Post Implementation Review of the Supply of Machinery (Safety) Regulations 2008 (S.I. 2008/1597) as amended

Presented to Parliament
by the Secretary of State for Business, Energy & Industrial Strategy
by Command of Her Majesty

August 2017

Cm 9493

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Post Implementation Review of the Supply of Machinery (Safety) Regulations 2008 (S.I. 2008/1597) as amended

Introduction

1. This document provides an overview of the Post Implementation Review (PIR) of the Supply of Machinery (Safety) Regulations 2008 (S.I. 2008/1597) as amended (the Regulations). These Regulations, as amended, implement Directive 2006/42/EC on machinery (as amended by Directive 2009/127/EC) (the Directive) into UK law.

2. This Command Paper and the associated PIR (Annex 1) set out the Government's views on the effectiveness of the Regulations. It considers:

- the extent to which the Regulations are working;
- whether Government intervention is still required;
- whether the Regulations and the way they are implemented are the most appropriate approach to meeting the policy aim.

Background

3. The Machinery Directive is one of many that support the single market for goods across the EEA while providing a common level of safety.

4. The Directive is implemented by the Supply of Machinery (Safety) Regulations 2008.

5. The Regulations were amended by the Supply of Machinery (Safety) (Amendment) Regulations 2011 to extend the scope to include certain pesticides equipment.

6. The Regulations support the Single Market for goods by ensuring that products within the scope are safe to be placed on the EEA market and meet the relevant essential health and safety requirements set out in the Regulations.

7. The Regulations apply to machinery that is placed on the market or put into service. They impose duties on manufacturers and authorised representatives that are involved in placing machinery on the market or putting it into service.

8. The Regulations also set out the enforcement powers which draw heavily on the Health and Safety at Work Act. The enforcement authorities for the Regulations are the Health & Safety Executive for business products, and local authority trading standards for consumer products.

9. On 23 June, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU. The assumptions used in this post-implementation review have been chosen accordingly.

Scope of the Post Implementation Review (PIR)

10. The PIR considers the impact of the Supply of Machinery (Safety) Regulations 2008 as amended.

11. The Government does not consider the Regulations to be particularly high profile or contentious. Therefore, in line with PIR guidance a light touch PIR has been applied to the analysis.

12. As the PIR was carried out prior to the Referendum and covers the period 2009 to 2014 it did not take into account the effect of Referendum result. However, our analysts have reviewed the evidence and consider the analysis in the PIR would not be different had it been carried out since the Referendum result. The PIR was reviewed by the Regulatory Policy Committee (RPC) and cleared as fit for purpose.

Research and Analysis

13. Guidance for conducting PIRs provides that three questions should be addressed in a PIR:

- To what extent are the Regulations working?
- Is Government intervention still required?
- Are the Regulations and the way they are implemented the most appropriate approach?

14. In order to answer these questions, questionnaires were sent to manufacturers, notified bodies and enforcement authorities. The questionnaire sought comment on:

- the impact of the Regulations;
- assessment of costs;
- identification of benefits;
- the challenges faced by business to meet the requirements;
- the impact on SMEs and microbusinesses.

15. As the Regulations are derived from an EU Directive questions were also sent to other EU Member States in order to gauge the impact of the Directive in their territories.

16. Information was also gleaned from our experience of dealing with stakeholders on a range of issues on a day to day basis. While the number of responses to the questionnaire was small, they generally provided a clear indication that the Regulations are working well.

To What Extent are the Regulations Working?

17. The answers to questionnaires suggested that the Regulations provided a good robust framework for promoting safety for a wide range of machinery. However, there was concern about a lack of knowledge of the technical requirements for machinery to meet the safety requirements and that this may lead to the availability of products that are non-compliant with the requirements of the Regulations. This has led to concerns from some respondents that more enforcement is required.

Is Government Intervention Still Required?

18. The UK has an obligation to implement Directive 2006/42/EC on machinery as amended into UK law. A legislative approach through the Regulations is an effective way of achieving this.

Other Issues Identified

19. The cost of standards that are used to support the Regulations is regarded by some in the industry as prohibitive especially for small and medium enterprises. Standards are voluntary but most manufacturers chose to follow the requirements as they provide a presumption of conformity with the requirements of the Regulations.

20. Manufacturers are concerned with enforcement. They report that they spend time and money in complying whilst others gain competitive advantage by placing unsafe products on the market and they are keen to ensure a level playing field.

Conclusions and Next Steps

21. The PIR analysis informed the Government's view that the Regulations should remain as in force, for the following reasons:

- The Regulations are meeting their stated objectives;
- There is anecdotal evidence that the Regulations have helped to improve; safety, and to help provide access to the Single Market;
- The benefits to manufacturers continue to outweigh the costs;
- The main concern raised by the PIR was a perceived lack of enforcement;
- Enforcement would not be improved by changing the Regulations which would risk gold plating the EU directive.

22. There is further work to be done, however, to increase the effectiveness of the Regulations. The Government will work with HSE and other stakeholders on the following:

- to improve awareness of the Regulations amongst manufacturers and consumers and recent initiatives to develop improved guidance will help to address this.

- to impress on manufacturers the need to address conformity of their product during the design phase and to properly consider the essential health and safety requirements to encourage good engineering practice to reduce development and production costs.

- to continue to work with other EU members states to improve market surveillance and understanding of the requirements of the Machinery Directive.

Title: The Supply of Machinery (Safety) Regulations as amended	Post Implementation Review
PIR No: BEIS031(PIR)-16-RD	**Date: 03/02/2017**
RPC No: RPC-3094(1)-BIS	**Type of regulation: EU**
Lead department or agency: BEIS	**Type of review: Statutory**
Other departments or agencies:	**Date measure came into force: 29/12/2009**
	Recommendation: Keep
Contact for enquiries: **Kevin Lane 020 7215 1774**	**RPC Opinion: Green**

1. What were the policy objectives of the measure?

The Regulations as amended implement European Directive 2006/42/EC as amended by Directive 2009/127/EC on Safety of Machinery into UK law. The Directive is one of many that support the Single Market for goods across the EEA while providing a common level of safety for machinery within scope. It was also necessary to revise the previous directive to improve and clarify the regulatory regime applying to machinery in the light of experience gained by industry and by European market surveillance.

The intended effects are that only machinery that is compliant with the relevant essential health and safety requirements set out in the Regulations are placed on the market or put into service and that industry has a single regulatory framework for the EEA.

The Regulations were further amended in 2011 to address specific problems with pesticide equipment.

On 23 June, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union and the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU. The assumptions used in this post implementation review have been chosen accordingly.

2. What evidence has informed the PIR?

The Department was unaware of any major issues of concern with the Regulations. As such a light touch questionnaire to minimise burdens on stakeholders and other interested parties was considered appropriate.

There have been some issues regarding interpretation of the Directive usually relating to whether a specific product is in or out of scope.These issues are resolved amicably by discussions between Member States Market Surveillance authorities and the European Commission.

To determine views of other interested parties a questionnaire was sent to industry, the UK Government appointed test houses; other member states and the European Commission to seek their views. The details of the questions asked are in Annex 2.

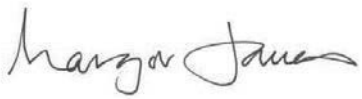
The questions were intended to provide insight into both those aspects that are outside of the UK to amend other than via the European process; we understand the European Commission are intending to commence gathering evidence in 2017 as to whether a revision is required; and also to seek insight into those aspects that are within the direct control of the UK these being aspects of Market Surveillance regime and penalties.

3. To what extent have the policy objectives been achieved?

The Regulations are considered to meet the Policy objectives; they do provide both a well understood regulatory framework for common requirement across the EEA and well understood routes for co-operation between Member States and Market Surveillance Authorities to resolve any issues that may arise.

Sign-off for Post Implementation Review: Minister

I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Signed:  Date: 3 February 2017

Further information sheet

4. What were the original assumptions?

For the Supply of Machinery (Safety) Regulations 2008 IA: The one-off familiarisation cost was £4million; this assumed that there was already a good understanding of the previous legislation and that only changes to the legislation needed to be understood. This is a reasonable assumption as the Regulations implement a European Directive that replaced a previous Directive and that replaced previous National Legislation that required machinery to be safe.

The annual average cost of the regulations was estimated to be £1 million. The average annual benefit was estimated to £2-11 million. The NPV was £45 million. The impact to business was not set out in the impact assessment.

In the updated assessment of this regulation taking into account the information obtained in response to the questionnaire the average annual internal market benefit was estimated to be £3-7m. The one off transition cost for adapting to the requirements of the Regulations was estimated to be £4m.

For the Final Impact Assessment for the Amendment to introduce Pesticides equipment to the Machinery Directive: The one-off transition cost was £0.03million. The average annual cost of the regulation was estimated to be £0.002-0.8million. The average annual benefit was estimated to be £0.4million. The NPV was £3.3million. The direct impact to business was a cost of £0.003million.

5. Were there any unintended consequences?

Examples of issues are differences in understanding of requirements of standards; concerns that standards are inadequate; whether certain products are in or out of scope. The Directive requires Member States and authorities to cooperate with each other to try and resolve issues as they arise and develop a common understanding. The Machinery Directive Administrative Cooperation (Adco) Group which consists of EU market surveillance authorities meets regularly to facilitate this understanding. As well as this, the European Commission chairs a Working Group (WG) to discuss issues of concern regarding the Machinery Directive. As well as MS, industry and trade associations are invited to attend the WG which provides an opportunity for these stakeholders to put forward their views on how the Directive is working. These meetings can also be used by industry and trade associations to enlist the assistance of their home MS authority to raise issue of concerns that they have with other MS and the Commission.

As entrepreneurs are now easily able to supply products globally e.g. online; the requirement for close co-operation and exchange of information between market surveillance authorities is essential in rapidly addressing issues at source rather than a traditional approach at UK borders.

The one key implication of evidence collected during the review also indicates that the process of familiarisation with the requirements of the Regulations by economic operators is much more complex than the model assumed in the initial impact assessment. Factors such as the type of firm, whether small or large, have an influence on the training process. Furthermore, qualitative evidence on enforcement indicates that not all stakeholders are fully aware of the measures and in reality familiarisation is not taking place as uniformly or consistently as we had assumed in the model.

In common with all sectors Conformity Assessment Bodies and some manufacturers are concerned that not enough enforcement of the Regulations has led to some manufacturers placing non-compliant machinery on the market.

Enforcement authorities had difficulties in enforcing regulatory measures when products are placed on market by manufacturers from other Member States or from countries outside the EU. This is because they have no jurisdiction in those territories. The Directive brings co-operation between Member States Authorities to better deal with any problems that arise. The UK takes an active role in these discussions and in reaching solutions.

The European Commission provides funding for market surveillance projects to improve co-operation between member States authorities and to allow specific and targeted enforcement on particular products for which market surveillance have concerns; often industry will provide suggestions for products that they would wish to see targeted by the authorities.

6. Has the evidence identified any opportunities for reducing the burden on business?

Alternatives that are less burdensome to business have not been identified.

7. For EU measures, how does the UK's implementation compare with that in other EU member states in terms of costs to business?

We do not have information on this aspect as none of the member states (MS) that responded provided anything on costs to business. Neither had any carried out a review of the implementation of the Directive in their country.

Post-Implementation Review of 'The Supply of Machinery (Safety) Regulations 2008 as amended by the Supply of Machinery (Safety) (Amendment) Regulations 2011'

1) Scope of this review

This post-implementation review ('PIR') of the Supply of Machinery (Safety) Regulations 2008 as amended by the Supply of Machinery (Safety) (Amendment) Regulations 2011 ('the Regulations') is a statutory requirement, set out in regulation 29 of the Regulations. The review was due on 1st December 2014. Unfortunately the process to conduct a review was only started in December 2014. This PIR reviews both the Supply of Machinery (Safety) Regulations and its subsequent amendment.

This report is required to:

- Set out the objectives of the Regulations,
- Assess the extent to which those objectives are achieved,
- Assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation, and
- Consider how the Directive is implemented in other member states.

Following the approach outlined in 'Guide for Conducting PIRs', this PIR will answer the following questions:

- To what extent is the existing regulation working?
- Is government intervention still required?
- Is the existing form of government regulation still the most appropriate approach?

As this is a PIR of the Implementing Regulations of an EU Directive, the following additional issues are considered:

- The impacts on UK based businesses relative to other European competitors, to ensure UK businesses are not put at a competitive disadvantage.
- Improving transposition in the UK.

2) The objective and intended outcomes of the Regulations

The objective of the Regulations is to transpose Directive 2006/42/EC (as amended by Directive 2009/127/EC) ('the EU Machinery Directive'). The EU Directive has the following main objectives:

1. To ensure the free movement of machinery falling within its scope across the Member States (an 'internal market' objective);
2. To provide for the appropriate level of health and safety for persons in the EU using and coming into contact with machinery (a 'health and safety' objective);
3. 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')

In 2011, the Regulations were amended to cover pesticide application equipment, transposing Directive 2009/127/EC. The overall objectives of the amended European Machinery Directive were broadly unchanged.

The UK Regulations (and the EU Machinery Directive) aimed to achieve its objectives by requiring that machinery conform to the 'essential health and safety requirements' before being first placed on the market or first put into service in the EEA. Since 1993 (when these requirements, set out in The Supply of Machinery (Safety) Regulations 1992, came into force) all new machinery in scope of the then Machinery Directive (Directive 1989/392/EEC, as amended by Directive 1991/368/EEC) has to be designed and constructed to meet common minimum EEA requirements for safety*. It should be said that there was a transitional period which meant that products in conformity the previous UK Regulations could be placed on the market until 31st December 1995, after which the requirements of the 1992 regulations became mandatory.*

To achieve compliance the Responsible Person (normally the manufacturer) who placed the machinery on the market or put it into service must undertake a conformity assessment process meeting all relevant essential health and safety requirements, producing user instructions, and producing a technical file to show how compliance has been achieved and a Declaration of Conformity. For certain specified higher risk products the conformity assessment process will require the use of an independent Notified Body.

The current Regulations build on prior existing EEA legislation regulating machinery safety. The 2008 Regulations and 2011 amendment implement the latest changes in a series of updates to the earlier EU Directive on machinery

3) Assessment of proportionality for level of evidence sought

As set out in the 'Guide for Conducting PIRs', the need for evidence sought should be balanced against other priorities to ensure value for money for taxpayers. The primary consideration for proportionality should be based on the legislation's expected impact on business and the wider economy. Secondary considerations include whether the impacts are contentious or uncertain, and the availability of established data sources.

Expected impact on business and the wider economy, based on the estimates in the Impact Assessments for the 2008 and 2011 Regulations

(i) Impact Assessment of the 2008 Regulations
The Impact Assessment of the 2008 Regulations estimates the following:

Table 1: Costs and Benefits for 2008 Regulations IA

Average Annual Benefit	£2 to £13m (£3-£7m)[1]

1 Bracketed numbers indicated updated cost and benefits assessed in this PIR (p 11)

One off transition cost	£4m (£3m)
Average Annual Cost	£1.2m (n/a)
NPV (Net Benefit)	£45m

The main affected groups are manufacturers and professional importers of machinery in the EU, UK businesses and consumers and UK users of machinery. The main costs are familiarisation and training costs, with some design and build costs. The main benefits are protection of life and property and enhancement of the 'internal market'.

Annual Benefit
The Single Market benefits are estimated to be between £2m to £12m per year. This estimate is based on estimates of the impact of the Internal Market programme (and the Services Directive in particular) on European GDP, data on machinery in UK manufacturing as a proportion of European GDP, and many assumptions about the extent to which the gains can be attributed to the Machinery Directive (MD). (Paragraphs 48 to 61 of the IA outline 3 separate methods to estimate this internal market benefit). This would include possible benefits from the reduction in trade barriers that could be attributed to the single market in machinery.

The Health and Safety benefits are estimated to be between £0.3 and £1m per year. This estimate is based on Health and Safety Executive (HSE) data on accidents, Department for Transport and HSE estimates of the economic cost of fatalities and injuries, and assumptions about the extent to which the reduction can be attributed to the MD and its improvements.

Transition Cost
The familiarisation and training costs are estimated to be £4m one-off and between £0.2m to £0.4m ongoing per year. This is based on estimates of the time required, valuing the time using wage costs (uplifted to include non-wage labour costs), and an estimate of the number of businesses and employees affected.

The costs of providing information on machinery and marking of machinery, providing Technical Files, and conformity assessments were not additional to existing requirements or deemed to be negligible, so no estimates were provided.

Annual Cost
The cost of meeting essential requirements was estimated to be £1m per year. Most of the requirements were not expected to result in significant costs because much modern machinery already meets many of the requirements, with the sole exception of guard fixings.

(ii) Impact Assessment of the 2011 Amendment Regulations

Table 2: Costs and Benefits for Amendment IA

Average Annual Benefit	£0.002m- £0.8m (£0.0003-£0.00045m)[2]
One off transition cost	£0.03 m (n/a)
NPV (Net Benefit)	£3m

Transition Cost
The Impact Assessment of the 2011 amendment to the Regulations estimates that there is a one-off transition cost of £0.03m for re-design and construction to manufacturers of pesticide application equipment that are not already compliant with the new legislation.

Annual Benefit
The average annual benefit of the 2011 amendment to the Regulations is estimated to be £0.002m- £0.8m, in reduced costs to users from more efficient use of pesticides in better designed equipment, and reduced rates of human injuries from lower pesticide exposure. Environmental benefits and Internal Market benefits are not estimated. The NPV is estimated to be £3.3m. The Direct Impact on Business (EANCB) was estimated to be 0.003m per annum.

Secondary considerations
The Regulations are not high profile or contentious. The need for essential health and safety requirements for machinery is well-accepted by stakeholders and the general public. Although businesses have often approached BIS with certain concerns with the Regulations these are generally with regard to unfair competition from non-compliant products and issues of interpretation of supporting standards. Nor are the Regulations particularly novel, risky or based on untested assumptions. The manufacturing industry has always looked to place safe products on the market due to the financial impact of civil damages should a product cause injury. Most of the requirements of the Regulations were not new in that they followed existing best practice, and for that reason much of the machinery placed on the market would have been able to meet the requirements before the Regulations came into force. The Directive has provided a continuous and comprehensive legislative framework for machinery product design and construction for health and safety and free movement since 1992. The UK has imposed obligations for safety of machinery prior to the current European legislation.

Finally, although a rerun of the IA was conducted (see section 5B), it must be noted that there were limitations in this analysis. There is a lack of established and consistent data sources to provide evidence of the impact of the Regulations, and substantial additional BIS resources would be required to make an appreciable difference to the quality of evidence collected. The nature and scope of the Regulations makes it difficult to go beyond high level assumptions about the counterfactual and the extent to which observed benefits could be causally attributed to the Regulations and the MD. This is particularly the case for estimates of the benefits, for example:

2 Bracketed numbers indicated updated cost and benefits assessed in this PIR (p 9)

- In attempting to estimate the Internal Market benefits, the observed changes to European and UK GDP were almost certainly impacted by factors aside from the Regulations. It is almost impossible (without making crude assumptions) to separate out the impacts of these myriad factors and to isolate the impact of the Regulations only.
- Similarly, for the Health and Safety benefits, the Regulations are comprehensive, apply to wide categories of machinery and came into force across the whole UK. Therefore, it is difficult to identify a relevant comparison (either a category of machinery or a geographical area for which the Regulations did not apply) which we could use to estimate what would have happened otherwise.
- Moreover, evidence suggests that familiarisation is more complex than the model assumed in the initial impact assessment. Factors such as the size of the firm have an influence on the training process. Furthermore, qualitative evidence on enforcement indicates that not all stakeholders are fully aware of the need for familiarisation.

In future iterations of appraisal and evaluation in policy making, it would worth factoring in some of the issues raised, including the size of the firm carrying out familiarisation training, or ways of separating out impacts on the internal market. However it is not the purpose of product safety legislation to educate and train industry in what should be good engineering practice; the Regulator should be able to assume that those placing products onto the market are technically competent to undertake the design, manufacture and conformity assessment of products,

Assessment of proportionality
In view of the considerations above, particularly the low estimated cost to business and the overall impact of the Regulations (combined NPV below £50m), a low level of evidence, as described in Section 2.2 of 'Guide to Conducting PIRs', is appropriate and proportionate for this PIR.

4) Evidence collection and methodology

BIS conducted a light-touch consultation of the principal affected stakeholders, collating evidence of known views and experiences in a time-efficient way. The full set of questions is in Annex A.

We contacted the following groups of UK stakeholders:
- HSE, the enforcement authority for the Regulations in workplaces,
- The East of England Group of Association of Chief Trading Standards Officers (ACTSO), the enforcement authorities for the Regulations for consumers and non-workplaces,
- The Machinery Directive Industry Forum, an informal group of larger manufacturers and trade associations affected by the Regulations, and
- The UK Group of Machinery Notified Bodies, who assess the conformity of machinery with the requirements of the Regulations.

We received written two responses from enforcement authorities, from four Notified Bodies[3], and one verbal response from a manufacturer. Although we only received this one response, the comments made matched those that had been made by other manufacturers and by correspondence over the last few years.

As these are UK Regulations implementing the EU Machinery Directive, it was also necessary to gather some evidence of how other Member States have implemented the Directive and their experience with it. See section 8 below on the 'Views of Member States'.

5a) Are the existing regulations working?

This section sets out BIS's assessment of the extent to which the Regulations have achieved and are achieving their objectives. It also considers whether there have been any unintended consequences of the Regulations.

Overall, two Notified Bodies agreed that the Regulations generally meet their objectives well. One Notified Body stated that the Regulations provide a fairly well-defined mechanism for businesses to consider safety in their design and manufacturing processes, and demonstrate that they have done so. One enforcement authority considers that the Regulations provide a comprehensive framework whilst permitting innovation and choice in the route to compliance.

On the internal market objective in particular, three Notified Bodies considered that the free movement of goods has been facilitated by the Regulations; they considered the Regulations provide a good framework for UK businesses to produce machinery which will be acceptable in other EU countries.

On the health and safety objective, one enforcement authority considers that the existing framework is robust, with enforcement tools available, including the triable either way option on prosecution for the significant health and safety issues. Over recent years a number of successful prosecutions have taken place on manufacturers that had placed non-compliant products on the market, although the penalties available to enforcement authorities may not always be considered a deterrent to manufacturers, especially the larger enterprises, reputational damage is just as likely to act as a deterrent. Companies will want therefore to avoid court cases if at all possible. Although some stakeholders consider that not enough enforcement is taking place, UK enforcement authorities can and do take action where enough evidence is provided to justify this. The UK co-operates with other Member States (MS) to share information regarding enforcement action taken in the UK. This helps to alert other MS to potential problems in their territories. In turn MS will raise issues with the UK.

Some problems experienced by UK manufacturers when placing products on the market can be down to local differences in interpretation of the Machinery

3 The two responses from enforcement authorities included one from an umbrella representational body. The four Notified Bodies represent around 18% of the Machinery Notified Bodies in the UK

Directive. The requirement for MS authorities to work together in working out these differences and developing guidance for market surveillance authorities and businesses helps to try and ensure that enforcement is carried out in a consistent manner.

On the environmental and animal safety objectives, two Notified Bodies stated that any improvement in the environment as a result of the regulations is difficult to assess. None of the other stakeholders commented on this aspect of the Regulations.

5b) Assessment of the actual costs and benefits of the Regulations

Overall, as with the original IAs, the coverage and quality of the available evidence and data collection for this PIR provided by stakeholders is relatively low. With the low level of available evidence, it is not possible to quantify the actual costs and benefits of the Regulations business have been asked for data but are unable to provide it which suggests the cost burden is small.

All stakeholders agree that it is difficult to estimate the costs and benefits to business of complying with the Regulations. The Regulations do not require manufacturers to provide any data to BIS or anyone else on the costs and benefits of complying with the regulations. Obtaining additional information as part of this exercise on costs and benefits could only be done where manufacturers were prepared to provide this on a voluntary basis.

Costs
On costs to businesses of compliance, two Notified Bodies consider that the additional costs of compliance (above what should be normal parts of the design process and maintaining technical files) are not large, especially once businesses are aware of how to ensure conformity with the requirements.

Benefits
On benefits to businesses of compliance, one Notified Body states that most responsible manufacturers are keen to apply the regulations correctly and welcome the guidance given by the regulations, because it gives assurance that they are doing things correctly and can be considered to have applied due diligence to the safety-related aspects of the equipment they sell. Businesses benefit from selling compliant products which are safe and do not cause harm, which have a right to free movement throughout the European market. The manufacturers surveyed did not comment on this issue.

There have been are some unintended consequences not considered in the IAs which is some cases may have increased costs to businesses and these are considered in the following section.

As part of conducting the Post Implementation Review, a reassessment of the cost and benefits using the original impact assessments were made using updated information. Qualitative evidence collected in the Post Implementation Review was not used in this update as the evidence could not

be extrapolated to a macro level, although some of the insights gathered have been included to caveat the assessment.

Monetised costs and benefits updated from the original impact assessments

(i) Updated Cost and Benefit assessment of the 2008 Regulations (see Table 1)

Transitional
Familiarisation and training costs:-
Using newly updated ASHE Data: we find that in 2009, Manufacture of machinery and equipment n.e.c. industry (SIC Code 28) employed approximately 228,000 people. The mean hourly wage for managers is £22.17, this increased to £26.80 with the non-wage labour cost uplift (Eurostat, 2009). We assume, as in the original impact assessment, that the new legislation affects only 10% of the employees, and that approximately 5 hours are required to familiarise with the legislation. This derives an estimated one off transition cost of £3 million.

The original IA also suggested that ongoing annual refresh training on the legislation might be required, and this was estimated to be approximately 5-10% of the original one off cost £0.15-£0.3million. The original IA also suggested a £1million cost of meeting essential requirement of the MD, this information has not been updated by the HSE and it was not deemed proportionate to collect this information for this PIR.

Recurring
Internal Market Benefits
The European Commission has estimated EU GDP was more than 2 per cent, or £170 billion (2009 prices), higher in 2008 than it would have been if the Single Market had not been launched in 1992. Using the most recent data, UK GDP is approximately 13% of the EU economy (nominal GDP 2014, IMF) and that manufacturing represents 15% of total GDP (ONS, 2015), and machinery and equipment represents 6% of manufacturing (ONS, 2015). The internal market can be assumed to have had an impact of £200 million. There was no proxy which we could use to find how much of this could be attributed directly to the directive. In light of this limitation, we have followed the methodology used in the original IA, we assume that 0.5-2 percent of the impact can be attributed to the improvement in the directive, this leads to a benefit of approximately £1- £4 million per annum.
Health and Safety Benefits

Health and Safety benefits were discussed both in the original IA and the amendment IA. HSE data for fatal injuries from coming in contact from moving machinery, across all sectors of the economy has fallen from approximately 19 per annum in the 1995/6 to 2005/6 period to an average of 10 per annum in 2009/10 to 2013/14 period. Although, it is not possible from this evidence to determine the extent to which the MD contributed to this reduction given the range of factors that could impact on the number of injuries, if we follow the assumption that was made in the Supply of Machinery (Safety) Regulations

impact assessment that the directive contributed in the region of 10 to 20 percent reduction in average number of fatalities, then this would imply a reduction in the average number of fatalities of just under 1-2 per annum. The economic cost of fatalities is given at £1.6million[4]: this leads to an overall benefit of between £1.6- £3.2million per annum.

For non-fatal accidents, Labour Force Survey data indicate that accidents caused by contact with moving machinery averaged 13,000 for the 2006/07 - 2008/09 period, the most recent indicator indicate this figure has fallen to 11,000 (for 2011/12-2013/14), this implies an estimated reduction of up to 200- 400 accidents per annum attributed to the directive: using the HSE estimation of cost of accidents to be £300, this derives an economic benefit of £60,000-£120,000 per annum.

(ii) Updated assessment of the 2011 Amendment Regulations (see Table 2)

Transition
The Pesticide Amendment IA calculated that the transition cost of adaption in design or production cost is approximately £0.03m to £0.3m (para 27). However, the data needed to estimate this cost is no longer available. Furthermore, it is worth noting that this is a sunk cost, and therefore not relevant for assessing the best option going forward for this particular regulation: therefore, it is viewed as disproportionate, to collect the evidence necessary to update this information in this particular case.

Recurring
For the 2011 Pesticide Amendment, a further health and safety benefit was estimated. Looking at the data on illness linked to pesticide exposure in the published Pesticide Impact Report[5]: to assess the benefits of the measure, we analysed the step change between the data prior to 2009 and post 2009.

	Mild injury	Moderate injury
2008/09	5	3
2009/10	15	2
2010/11	6	0
2011/12	5.5	0
2012/13	6	0

As in the original IA, if we make the assumption that half the reduction in incidents reported can be attributed to the measure, then the step change can be estimated to be 1-1.5 for moderate incidents and up to 4.5 for mild incidents. If the estimation £300 cost to injuries is used again, this leads to an economic benefit of £300-450 per year[6]. This leads to an economic benefit of £300-£450 per year.

4 http://www.hse.gov.uk/risk/theory/alarpcheck.htm#footnotes (up weighted to 2009 prices)
5 http://www.hse.gov.uk/agriculture/resources/pesticides
6 http://www.hse.gov.uk/risk/theory/alarpcheck.htm#footnotes

Other benefits

Due to lack of availability of data, we were unable to measure that reduction in cost to users in inefficient use due to the introduction of the Pesticide amendment. This was assessed to be £400,000 per year in the original IA.

6) What if any have been the unintended consequences? What are the areas for improvement?

One Notified Body notes that a lack of enforcement means that compliant manufacturers may be put at a financial or competitive disadvantage to less scrupulous manufacturers.

Both an enforcement authority and one Notified Body noted the very high cost of accessing harmonised standards as a significant cost to business. The enforcement authority notes that the cost is often cited as prohibitive to all but the larger businesses. The Notified Body states that there are cheaper ways to buy or view standards in the international market, rather than via the British Standards Institute, but these are not widely known. This limits business access to the vast amount of useful design information available in standards. Though the use of standards is voluntary their use does simplify confidence of compliance; currently this issue is receiving a lot of attention from the European Commission and the Member States to investigate simplifying access, particularly from SMEs.

There is also a significant cost in understanding and using standards, and both an enforcement authority and one Notified Body focused on one example in particular. The Notified Body stated that safety-related control system requirements based on EN 13849/62061 in particular are very complex and widely misunderstood and misapplied. It notes that ineffective equipment is often added to machines, increasing cost but not actually improving safety performance. In the respondent's opinion, this particular standard is not achieving its objectives because it is too complex and badly written. Similarly, the respondent from the enforcement authority also cites EN ISO 13849-1 on control systems as an example of a particularly difficult standard to understand and requires significant expertise to implement, despite the fact that it is a basic fundamental standard for almost all machines and essential for any with complex control and safety systems. Though these comments are not relevant to the regulatory framework these comments demonstrate the lack of technical competence in industry in relation to the incorporation of high and innovative technology; also the lack of interconnect through BSI from the technical committee comprising usually manufacturers and users of products with those likely to use the standard who are of less than average competence. This is confirmed by the observation by two Notified Bodies that many businesses are not aware of the state of the art and standards that are applicable to their equipment. One of the Notified Bodies considers that many manufacturers choose to use a harmonised standard as a way to comply with the Directive, and that the use of standards often inhibits innovation by giving a proscribed route to design. Best standards drafting requires the setting of

objectives and testing for the compliance with the objectives; poor drafting sets constructional requirements while much work has been done in pressing standardisers to improve drafting more work is clearly needed. BIS along with the European Commission, other Member States and the European Standards Bodies, including BSI, are actively encouraging better drafting from standardization technical committees.

Enforcement
All four Notified Bodies and the one manufacturer that responded stated that enforcement of the Regulations could be strengthened, particularly enforcement activity focused on manufacturers and distributors who place unsafe equipment on the market, rather than only on users who have accidents. It seems there is a lack of awareness of the activity of the enforcement authorities in relation to investigations of products on the markets BIS and they need to do more to publicise their successes and interventions.

One Notified Body expressed concern that the system of declaring compliance is open to abuse. Without proactive enforcement of the Regulations, safety is only improved by those manufacturers that bother to observe the requirements. As the NB was of the view that no checks are made to ensure that machinery being placed on the market is compliant, the interpretation of the requirements is left to manufacturers, who may choose to ignore or flexibly interpret the minimum requirements. As an example of this, one Notified Body alleged that in some cases, manufacturers are applying standards that do not relate to the equipment they make. This view from NBs may be biased as they have a vested interest in mandatory 3rd party testing. Self-assessment is used in other product safety areas and is now considered appropriate for this type of equipment. HSE do undertake a number of investigations on manufacturers to determine compliance; they are currently trialling a new system whereby the cost of investigations and any follow up action is chargeable where there is non-compliance.

One Notified Body went further and stated that, even when reactive enforcement occurs after an accident or prosecution, the fines are too low to deter manufacturers from breaching the Regulations. The HSE have also expressed concerns at the fines imposed by the Courts. The Ministry of Justice have also amended all penalties for England Wales to remove the maximum limits for all Courts. While this provides the Courts with the possibility to impose penalties that stakeholders consider to be more appropriate it will down to the Courts to decide what penalty they actually impose.

In the view of enforcement authorities, the main challenges facing them are the limited resources and scarce expertise to conduct proactive enforcement and market surveillance activity. Compliance testing is difficult and time-consuming, even with access to expertise. Proactive market surveillance activity, including at the borders, is not easy as many industrial products are not amenable to examination and sampling at that point (may need assembling and putting into use first to be able to evaluate).

Another enforcement authority notes that typically Trading Standards Officers lack experience and knowledge of the technical aspects of the Regulations to proactively enforce the Regulations. As a result of this, it is difficult for enforcement authorities to assess the overall level of compliance to the Regulations. In many cases, the authorities only get involved if there has been an incident. However, one enforcement authority notes that the level of compliance varies greatly across manufacturers, and that the overall level of compliance has probably not changed much since 1992. It further noted that enforcement authorities continue to encourage compliance through education and enforcement, but this may have been counteracted by the increase in products from non-EU sources, which may be less aware of the EU system. These issues are likely to be at least partly addressed by HSE charging for investigations where non-conformity is identified and by the recent removal of maximum limits for fines enabling stronger fines to be imposed by the Courts which may now become persuasive. There is also a review of Trading Standards Services in progress that may address some of the concerns raised here.

Importers and distributors
Three Notified Bodies noted that there needs to be a stronger emphasis on the responsibilities of importers and distributors. In the view of one Notified Body, direct purchase of machinery from outside the EU, which often does not meet EU safety requirements, is increasing, and where an importer/distributor is involved, they often have no idea of the safety requirements. Similarly, one enforcement authority states that one of the main challenges it faces is that many fundamental duty holders are outside legal jurisdiction.

7) Is government intervention still required? Is the existing form of government regulation still the most appropriate approach?

This section sets out BIS's assessment of whether the Regulation's objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

From our updated assessment of the costs and benefits, the ongoing benefits still exceeds the ongoing cost (see Section 5B); the Regulations' objectives therefore remain appropriate. The UK remains committed to improving health and safety and environmental and animal protection.

The objectives of the Regulations could not be achieved with a system that imposes less regulation; the current Regulations are still considered to set a light touch and impose minimal requirements over and above good engineering practice. The concerns with the Regulations raised by all responding stakeholders consider that more enforcement of the existing regulations is required rather than a change being needed in the Regulations. The IA for the 2008 Regulations did not consider alternatives to regulation. There is a role for Government and enforcement authorities to improve awareness of the requirements of the regulations which could help reduce incidents of non-compliance by manufacturers.

The IA of the 2011 amendment considered an alternative to regulation, by providing guidance to manufacturers to allow them to pursue voluntary agreements to comply with EU standards. The IA considered that, although it is likely that companies will adopt EU standards regardless of UK enforcement, not regulating may leave some UK companies at a competitive disadvantage in the internal market if they do not adopt EU standards. Furthermore, the UK would face reputational risks and risk of infraction proceedings for not implementing the EU Directive. It was also considered that there would be higher non-monetised costs to users of pesticides application equipment (PAE) due to less efficient use of pesticides.

At present the changes the UK can make to improve the Regulations are primarily limited to penalties and the enforcement regime. The technical and administrative requirements are set out in an EU Directive that will not be revised for several years. Overall BIS does not consider there is a need to amend the Regulations. Issues highlighted by the PIR as needing attention are related to the need for better *enforcement* of the UK Regulations which is a performance issue of the existing enforcement bodies (HSE & Trading Standards) who remain the most appropriate bodies in the UK. As noted previously both the HSE initiative with charging for investigations where non-conformity is identified and the review of Trading Standards may assist in improving compliance and in undertaking increased proactive inspections.

7) EU-derived regulations

This section considers how the Directive is implemented in other member states; the impacts on UK based businesses relative to other European competitors and whether UK businesses are put at a competitive disadvantage by the Regulations; and improving transposition in the UK.

One Notified Body reported that they were aware of some rare cases where national interpretations and practice vary, and a few problems with differing interpretations or incorrect application of the Directive by enforcement offices outside the UK.

The UK is convinced that there is no gold-plating in the implementing Regulations; industry and enforcement authorities in their EU activities use the Directive text and therefore any anomalies would have been identified. Unintentional gold-plating was identified in the 2008 Regulations but was subsequently removed in the 2011 amendment. This removed a provision in relation to the duties of those putting machinery into service, which duplicated obligations imposed under other health and safety legislation

UK authorities have received occasional complaints from UK businesses (not as part of this review) about difficulties in placing products they consider to be compliant on the market in other MS. These problems tend to be differing interpretations of the requirements by MS. These problems have been resolved by the UK working with other MS through co-operation facilitated by the European Commission and via the independent SOLVIT initiative.

8) Views of Member States

We received comments from four MS regarding the implementation of the Machinery Directive in their country.

Implementation
There is no common approach to implementation some, like the UK, use a single implementing piece of legislation; while others use two or more pieces. The approach being what works best for them.

Objectives of Directive
There were differing views as to whether the objectives of the MD were being fully met. The general consensus is that the MD is achieving its objectives but should be fully aligned to the New Legislative Framework. Views were expressed that while the health and safety aspects were good enough and the single market was functioning well the protection of the Union required all Member States to provide adequate resources for market surveillance and publicity. Some concerns were expressed with the marketing of products being poorly covered by the MD, however this is to be expected as marketing is fully dealt with in other Union legislation. It was a concern that due to a lack of information exchange between authorities the necessary levels of safety and health protection are not always achieved. There were mixed views as to whether machines are more environmentally friendly.

Enforcement in other Member States
Operational procedures and resources vary between Member States and as such expectations with regard to co-operation differ leaving some Member States considering co-operation is not always as good as could be hoped but at least there are channels for co-operation which are improved with experience. Of particular note being the ICSMS secure internet system allowing the passing of information between Member States enforcement authorities electronically.

Particular concerns highlighted are e-commerce and a need to tighten control at ports. The UK does have an initiative with Trading Standards working closely with HM Customs which is proving very successful.

One MS said that it had been difficult to convince market players to accept that the changes introduced by the Directive were designed to improve safety while at the same time promoting the single market for goods.

Review
None of the MS had carried out a review of the implementation of the MD in their country.

Views of stakeholders in other Member States
One MS said that stakeholders had not made any complaints to them about the Directive. Another said that stakeholders are generally happy with the Directive and see advantages to it for trading products. Complaints about

other MS making extra requirements that are technical barriers to trade for products have fallen away since the Directive was introduced. One MS said that generally speaking manufacturers are aware of their obligations.

9) Comments from the European Commission

No assessment of the transposition of the Directive by MS has been carried out. Neither has a review of the Machinery Directive been carried out. However, an evaluation study into the Machinery Directive was launched in 2016. This is the start of the process to review the Directive and consider any possible revision.

10) Next Steps

The Regulations should remain as is (renewal), for the following reasons:

- They must remain in place to support our obligation to implement the EU Machinery Directive.
- The policy is on course to achieve its objectives and key success criteria have been met.
- Compliance levels are sufficient to support achievement of objectives.
- Government intervention is still required. If intervention was withdrawn, the UK would risk reputational damage and infraction proceedings. UK companies may be placed at a competitive disadvantage in the internal market if they do not adopt EU standards. Withdrawing government intervention may lead to some deterioration in health and safety and environmental protection.
- As assessed by the IAs costs have been proportionate to benefits.
- An updated assessment of the IAs has shown that the ongoing benefits continue to exceed ongoing costs.
- Alternatives that are less burdensome to business have not been identified. Amending the existing UK Regulations to strengthen the penalties is not warranted now that Ministry of Justice have remove d the upper limit for penalties.
- While more robust enforcement is called for HSE as principal enforcer with Trading Standards for consumer products remain the most appropriate UK enforcers. The evaluation of the HSE initiative to charge for investigations should be taken into consideration before any initiative to change HSE enforcement activity.
- To consider how the Courts can be encouraged to apply penalties that are persuasive.
- On completion of the review of the Trading Standards Services consider whether any review of their enforcement activity is required.

There is a role for government to improve awareness of the Regulations among business and consumers. Two Notified Bodies state that manufacturers often address conformity with the Regulations after their machine has already been designed and built. By this time, it is too late and often expensive, difficult or impossible to correct the mistake. It is vital that conformity and especially risk assessment forms part of the design process,

and more education and improved awareness among manufacturers is needed.

A common concern raised by stakeholders was that there was not enough enforcement. Industry wants a level playing field and do expect robust enforcement to ensure all are following the same requirements. Government needs to consider ways to improve enforcement that minimise burdens on compliant manufacturers, but bites on non-compliant manufacturers, to ensure the cost of non-compliance exceeds the cost of compliance. The impact of the removal of maximum limits for fines and the HSE charging for investigations needs to be considered once these initiatives have been running sufficiently long to evaluate their impact.

Other EU Member States raised concerns about enforcement of the MD similar to those experienced in the UK. It is therefore important that MS continue to work together to improve enforcement so that any difficulties can be promptly resolved to improve the operation of the single market for all stakeholders.

Annex 2

Questions for Stakeholders

1) To what extent have the Regulations met their policy objectives? (e.g. to improve safety; facilitate the free movement of goods and improve the environment)
2) What is your assessment of the costs and benefits to your business of complying with the Regulations on a yearly basis?
3) What are the main challenges faced by businesses in ensuring their products meet the requirements of the Regulations?
4) If you are a Smaller business (up to 50 employees) or Micro business (up to 10 employees) please let us have your assessment as to whether the burden of the Regulations falls disproportionately on your business compared to larger organisations?
5) If there is anything else you like to mention in connection with the Regulations not covered above please let us know.

Questions for Notified Bodies

1) To what extent have the Regulations met their policy objectives? (e.g. to improve safety; facilitate the free movement of goods and improve the environment)
2) What is your assessment of the costs and benefits to business of complying with the Regulations on a yearly basis?
3) What are the main challenges faced by businesses in ensuring their products meet the requirements of the Regulations?
4) As a Notified Body what are the main challenges you are faced with in helping manufacturers to comply with the Regulations?
5) If there is anything else you would like to mention in connection with the Regulations not covered above please let us know.

Questions for Enforcement Authorities

1) To what extent have the Regulations met their policy objectives? (e.g. to improve safety; facilitate the free movement of goods and improve the environment)
2) What is your assessment of the costs and benefits to business of complying with the Regulations on a yearly basis?
3) What are the main challenges faced by you as an enforcement authority in ensuring that products meet the requirements of the Regulations?
4) a) As an enforcement authority what is your assessment of level of compliance of products under the Regulations? b) Has this level of compliance changed since the Regulations were introduced?
5) If there is anything else you would like to mention in connection with the Regulations not covered above please let us know.

Questions were sent to Member States covering:

1. Implementation,
2. Whether objectives of the Directive have been achieved
3. Any enforcement concerns
4. Whether a review had been carried out

5. Views of stakeholders

Questions were sent to the European Commission covering:

1. Implementation of the Directive by MS
2. Whether the objectives of the Directive have been achieved
3. Implementation and enforcement
4. Future plans for the Directive
5. Possible gold plating by MS
6. Compliance of manufacturers