinery specifically for nuclear purposes;
- (d) Weapons, including firearms;
- (e) Agricultural and forestry tractors;

- (f) Motor vehicles and their trailers, and motor vehicles exclusively intended for competition;
- (g) Means of transport by air, on water and on rail, and seagoing vessels and mobile offshore units;
- (h) Machinery specifically for military or police purposes;
- (i) Mine winding gear;
- (j) Electrical and electronic products falling under the Low Voltage Directive LVD;
- (k) High voltage switch gear, control gear, and transformers;
- (l) Machinery for research for temporary use in laboratories;
- (m) Machinery used to move performers during artistic performances.

31. Though the new Machinery Directive takes its scope from the existing Machinery Directive it applies its requirements to two additional types of machinery. These are:

- (a) Construction site hoists intended for lifting persons or persons and goods;³
- (b) Portable cartridge-operated fixing devices.⁴

32. In addition, there are some small changes in scope caused by a revised definition in relation to the Low Voltage Directive (LVD), and a clearer demarcation between the Machinery Directive and the Lifts Directive. The latter is likely to result in more lifting platforms and other 'slow' lifts being covered by the Machinery Directive.⁵ The scope of the new Machinery Directive is reflected in BERR's SI.

33. The new Machinery Directive, and therefore BERR's SI, requires manufacturers of machinery (or their 'authorised representatives') to undertake the following activities before they can place machinery on the European market or put it into service:

- (i) Ensure the machinery satisfies relevant essential health and safety requirements;
- (ii) Ensure a technical file is made available, demonstrating that the design, manufacture, and operation of machinery complies with certain essential health and safety requirements;
- (iii) Provide necessary information, relating to the machinery, such as instructions for use;
- (iv) Carry out appropriate procedures for assessing conformity, draw-up a declaration of conformity, and ensure this accompanies the machinery;
- (v) Affix a CE marking to the machinery.

34. In addition, before placing 'partly completed machinery' on the market, a manufacturer (or his 'authorised representative') is required to: prepare technical documentation covering the design, manufacture, and operation of the partly completed machinery; prepare and provide assembly instructions for the partly completed machinery; and provide a 'declaration of incorporation' to show that partly completed machinery conforms to the necessary essential requirements of the new Directive.

35. The requirements on manufacturers (or their 'authorised representatives') in relation to machinery contained within the new Machinery Directive are broadly the same as those contained in the existing Machinery Directive, except where the two new types of machinery have been brought into scope, and where there are more specific requirements for partly completed machinery.⁶ These Directive requirements are reflected in BERR's SI.

Sectors and groups affected

36. Because of the nature and scope of the Machinery Directive itself, it is difficult to estimate with precision the number of businesses, users and consumers that will be affected by BERR's SI. The Machinery Directive covers a vast array of different types of 'machinery'. The European Commission's Explanatory Memorandum to the new

³ As there is no specific legislation in this area currently with regard to their being placed on the market.

⁴ Such as fixing tools, stunning pistols, and marking guns, for which there is no specific legislation with regard to their being placed on the market.

⁵ The Machinery Directive amends the Lifts Directive such that lifts that move slower than 0.15 metres per second are to be covered by the Machinery Directive and not the Lifts Directive.

⁶ In terms of its health and safety requirements, 'partly completed machinery' needs to be treated as if it were 'complete' machinery.

Machinery Directive⁷ uses statistics from the engineering sector to proxy those who could be impacted by the new Directive.

37. BERR's SI will affect, at least, the following sectors and groups:

- Businesses falling under the Standard Industrial Code (SIC) DK 29, i.e. '*Manufacture of Machinery and Equipment not elsewhere classified*';
- Some businesses falling under SIC Codes DL 30, '*Manufacture of Office Machinery and Computers*', and DM 34, '*Manufacture of Motor Vehicles, Trailers and Semi-Trailers*'.
- Professional Importers of machinery into the UK;
- Users of machinery;
- Domestic animals coming into contact with machinery.

38. Data from the Office of National Statistics (ONS) for category DK (SIC Code 29) "*Manufacture of Machinery and Equipment not elsewhere classified*" reports that in 2005, some 12,900 enterprises operated in this sector in the UK, having a turnover in excess of £34 billion and employing some 289,000 people. Within category DL 30 and category DM 34 not all enterprises will produce machinery or machinery that is within the scope of the new Machinery Directive. We can take data from DK 29 as an estimate for the number of businesses that could be affected by the SI, though even some businesses in this category will be producing machinery that is outside the scope of the new Machinery Directive.

39. It is unclear how many people use, or come into contact with, machinery on a day-to-day basis in the UK, and it is also unclear how many animals come into contact with machinery. The following estimates of benefits and costs are calculated over a twelve year calendar period to reflect the fact that the requirements of the new Machinery Directive do not come into effect until 2010, and we assess its impacts for ten years from that date, to 2020.

Benefits

40. The benefits of BERR's SI to transpose the new Machinery Directive into UK law are difficult to quantify. The Machinery Directive covers a vast array of machinery, used in a large number of sectors and across a wide range of applications.

41. In general terms, the benefits of the SI can be seen in terms of the following:

- positive contributions to the effective operation of the European Union 'Internal Market';
- positive contributions to health and safety for those using, or coming into contact with, machinery;
- positive contributions to improvements in animal welfare and protection of the environment where machinery is involved.

Internal Market benefits

42. As noted above, the 'New Approach' of the European Union aims to achieve technical harmonisation and standardisation across a range of product sectors to promote the free movement of goods across the European 'Internal Market'. The adoption of diverging national technical standards and regulations can cause concern because these can become a barrier to trade – a so-called 'non-tariff trade barrier'. Removal of such non-tariff trade barriers can have positive impacts on efficiency, innovation, and subsequently, on growth.

43. The existing Machinery Directive has been in operation for a number of years and will have already produced the main positive impacts across Europe from 'liberalisation' of the market for machinery. It is not straightforward to estimate the benefits that may accrue to the UK from BERR's SI, as a consequence of the removal of any additional barriers to trade involving machinery.

44. The European Commission's *Explanatory Memorandum (EM)* to the new Directive says that "*..carrying out a proper cost-benefit analysis..of the Directive for every specific situation is virtually impossible, given the variety of*

⁷ *Proposal for a Directive of the European Parliament and of the Council on machinery and amending Directive 95/16/EC*, Commission of the European Communities, COM (2000) 899 final, 26/1/2001.

*possible situations.”*⁸ But, the EM also says that “*..those consulted agree that the revision of the Directive has improved a number of points whose interpretation has caused uncertainty.*”⁹

45. The new Machinery Directive will impact on trade in machinery across Europe, affecting all member States that export and import machinery. In terms of those exporting machinery into the EU, this includes non-EU countries, and so it is difficult to estimate the benefits to the UK specifically, of any growth in export trade in machinery following introduction of the new Machinery Directive.

46. In addition, a further reduction in non-tariff barriers in machinery, as it leads to increased competition, may have positive impacts on the quality of machinery, as well as bringing reductions in the price of machinery, which would be of benefit to UK businesses importing machinery, and subsequently to UK consumers purchasing goods and services from the use of machinery. But again, such benefits are difficult to quantify.

47. Below we provide a range of estimates, which, though somewhat crude, may provide an indication of the potential ‘Internal Market’ benefits from BERR’s SI.

48. One method of estimation is to view the new Machinery Directive in the context of the European Union’s Internal Market programme. A paper by the European Commission¹⁰ attempts to estimate the economic gains to the European Union resulting from the Internal Market programme by using a model to simulate the competition and innovation effects of the programme.

49. The Commission’s paper estimates that in 2006 the Internal Market programme had a positive effect on European GDP in the region of 1.8 per cent, and that this was equivalent to 180 billion Euros in 2002 prices.

50. The UK represents around one-sixth of the European economy. Manufacturing represents around 15 per cent of UK GDP, and machinery is estimated to represent around 8 per cent of manufacturing. Up-rating the Commission’s estimate to today’s prices, and using the percentage splits above implies that the Internal Market programme may have had a positive impact on the machinery sector of the UK in the order of £270 million in 2006.

51. The Internal Market programme consists of a wide range of policies and initiatives of which the ‘New Approach’ and the ‘Machinery Directive’ are only one part. Though the Machinery Directive is an important Directive it is unlikely in itself to provide a significant proportion of the total gains of the Internal Market programme. If it represented some 10-20 per cent of the impact of the total programme for the machinery sector it could have been responsible for benefits in the region of £27 million to £54 million to the ‘machinery sector’ of the UK in 2006.

52. The new Machinery Directive updates and simplifies the existing Directive, and in this context can be seen as an improvement over the existing Directive, but the extent of this improvement is difficult to quantify.

53. One of the main areas of improvement in the new Directive is the simplified conformity assessment procedures for certain machines considered to be of higher risk, and listed in Annex IV of the Directive. Other areas of improvement include up-dated and clearer definitions of the scope of the Directive; the application of the Directive to ‘partly completed machinery’; and the relationship of the Directive to the Lifts Directive, the Low Voltage Directive, and the Tractors Directive.

54. An estimate for the extent of these improvements over and above the existing Directive is difficult to quantify, but an estimate in the region of 5 to 10 per cent may not be unreasonable. If this improvement resulted in similar levels of improvement in benefits to the ‘machinery sector’ this would imply an estimate of the internal market benefits of BERR’s SI to the ‘machinery sector’ of the UK in the region of up to £2 million to £7 million per annum in today’s prices over the period 2010-2020.

55. An alternative estimate can be based on estimates of the benefits that could be achieved by removing barriers to trade in services across the Internal Market. A report by Copenhagen Economics for the European Commission¹¹ on the potential benefits resulting from the Services Directive estimated that the Services Directive could lead to a reduction in non-tariff barriers in services of over 50 per cent, with a subsequent positive impact on value added in the services sector of just over 1 per cent.

⁸ Explanatory Memorandum, COM 2000 (899) final (page 12).

⁹ Ibid, page 13.

¹⁰ *Steps towards a deeper economic integration: the Internal Market in the 21st century - A contribution to the Single Market Review*, European Commission Economic Papers No. 271, January 2007.

¹¹ *Economic Assessment of the Barriers to the Internal Market for Services*, Final Report, Copenhagen Economics – January 2005.

56. One of the main aims of the existing Machinery Directive was the reduction in barriers to trade in machinery. However, these barriers were unlikely to be as high as those that potentially exist in services because, prior to the first Machinery Directive, there was a well-established international market in machinery.

57. If we assume that the first Machinery Directive had around half of the expected impact of the Services Directive, then based on the 'machinery sector' share of UK GDP (of just over 1 per cent) this would imply that the existing Directive may have contributed in the region of £86 million to 'machinery' value added.¹² If the new Directive brings additional benefits of between 5 - 10 per cent, this would imply benefits from the SI in the region of £6 million to £12 million per annum in today's prices over the period 2010-2020.

58. A further estimate can be made by comparing possible gains from increasing compliant activity as a proportion of total activity in the machinery sector, compared to activity in the manufacturing sector generally. This estimate is based on estimates of the relative average rate of return achievable from using resources in the machinery sector, compared to the average rate of return available from the next best alternative use of these resources, assumed here to be manufacturing generally.

59. If we assume that the existing Machinery Directive has contributed to reducing the proportion of non-compliant activity by, for example, up to a maximum of 10 per cent then based on figures for EU 'consumption' of mechanical engineering equipment this would imply that the existing Directive has increased compliant activity across Europe by some £25 billion.¹³ The average rate of return in UK manufacturing is estimated at around 7 per cent currently, and, because of its potential greater risk and use of technology, we could expect average returns in mechanical engineering to be slightly greater than that in manufacturing generally, say up to 5 per cent higher, and so producing an average return of around 7.4 per cent.

60. Again if we assume that the new Directive will bring an additional improvement of between 5 to 10 per cent over the existing Directive this would imply benefits from the SI in the region of £5 million to £12 million per annum in today's prices over the period 2010-2020.¹⁴

61. All of the above estimates are rather crude and rely on a significant number of assumptions being made. Thus they can only be viewed as being indicative estimates of the possible gains from the SI transposing the new Machinery Directive into UK law. These indicative estimates are summarised in Table 1.

Table 1: An Estimate of the Internal Market Benefits from BERR's SI (£ million)

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Internal Market Benefits	2-12	2-12	2-12	2-12	2-12	2-12	2-12	2-12	2-12	2-12	2-12
Present Value of Benefits	14-94										

Health and Safety Benefits

62. One of the objectives of the new Machinery Directive is to "*..lay down the essential health and safety requirements in relation to design and manufacture in order to improve the safety of machinery placed on the market*" (Recital 28 of the new Machinery Directive).

63. The use of machinery in the work place has risks which can result in fatalities, major injuries, and minor injuries. The Health and Safety Executive (HSE) collects and publishes accident statistics resulting from contact with moving machinery or material being machined. These statistics are categorised by three types: fatal injuries; non-fatal major injuries (averaging greater than 3 months off work); and 'over 3 days' off work injuries.

64. To estimate the health and safety benefits resulting from BERR's SI a number of steps need to be taken. First, an estimate of the impact of the existing Machinery Directive on the number of injuries resulting from the use of

¹² Calculated as UK GDP of around £1.3 trillion multiplied by 15 per cent, multiplied by 8 per cent, with 0.5 per cent of value added in machinery being attributable to the existing Machinery Directive.

¹³ Figures for EU 'consumption' of mechanical engineering suggest that the market is worth over 350 billion euro across Europe. One of the aims of the Machinery Directive is to ensure that all machinery sold in the EU conforms to essential health and safety requirements, and machinery that does not conform to such requirements is denied access to the market. Of the total market we assume that some proportion of this was taken by non-compliant machinery prior to the Machinery Directive.

¹⁴ Calculated as 10 per cent increase in compliant activity over that attributed to existing Directive, and that activity earning a return of around 7.4 per cent compared to a return of 7 per cent in manufacturing generally.

machinery needs to be made; secondly, an estimate of the additional impact of the new Machinery Directive on these injuries needs to be made; thirdly, these additional impacts need to be valued using estimates from established methodologies; and fourthly, these values need to be discounted to present values when they occur over time.

65. With regard to fatal injuries, HSE data shows that for employees and the self-employed coming into contact with moving machinery (across all sectors of the economy), the number of fatalities has fallen from 34 in 1988/89 to 23 in 2005/06. However, the nature of injuries as accidents means that this fall in fatalities over time has not been smooth.

66. Accidents by their vary nature can have a large random element, and accidents involving machinery are determined by a number of factors. These include 'general' factors, such as the level of activity in the economy (affecting the level of use of machinery), and technological developments (affecting levels of exposure to machinery), and 'individual' effects, such as the conditions for maintenance and use of machinery, and the qualities of the person using a specific type of machinery. This means it is difficult to isolate the specific impacts of the Machinery Directive on injuries.

67. The existing Machinery Directive came into force across Europe in 1998. However, this was largely a consolidation of existing European legislation on machinery first introduced in 1989, and transposed by UK Regulations coming into force in 1993. The 1998 Machinery Directive, being a consolidation, did not require new and specific UK legislation. This means that the effects of the Machinery Directive on UK trends in health and safety can be considered by comparing events prior to 1993 with those after 1993.

68. HSE data for fatal injuries from coming into contact with moving machinery, across all sectors of the economy, shows that between 1988/89 and 1993/94 fatal injuries averaged some 27 per annum. From 1995/96 to 2005/06 fatal injuries averaged almost 19 per annum.

69. It is difficult to attribute all of this fall in the average number of fatalities to the Machinery Directive. Indeed, given the range of factors that could impact on the number of injuries from the use of machinery, the Machinery Directive is likely to contribute only a proportion of any reduction. However, the essential requirements of the Machinery Directive will have had some positive impact in terms of contributing to reducing the number of fatalities resulting from contact with, or use of, machinery.

70. If we assume that the existing Machinery Directive contributed in the region of 10 per cent to 20 per cent of the reduction in the average number of fatalities from contact with machinery, then this would imply that the Machinery Directive led to a reduction in the average number of fatalities of just under 1-2 per annum.

71. The new Machinery Directive updates the existing Directive to increase its clarity and simplify its text, and to make its application more robust and straightforward. Such action is likely to reduce uncertainty with respect to the risks associated with the use of, or coming into contact with, machinery. This should have subsequent positive impacts on reducing injuries where machinery is involved.

72. Using the assumption that the new Directive is an improvement in the region of 5 to 10 per cent over the existing Directive (as we did to estimate the Internal Market benefits outlined above), and that this improvement has subsequent positive impacts on the effectiveness of the Directive in terms of health and safety, then the possible reduction in the average number of fatalities resulting from the new Directive could be in the region of 0.1-0.2 per annum.

73. The Department for Transport (DfT) estimates the average cost of a fatal injury from a road accident in the region of £1.43 million.¹⁵ Up-rating this figure¹⁶ and applying it to the number of fatalities that could be avoided as estimated above, enables an estimate to be made of the value of the number of fatalities that could be avoided in the UK as a consequence of BERR's SI.¹⁷

¹⁵ Highways Economic Note No. 1, January 2007. The DfT figure is for 2005 and is made up of estimates of the costs of lost output, medical and ambulance costs, and human costs. Human costs are the largest proportion of costs and represent "...pain, grief and suffering to the casualty, relatives and friends, and for, fatal casualties, the intrinsic loss of enjoyment of life over and above the consumption of goods and services."

¹⁶ Based on growth in nominal GDP.

¹⁷ Though it is recognised that it is not necessarily appropriate to apply road accident figures to accidents involving machinery. Impacts on health can be seen as having a broadly constant utility value over time, regardless of changes in income. Future health benefits (or costs) can then be valued in today's values by being discounted at a pure time preference rate. Within the Government's current discount rate, pure time preference represents 1.5 per cent. An alternative method of estimating future health impacts is to calculate a rate of increase in their value over time and discount these at the 'full' discount rate (currently 3.5 per cent).

74. HSE data is also available for non-fatal injuries. The two main categories of injury here are, “major injuries” averaging greater than 3 months off work, and “>3 day injuries”, averaging more than 3 days off work.

75. Between 1988/89 and 1993/94 ‘major injuries’ from coming into contact with moving machinery averaged some 1,700 per annum. Since then this figure has averaged some 1,500 per annum. Using the same methodology as that for fatal injuries outlined above, enables an estimate to be made of the possible benefits of the new Machinery Directive in terms of reducing the average number of ‘major’ injuries per annum. This estimate is in the range of, on average, 1 to 4 accidents per annum.

76. The HSE values the economic cost of a ‘major injury’ at £38,500 per injury currently, and uprating this number enables a monetary estimate to be made of the value of avoiding such injuries.¹⁸

77. Between 1988/89 and 1993/94, ‘>3day injuries’ from coming into contact with moving machinery averaged just over 7,000 per annum. Since then this figure has averaged some 5,100 per annum. Using the same methodology as that for fatal and major injuries, enables an estimate to be made of the possible benefits of the new Machinery Directive in terms of reducing the average number of ‘>than 3 days’ injuries per annum. This estimate is in the range of an average between 11 to 44 accidents per annum.

78. The HSE values the economic cost of a >3day injury to be £5,500, and uprating this number enables a monetary estimate to be made of the value of avoiding such injuries.¹⁹

79. In the estimates outlined above for possible injuries avoided, we have used data for injuries from coming into contact with moving machinery. However, there are injuries reported under other categories, which may also involve machinery, the major one of which is likely to be injuries as a consequence of falling from height, but also injuries from being struck by a moving or flying object, or from being struck by a moving vehicle. The data does not enable us to isolate instances where machinery may be involved.

80. Anecdotal evidence suggests that the actual number of injuries where machinery is involved may be up to 50 per cent higher than an estimate based on injuries from using, or coming into contact with, machinery alone. Using this produces estimates of the monetary value of health and safety benefits, i.e. from the possible avoidance of fatal, major, and ‘>3 day’ injuries, from BERRs SI as summarised in Table 2. It should be noted that given the number of assumptions that need to be made to arrive at these estimates, they should be seen as being indicative estimates. Also, these estimates do not include the avoidance of possible injuries from the use of machinery in non-workplace/industrial environments, such as the use of cordless power tools (CPTs) in households, which would increase the level of health and safety benefits.

Table 2: An Estimate of the Value Health and Safety benefits in the UK from BERRs draft SI (£ million)

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Health and Safety Benefits	0.3-1	0.3-1	0.3-1	0.3-1	0.3-1	0.3-1	0.3-1	0.3-1	0.3-1	0.3-1	0.3-1
PV of Benefits	3-11										

Environmental and Animal Welfare Benefits

81. The new Machinery Directive, like the existing Machinery Directive, has as one of its aims protection of the environment and protection of animal welfare where machinery is used, and where animals come into contact with machinery.

82. Government policy with respect to the health and welfare of animals is largely concerned with the prevention of outbreaks of disease which can have negative impacts on public health, animal welfare and the environment. However, the promotion of animal welfare goes beyond disease prevention.

83. The Government’s *Animal Health and Welfare Strategy for Great Britain*²⁰ says that “..society cares about the welfare of animals as sentient creatures.” The Farm Animal Welfare Council has as part of its ‘Five Freedoms’, that

¹⁸ HSE Economic Analysis Unit (EAU) Appraisal Values, 13/04/07. The cost of a major injury consists of the costs of lost output, costs of medical treatment, investigation costs etc, and human costs. Human costs (reflecting pain, grief and suffering to the casualty, relatives, and friends) represent almost 50 per cent of total costs. We up-rate the HSE figure to today’s prices based on estimates of GDP growth.

¹⁹ The cost of a ‘>3 day’ injury consists of the costs of lost output, medical treatment etc, and human costs. Human costs (reflecting pain, grief and suffering to the casualty, relatives, and friends) represent almost 50 per cent of total costs. We up-rate the HSE figure using estimates of GDP growth.

²⁰ Defra, Welsh Assembly and Scottish Executive, 2004.

animals should be free from discomfort, pain, injury, and fear and distress. As far as the new Machinery Directive promotes such 'freedoms' where animals come into contact with machinery, this should result in positive impacts on animal welfare and on the welfare of society generally, but these impacts are difficult to quantify given that there is no data available on injuries to animals resulting from machinery.

Costs

84. The costs of BERR's SI transposing the new Machinery Directive into UK law will fall largely on businesses designing and manufacturing machinery, though there will also be some costs to the public sector from market surveillance and conformity assessment activities. It is not clear that there will be any additional requirements on users of machinery as a result of the new Directive.

(i) Familiarisation and Training Costs

85. There will be costs to businesses in terms of making themselves aware of the new SI and in terms of disseminating and applying the SI.

86. Regulatory Impact Assessments (the precursors to IAs) generally considered these costs in terms of so called "familiarisation costs" which relate the length of time businesses need to read and understand new legislation, and in terms of "training costs" which relate to the length of time businesses need to disseminate and train managers and staff in new legislation. The following are some estimates from some RIAs:

- The Health and Safety Executive's (HSE's) RIA for the 'Control of Noise at Work Regulations' (2006) estimates the costs of "familiarisation" as the costs of a manager taking one hour to familiarise him/herself with the Regulations, and values this time based on wage costs from the new earnings survey including a 30 per cent mark-up for non-wage labour costs. This is then multiplied by an estimate of the total number of businesses affected by the Regulations. These costs are taken as one-off costs incurred in the first year following the Regulations coming into force. The RIA estimates costs of providing information and training to workers by assuming that each worker spends 15 minutes per year "*reading/listening to information*", valuing this time, and multiplying this by the estimated number of workers affected.
- The HSE's RIA for the 'Work at Height Regulations' (2005) estimates "familiarisation costs" by assuming that "*small businesses will require 2 hours and large businesses 4 hours to familiarise themselves with the proposed Regulations*". Here, a manager's time was valued at an average of £20 an hour (including non-wage labour costs).

87. In terms of BERR's SI transposing the new Machinery Directive, it is estimated that some 13,000 businesses could be affected.²¹

88. BERR's SI seeks to update and modernise existing UK legislation in relation to machinery. Thus industry is already aware of the nature, scope and aims of the existing legislation. Because of this it is unlikely that UK industry would need to spend a significant amount of time familiarising itself with the new legislation.

89. Under SIC Code 29 some 289,000 people are 'employed in machinery'. However, the new legislation is relevant only to a proportion of these employees, consisting largely of designers, technical writers and engineers. These employees are estimated to make up around 10 per cent of total employees, and it is estimated that they may need to spend up to five hours familiarising themselves with the new legislation when it is introduced. Using an estimate of the value of this time, implies a one-off cost for familiarisation in the region of £4 million in 2009.²²

90. In addition, there may be ongoing costs as a result of relevant staff needing to 'refresh' their knowledge of the new legislation and new staff being made aware of the new legislation. However, it is possible that these costs may not be additional costs because they could have been incurred anyway, as there would be a need for similar 'refreshing', and education of new staff, for the existing legislation on machinery. In as far as the new legislation requires additional levels of training, over and above that for the existing legislation, this is not expected to be significant, as the new legislation applies to only two new additional types of machinery, and requires 'partly completed machinery' in terms of its health and safety requirements to be treated like 'completed' machinery. A

²¹ Based on SIC Code DK 29. Given the scope and nature of the Machinery Directive it is difficult to give precise estimates, and more businesses could be affected, though to a lesser extent than those in the main sectors affected.

²² Using an estimate of average wages for the relevant employees in 2009 with a 30 per cent mark-up for non-wage labour costs. The SI itself will come into force in the second half of 2008, and is to be operational from 29 December 2009.

figure of 5 to 10 per cent of the total one-off costs may not be an unrealistic estimate, and this would imply annual costs in the region of £0.2 - 0.4 million from 2010 onwards.

(ii) Costs of providing information on machinery and marking of machinery

91. The new Machinery Directive requires manufacturers to provide certain information on machinery in terms of instructions in numerous languages, and in terms of marking machinery with the 'CE' mark. However, these requirements are largely contained within the existing Directive and so are not expected to lead to any additional costs to business. Where the scope of the Machinery Directive has been extended to the two new types of machinery this is likely to result in additional costs in terms of instruction provision and marking but these are difficult to quantify, because it is unclear how many businesses or products may be affected.

(iii) Costs of providing Technical Files

92. Manufacturers of machinery need to provide technical files on the machinery they produce. However, this is already a requirement of the existing Directive and so is not expected to result in any additional costs to business. Indeed, Annex X of the new Directive may lead to a reduction in the level of existing costs as it provides manufacturers with the option of obtaining approval of their processes as opposed to approval of each type of product they produce.

(iv) Costs of conformity assessment

93. Manufacturers of machinery need to carry out procedures for assessing the conformity of the machinery they produce, and produce a declaration of this conformity. There is a new requirement to print a generic copy of the Declaration of Conformity with the instructions for use of machinery. This is likely to lead to additional costs to manufacturers but these are not expected to be significant, given that the format of the Declaration is expected to be in the same format as that of the instructions for use.

94. The new Machinery Directive places specific requirements on manufacturers of partly completed machinery similar to those who produce 'complete' machinery. Any additional costs from this are expected to be small, with the main impact being a possible shift of existing costs from users of partly completed machinery to manufacturers of partly completed machinery.

(v) Costs of meeting essential requirements

95. Manufacturers of machinery will need to design and build machinery that satisfies the relevant essential requirements of the new Machinery Directive with respect to the machinery they place on the European market. Where the scope of the Machinery Directive has been extended to the two new types of machinery this is likely to result in additional costs

96. The new Machinery Directive introduces more specific requirements in terms of the following: ergonomics, lightning protection, provision of seating at workstations, and guard fixings. There is also a requirement to estimate the uncertainty of measurements for noise and vibration reporting. In addition, there are some extra requirements for lifting platforms for people, bringing these more into line with the Lifts Directive.

97. Most of these requirements are not expected to result in significant costs because much modern machinery already meets many of the essential requirements of the new Directive. However, the requirements for guard fixings are expected to result in costs in the region of £1 million per annum based on estimates of the number of guards used and the average number of fixings per guard.

98. Table 3 outlines these estimates of the costs to business from BERRs SI.

Table 3: An estimate of costs to UK businesses from BERR's SI (£ million)

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Familiarisation and Training	4	0.2-0.4	0.2-0.4	0.2-0.4	0.2-0.4	0.2-0.4	0.2-0.4	0.2-0.4	0.2-0.4	0.2-0.4	0.2-0.4	0.2-0.4
Essential Requirements, Marking and Information	1	1	1	1	1	1	1	1	1	1	1	1
PV of Total Costs	15-17											

Costs to Public Sector

99. The existing Machinery Directive which is reflected in current UK legislation requires the Government to undertake a number of tasks to ensure effective implementation of the Directive in the UK. These include direct

enforcement of the UK's Regulations by the Health and Safety Executive (HSE), the Office of Rail Regulation (ORR), and Trading Standards Officers (TSOs) of Local Authorities (LAs), through, for example, reactions to complaints from manufacturers or consumers, or following accidents, and from factory or retail outlet inspections. The current level of this direct enforcement is not expected to be affected significantly by the new Directive.

100. In terms of administering the UK's Regulations, one-off costs will be incurred in terms of training relevant staff, preparing and issuing new Guidance material, but these are not expected to be significant. Representation of UK interests at European level is not expected to entail any additional significant costs.

Small Firms Impact Test

101. BERR's SI is not expected to have a disproportionate impact on small and medium-sized enterprises (SMEs) in the UK, because the new Machinery Directive is not a radical departure from the existing Directive, and little evidence has come to light that the existing Directive has had a disproportionate impact on SMEs.

102. There could be a transfer of some costs from large businesses to SMEs as a result of the requirements on producers of partly completed machinery in the new Directive, and as a consequence of some products that were previously covered by the Low Voltage Directive (LVD) now being covered by the Machinery Directive. However, these costs are not expected to be disproportionate, but rather relate to the level of activity undertaken by a particular business.

103. Moreover, Annex X of the new Directive relating to 'full quality assurance' for conformity assessment should be of benefit to SMEs because of, for example, its relatively easier application to the production of prototypes with which SMEs are particularly closely associated.

Competition assessment

104. Since 2002 it has been a requirement that RIAs (now IAs) contain an assessment of the potential impacts on competition of the proposal under consideration. The current competition assessment consists of four questions, to aid assessment of the impact of proposed regulation on markets.

105. The first question asks if the proposed regulation limits the number, or range, of suppliers. This is more likely to be the case if the proposal is to award exclusive rights or create licenses. The new Machinery Directive, and so BERR's SI, does not limit the ability of businesses to place machinery on the market, but rather requires all businesses doing so to meet similar relevant essential requirements.

106. The second question asks if the proposal indirectly could limit supply by, for example, raising the costs of new compared to existing suppliers, or affecting entry into or exit from the market. The SI affects all businesses placing machinery (within its scope) on the market, and costs will be incurred largely depending on the level of activity determined by businesses themselves.

107. The third question asks if the proposal limits the ability of suppliers to compete, for example, by limiting innovation, sales channels, or production processes. The new Machinery Directive is based on the principles of the EU's 'New Approach' which aims to introduce essential requirements but not to specify particular technologies, or production methods or processes.

108. The fourth question asks if the proposal reduces incentives for suppliers to compete by, for example, requiring them to reveal price, cost or sale information, or making it more difficult for consumers to switch supplier. The SI does not require businesses to reveal market-sensitive information or restrict consumers in their choice of machinery supplier.

Enforcement, sanctions and monitoring

109. The enforcement provisions of member States and the sanctions they apply are not addressed by the new Directive, although Article 19 of the new Directive requires member States to co-operate more effectively between themselves in this regard. Article 23 of the new Directive also requires penalties to be effective, proportionate and dissuasive.

110. With respect to enforcement BERR's SI carries forward what is already in place in the UK, with one exception. This exception reflects the fact that the Office of Rail Regulation (ORR) has taken over some of the responsibilities of the HSE, including, at the margins, some that are relevant to the enforcement of the new Machinery Regulations. The ORR is therefore cited in the Regulations as an enforcement authority alongside HSE and local weights and measures authorities. With respect to sanctions, the UK enforcement authorities believe that the revised set of penalties introduced in the UK in 2005 satisfy the criteria of Article 23 of the new Directive and these are therefore carried forward unchanged.

111. There will be some initial training costs to familiarise enforcing authority staff with the new Regulations, but these are not expected to be significant, and once this is complete the annual cost of enforcing the SI will not differ significantly from the current position. At present the products and safety requirements in the proposed SI are covered by the existing Supply of Machinery Regulations 1992, or other more general legislation such as Section 6 of the Health and Safety at Work Act 1974, and so will not introduce new areas of work.

112. Historically, for large-scale industrial machinery the HSE has been the enforcement body. Given its size and nature, such equipment has been monitored by market surveillance, and by inspection on site once it is in use (in tandem with the UK's Provision and Use of Work Equipment Regulations (PUWER)). The 'New Approach' basis of the new Machinery Directive is likely to result in more pro-active project work in the HSE, which will be aided by the use of a European database system (ICSMS). These changes will facilitate improvements in information gathering and responses to intelligence which should enable the enforcement authorities to concentrate their resources and enforcement further in line with the principles set out in the Hampton Report (March 2005). Any extra costs of informing the EU Commission of enforcement action concerning the new products brought into scope by the SI will be counter balanced by resulting savings in inspectors' time due to the SI being more specific to these products and hence easier to apply than the previous more general legislation.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	Yes
Sustainable Development	No	Yes
Carbon Assessment	No	Yes
Other Environment	Yes	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

SPECIFIC IMPACT TESTS

Legal Aid

It is not clear to what extent those who would be subject to the SI transposing the Machinery Directive are eligible for legal aid, but as the SI is not expected to have any material effect on the criminal or civil liability of those who are subject to the Regulations implementing the Directive, it should not have any impact on legal aid in the UK.

Sustainable Development

The SI is not expected to have any significant impact on sustainable development in terms of, for example, greenhouse gas emissions, impacts on air or water quality, or impacts on waste management.

Carbon Impact Assessment

The SI is not expected to have any significant carbon impact. The main aims of the SI are to promote the European 'Internal Market', to promote health and safety, and to provide protection for the environment and animals, where machinery is involved.

Race Equality Assessment

The SI does not have as one its aims race equality explicitly. However, one of the aims of the SI is to provide equal, and high, levels of health and safety protection for all users of machinery, irrespective of race.

Disability Equality

The SI does not have disability equality as one of its aims explicitly. However, in the drafting of the new Machinery Directive that the SI implements, the impact on disability equality was considered at some length and included by the European Parliament during its 'First Reading'.

There were two main areas of concern. First was that the section on ergonomic requirements should be strengthened to make it clear the extent of the human factors that needed to be considered in the design of machinery. Secondly, that lifting platforms, mainly used by people with reduced mobility, should have the same level of safety requirements as those for the general population, and should not be specifically listed as for disabled persons. In taking this decision it was recognised that persons with impaired mobility needed to have their children and other non-disabled persons accompany them, and there must be no tendency to suggest lower levels of safety requirements for these types of lift. The European Parliament queried if lifts giving access to work stations should have braille controls to make them accessible to persons with visual impairment, but this was not included in the Directive due to the variety of work stations involved, many of which required a high standard of vision of the worker, an example being a lift to the operating position of a tower crane.

Gender Impact Assessment

The SI impacts on all manufacturers and users of machinery. It is not aimed at overcoming gender inequalities or eliminating barriers to inequality, but the fact that it sets down health

and safety requirements for all users of machinery should mean that it contributes positively to gender equality.

Human Rights

The SI is not expected to impact on the rights and freedoms of individuals as set out in the Human Rights Act 1998.

Rural Proofing

The SI is significant in the rural economy because of the wide range of agricultural applications using products that fall within the scope of the new Directive.

However the SI is not expected to have significant impacts on rural areas or circumstances because the treatment of these products has not changed significantly from the old to the new Directive.

Transposition note for Directive 2006/42/EC of the European Parliament and of the Council on machinery, and amending Directive 95/16/EC (recast) (“the Directive”)

The relevant provisions of the Directive have been transposed into UK law by the Supply of Machinery (Safety) Regulations 2008 (“the Regulations”) as set out in the table below.

Overall, the Directive aims to promote the free movement of machinery products within the EEA and make such products safer by requiring that they conform to certain “essential health and safety requirements” before being first placed on the market or first put into service in the EEA. The obligations imposed by the Directive fall to be carried out by those who place machinery on the market or put it into service (“responsible persons”); by the “notified bodies” who in many cases are required to assess the conformity of machinery with the essential health and safety requirements; by enforcement authorities; or by the Secretary of State.

Article of the Directive	Objectives	Implementation in the Regulations	Responsibility
Article 1(1)	Lists categories of products which are covered by the Directive	Regulations 4 and 6	N/a
Article 1(2)	Excludes certain products which would otherwise be covered	Regulations 4(1)(a)(ii) and 6(2)(b); Schedule 3	N/a
Article 2(a)-(g)	Defines the categories listed in Article 1(1)	Regulations 4(1)(a)(i) and (2); 6(1)	N/a
Article 2(h) and (k)	Defines “placing on the market” and “putting into service”: these are key terms since most of the obligations in the Directive arise when machinery (as defined) is about to be placed on the market or put into service	Regulation 3(1)	N/a
Article 2(i), (j) and (l)	Defines further key terms, in particular the “manufacturer” and the manufacturer’s “authorised representative”, on whom most of the obligations in the Directive fall	Regulation 2(2)	N/a
Article 3	Avoids “doubling up” of regulation at EC level by providing that the Directive does not apply to machinery which is subject to other directives which make more specific provision about the hazards listed in the Directive	Regulation 5	N/a
Article 4(1), 4(2)	Member States are to ensure machinery and partly completed machinery satisfies the relevant provisions of the Directive and does not endanger people, domestic animals or property.	All, but see in particular Part 3 (especially regulations 7(1), 7(2), 8(1) and 9, the definition of “safe” in regulation 2(2), and Part 6.	Legislative responsibility lies with the Secretary of State. Practical responsibility under the Regulations falls on the “responsible person” (i.e. the manufacturer or authorised representative) in the

Article of the Directive	Objectives	Implementation in the Regulations	Responsibility
			first instance, but (except in the case of partly completed machinery) is not limited to them.
Article 4(3), 4(4)	Member States are to appoint competent authorities to enforce the Directive.	Regulation 20 and Schedule 5	The Secretary of State is responsible for appointing competent “enforcement authorities”. Depending on the context in which machinery is to be used, the enforcement authority appointed in relation to it may be the Health & Safety Executive (or its Northern Ireland counterpart), local authority trading standards departments, the Office of Rail Regulation or the Secretary of State.
Article 5(1)(a) to (f)	Specifies what responsible persons must do in relation to machinery before placing it on the market or putting it into service	Regulation 7(2)(a) to (f)	Responsible persons
Article 5(2)	Specifies what responsible persons must do in relation to partly completed machinery before placing it on the market	Regulation 8(1)	Responsible persons
Article 5(3)	Responsible persons must have access to adequate testing facilities etc.	Regulation 7(3)	Responsible persons
Article 5(4)	Explains the significance of “CE marking” in cases where machinery is covered by more than one directive	Regulation 14	(Responsible persons by implication: they must generally ensure that CE-marked machinery which is subject to more than one directive complies with all of them.)
Article 6(2)	Member States must not restrict the free movement of products covered by and complying with the Directive.	No transposition required	Secretary of State, enforcement authorities, HMRC.
Article 6(3)	Machinery which does not comply with the Directive may be shown at trade fairs etc, subject to certain safeguards.	Regulation 3(2)(b)	Secretary of State, enforcement authorities, HMRC; exhibitors

Article of the Directive	Objectives	Implementation in the Regulations	Responsibility
Article 7(1)	CE-marked machinery is to be presumed to comply with the Directive.	Regulation 13(1)	Secretary of State, enforcement authorities, courts.
Article 7(2)	Machinery manufactured in conformity with harmonised standards is to be presumed to conform to corresponding Directive requirements.	Regulation 7(4)	N/a (universal presumption)
Article 7(3)	Commission to publish references to harmonised standards	No transposition required	Commission
Article 7(4)	Member States to enable social partners to influence preparation of standards	No transposition required (requirement is consistent with existing procedures of BSI)	British Standards Institute (ultimate responsibility rests with Secretary of State if e.g. BSI were to change its way of working)
Article 8	Actions which Commission can take under Article 22 (comitology procedure)	No transposition required	Commission
Article 9	What Commission and Member States may do where they have concerns about a harmonised standard	No transposition required	Commission / Secretary of State
Article 10	Disputing harmonised standard before the Directive 98/34/EC committee	No transposition required	Commission / Secretary of State
Article 11(1)-(4) and (6)	Member States may act where they consider that ostensibly "compliant" machinery is unsafe.	No transposition required	Secretary of State
Article 11(5)	Member States must take action where non-compliant machinery has been CE-marked.	Regulations 15(1), 21(1)(b)(iii), 21(3) and 22	Enforcement authorities.
Article 12(1)	Responsible persons must follow the conformity assessment procedure appropriate to each type of machinery.	Regulation 7(2)(d)	Responsible persons (and "notified bodies" responsible for conformity assessment)
Article 12(2), 12(3), 12(4)	Specify which conformity assessment procedures apply to specific categories of machinery	Regulations 10, 11, 12	Responsible persons (and "notified bodies" responsible for conformity assessment)
Article 13	Specifies what responsible persons must do before placing partly completed machinery on the market	Regulation 8	Responsible persons
Article 14(1)	Member States must notify appointment of "notified bodies" (responsible for conformity assessment) to the Commission.	No transposition required (but see Regulation 16(3))	Secretary of State

Article of the Directive	Objectives	Implementation in the Regulations	Responsibility
Article 14(2)	Notified bodies must be monitored regularly	Regulation 16(11)	Secretary of State
Article 14(3) and (5)	Member States must apply certain criteria and presumptions when appointing notified bodies.	Regulation 16(6) and (7)	Secretary of State
Article 14(4)	Commission to publish list of notified bodies	No transposition required	Commission
Article 14(6)	What action notified bodies and Member States are to take where notified bodies find that the requirements of the Directive are no longer being complied with	Regulation 18(3)-(7) and Schedule 4	Notified bodies, Secretary of State
Article 14(7)	Commission to facilitate sharing of experience about notified bodies among Member States	No transposition required	Commission
Article 14(8)	Member States to withdraw notification of notified bodies (and notify Commission of withdrawal) in certain circumstances	Regulation 17(4)	Secretary of State
Article 15	Member States may still legislate in relation to machinery	No transposition required	Secretary of State
Article 16(1)	What the CE marking should look like	Regulation 7(2)(f)(ii) and definition of "CE marking" in regulation 2(2)	Responsible persons
Article 16(2)	How the CE marking should be affixed	Regulation 7(2)(f)(i)	Responsible persons
Article 16(3)	How the CE marking should not be affixed	Regulation 15(2) and (3)	Responsible persons
Article 17	How Member States are to treat certain failures in relation to CE marking	Regulation 21 and Schedule 5 paragraphs 8(e) and 10(d)	Secretary of State (implemented by provision applying generally)
Article 18	Information to be kept confidential	Regulation 26 and Schedule 7, paragraph 5	Secretary of State, enforcement authorities and notified bodies (obligations on notified bodies to be covered by their terms of appointment to the extent not covered by legislation or common law of confidentiality)
Article 19	Member States and Commission to facilitate co-operation between themselves	No transposition required	Secretary of State, Commission
Article 20	Decisions to restrict free movement of machinery to be properly reasoned etc	No transposition required	Secretary of State, enforcement authorities, Commission

Article of the Directive	Objectives	Implementation in the Regulations	Responsibility
Article 21	Commission to enable information about implementation to be made available	No transposition required	Commission
Article 22	Comitology rules	No transposition required	Commission
Article 23	Compliance to be backed (in legislation) with effective penalties etc	Regulation 22	Secretary of State
Article 24	Amending the Lifts Directive (95/16/EC)	Regulation 25 and Schedule 6	Secretary of State
Article 25	Repeal of Directive 98/37/EC	No transposition required, but see revocation of UK Regulations implementing Directive 98/37/EC (regulation 1(2) and Schedule 1)	Secretary of State
Article 26	Directive to be transposed by 29 June 2008 and come into force on 29 December 2009	All (including Explanatory Note as regards third paragraph of Article 26(1))	Secretary of State
Article 27	Member States may choose to delay commencement in respect of impact machinery until 29 June 2011	Article 28	Secretary of State
Article 28	Fixes entry into force date of Directive	No transposition required	N/a
Article 29	Directive is addressed to Member States	No transposition required	N/a
Annex I	Sets out detail of essential health and safety requirements	Schedule 2, Part 1 (and regulation 7(2)(a))	Responsible persons
Annex II	Sets out requirements in respect of declaration of conformity and incorporation	Schedule 2, Part 2 (and regulations 7(2)(e) and 8(1)(c))	Responsible persons
Annex III	Sets out details of the CE marking	Schedule 2, Part 3 (and regulation 7(2)(f)(ii))	Responsible persons
Annex IV	Lists categories of machinery which are subject to particular forms of conformity assessment	Schedule 2, Part 4 (and regulations 11 and 12)	Responsible persons
Annex V	Sets out indicative list of safety components	Schedule 2, Part 5 (and regulation 4 (2)(c))	Responsible persons
Annex VI	Sets out requirements for assembly instructions for partly completed machinery	Schedule 2, Part 6 (and regulation 8(1)(b))	Responsible persons
Annex VII	Sets out requirements in respect of technical files and documentation	Schedule 2, Part 7 (and regulations 7(2)(b) and 8(1)(a))	Responsible persons
Annex VIII	Describes the procedure for conformity assessment within internal checks on manufacture	Schedule 2, Part 8 (and regulations 10, 11(2) and 12(2)(a))	Responsible persons

Article of the Directive	Objectives	Implementation in the Regulations	Responsibility
Annex IX	Sets out the requirements in respect of EC type-examination	Schedule 2, Part 9 (and regulations 11(2)(b), 12(2)(a) and 18(1))	Responsible persons and notified bodies
Annex X	Sets out the requirements in respect of full quality assurance	Schedule 2, Part 10 (and regulations 11(2)(c), 12(2)(b) and 18(1))	Responsible persons and notified bodies
Annex XI	Sets out notified body criteria	Schedule 2, Part 11 (and regulation 16(6))	Secretary of State and notified bodies
Annex XII	Lists derivation of provisions of the Directive from those of its predecessor (Directive 98/37/EC)	No transposition required	N/a