

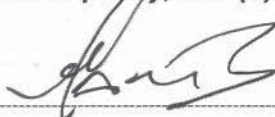
Title: Final Impact Assessment for Pesticides Amendment to the Machinery Directive Lead department or agency: BIS Other departments or agencies: HSE	Impact Assessment (IA)
	IA No: BIS0279
	Date: 20/05/2011
	Stage: Final
	Source of intervention: EU
	Type of measure: Secondary legislation
Contact for enquiries: Krupa Kothari	

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary? The IA considers an amendment to the Machinery Directive with regards to Pesticide Application Equipment. Government intervention at EU level is necessary to: i) establish the legal framework for the effective functioning of the 'internal market' in Pesticides Application Equipment (PAE) - to reduce barriers to trade and uncertainty around requirements through harmonisation of standards and provision of guidance. ii) correct market failures: - Information failures on requirements around PAE standards lead to PAE being produced to different standards across Member States. - negative externalities associated with increased risk of environmental and health detriment via the overuse of pesticides from PAE, above the amount necessary, which mean that the social costs can exceed the private costs.	
What are the policy objectives and the intended effects? Support BIS's departmental priority number 3: Stimulate exports and inward investment by promoting open and fair global markets. Support Defra's structural reform priority number 2: Help to enhance the environment and biodiversity to improve quality of life - to enhance and protect the natural environment. Key objectives are to achieve, at least cost to business: -a 'level playing field' across the Internal Market in PAE and -an appropriate level of environmental (and human/animal health) protection minimising the risk of higher than necessary dumping of pesticides in the environment caused by the use of PAE.	
What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base) 1. Do nothing 2. Pesticides Amendment in the Machinery Directive Option 2 is the Governments preferred option. An Initial IA from December 2008 assessed an alternative amendment to the Directive i.e. the Inclusion of PAE into Annex IV of the Machinery Directive. This option was not favoured by the Government due to higher associated cost to business. The Governments' preferred option does not require new regulation - rather an amendment to existing regulation. The pesticides amendment to the Machinery Directive was published in the Official Journal of the EU on 25.11.09 and must be transposed into Member State law by 15.06.11. The provisions set out in the amendment apply in Member states from the transposition deadline of 15.12.11. This is in line with the Government's preferred policy.	
Will the policy be reviewed? It will be reviewed. If applicable, set review date: 12/2014 What is the basis for this review? Duty to review. If applicable, set sunset clause date: Month/Year	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

SELECT SIGNATORY Sign-off For final proposal stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible SELECT SIGNATORY:  Date: 5/9/11

Summary: Analysis and Evidence

Policy Option 1

Description:

Do Nothing.

Price Base Year 2011	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	High:	Best Estimate:

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

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

This is a hypothetical counterfactual therefore monetised costs are zero

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

Compared to option 2 there will be an increased risk of adverse impacts on human health and the environment. Relative to option 2, there will be higher costs to users of PAE due to less efficient use of pesticides as well as negative repercussions on trade and competition. Reputational risk and risk of infraction proceedings against the UK for not implementing a European level agreed amendment.

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

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

This is a hypothetical counterfactual - monetised benefits are zero

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

Compared to option 2, manufacturers of PAE would not incur the transition cost associated with the adaption of designs to ensure they were compliant with new guidance as set out in the amendment.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5
Reputational risk and risk of infraction proceedings against the UK for not implementing Pesticides Amendment to the Machinery Directive.		

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: 0	Benefits: 0	Net: 0	No	NA

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?	United Kingdom				
From what date will the policy be implemented?	15/12/2011				
Which organisation(s) will enforce the policy?	HSE/NIHSE/LAs				
What is the annual change in enforcement cost (£m)?	£0				
Does enforcement comply with Hampton principles?	Yes				
Does implementation go beyond minimum EU requirements?	No				
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)	Traded: N/A		Non-traded: N/A		
Does the proposal have an impact on competition?	Yes				
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?	Costs: 0		Benefits: 0		
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	Micro	< 20	Small	Medium	Large
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

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

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

Does your policy option/proposal have an impact on...?	Impact	Page ref within IA
Statutory equality duties ¹ Statutory Equality Duties Impact Test guidance	No	15
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	15
Small firms Small Firms Impact Test guidance	No	15
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	16
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	16
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	16
Human rights Human Rights Impact Test guidance	No	16
Justice system Justice Impact Test guidance	No	16
Rural proofing Rural Proofing Impact Test guidance	No	16
Sustainable development Sustainable Development Impact Test guidance	No	16

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

Summary: Analysis and Evidence

Policy Option 2

Description:

Implementation of amendment to Machinery Directive relating to pesticides application equipment

Price Base Year 2011	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0.02	High: 6.4	Best Estimate: 3.3
COSTS (£m)					
		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)	
Low		0	optional	0	
High		0.29	optional	0.29	
Best Estimate		0.03	optional	0.03	
Description and scale of key monetised costs by 'main affected groups'					
Transition costs for re-design and construction to manufacturers of PAE that are not already compliant with the new legislation. These costs are only incurred in year one and may be passed on to users of PAE.					
Other key non-monetised costs by 'main affected groups'					
Reoccurring costs to manufacturers of PAE associated with meeting additional obligations of conformity assessment related to environmental protection. As PAE manufacturers already undergo a self certification process and conformity assessment, it is unlikely this will constitute much of a change - therefore zero additional cost is assumed.					
BENEFITS (£m)					
		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)	
Low		0	0.002	0.02	
High		0	0.8	6.7	
Best Estimate		0	0.4	3.4	
Description and scale of key monetised benefits by 'main affected groups'					
Reduced cost to users from more efficient use of plant production products (PPP) i.e. pesticides in better designed PAE. Benefit of reduced rate of human injuries associated with pesticide exposure due to improved PAE machinery.					
Other key non-monetised benefits by 'main affected groups'					
Environmental benefits to surrounding water and biodiversity sources from more efficient / targeted use of pesticides. Internal Market benefits for PAE with a level playing field across Member States on standards for manufacture of PAE.					
Key assumptions/sensitivities/risks					Discount rate (%) 3.5
Benefits: *The number of new PAE on market per annum affected by the amendment is based on an estimate of 38000 stock of PAE in the UK (EU IA) that are assumed to have a 12 year lifespan. *Equal usage of Pesticides across all PAE on market is assumed. *Projected volume and sales value of pesticide reflected in 2009 levels. *Compliance rate for existing PAE as per new requirements is 80% to 100% of PAE coming onto the market. *Rate of injuries derived from pesticide incidents and accidents report. *Transition cost derived from increase in production cost of 1% to 5%. *No additional costs from higher conformity requirements.					
Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as	
Costs: 0.003	Benefits: 0	Net: 0.003	No	NA	

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?		United Kingdom			
From what date will the policy be implemented?		15/12/2011			
Which organisation(s) will enforce the policy?		HSE/NIHSE/LA			
What is the annual change in enforcement cost (£m)?		0			
Does enforcement comply with Hampton principles?		Yes			
Does implementation go beyond minimum EU requirements?		No			
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)		Traded: N/A		Non-traded: N/A	
Does the proposal have an impact on competition?		Yes			
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?		Costs: 0%		Benefits: 0%	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	Micro	< 20	Small	Medium	Large
Are any of these organisations exempt?	No	No	No	No	No

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Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	14
Wider environmental issues Wider Environmental Issues Impact Test guidance	Yes	14
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	15
Human rights Human Rights Impact Test guidance	No	15
Justice system Justice Impact Test guidance	No	15
Rural proofing Rural Proofing Impact Test guidance	Yes	15
Sustainable development Sustainable Development Impact Test guidance	No	15

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

Evidence Base (for summary sheets) – Notes

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

References

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

No.	Legislation or publication
1	Crop Protection Association, 2009 data on pesticide usage and price: http://www.cropprotectionassociation.com/DocFrame/DocView.asp?id=681&sec=-1
2	BIPRO Report (October 2004) http://ec.europa.eu/environment/ppps/pdf/bipro_ppp_final_report.pdf
3	Thematic Strategy on the sustainable use of pesticides (2006) http://ec.europa.eu/environment/ppps/pdf/sec_2006_0894.pdf
4	Machinery Directive (Directive 2006/42/EC) http://www.legislation.gov.uk/ukxi/2008/1597/contents/made
5	Pesticide Incidents Report, Field Operations Directorate investigations, 1 April 2009 – 31 March 2010 http://www.hse.gov.uk/agriculture/resources/pesticides.htm

Evidence Base

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

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

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

	Y ₀	Y ₁	Y ₂	Y ₃	Y ₄	Y ₅	Y ₆	Y ₇	Y ₈	Y ₉
Transition costs	0.03	0	0	0	0	0	0	0	0	0
Annual recurring cost	0	0	0	0	0	0	0	0	0	0
Total annual costs	0.03	0	0	0	0	0	0	0	0	0
Transition benefits	0	0	0	0	0	0	0	0	0	0
Annual recurring benefits	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Total annual benefits	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4

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

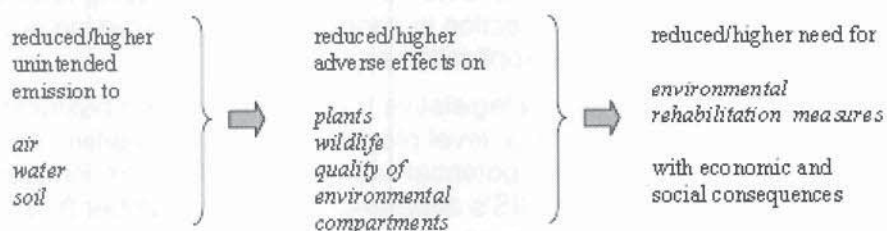


Microsoft Office
Excel Worksheet

Evidence Base (for summary sheets)

1. The European Parliament and Council's Sixth Community Environment Action Programme (6th EAP, July 2002) established an overarching aim of further reducing the negative impacts on human health and the environment from the use of pesticides. Whilst recognising the importance of pesticides to crop protection, it called for a more sustainable use of pesticides in the future. The consequence of this was the European Commission's Communication *A Thematic Strategy on the Sustainable Use of Pesticides* (2006).
2. This Thematic Strategy set out five main objectives, the first of which, "...to minimise risks to health and the environment from the use of pesticides.", is the basis of the Directive to amend the Machinery Directive with respect to machinery for pesticide application. The amendment to the Directive will introduce "...essential environmental protection requirements for the design and construction of new machinery for pesticide application." (Official Journal of the EU, Directive 2006/42/EC).
3. The Commissions IA noted that European intervention was necessary now to prevent the continuation of "...different levels of protection of health and environment and diverging conditions for the main users of pesticides (i.e. farmers) in the Member States, which would be against one of the fundamental objectives of the Treaty. Currently, some Member States have already adopted measures to reduce the risks for health and the environment linked to pesticide use, while others have not yet taken such action. This creates a situation where there is no level playing field for pesticide users and pesticide industry, which can amount to unfair competition for economic actors in different Member States. Furthermore, there is no equal level of protection of human health or the environment throughout the Community" The divergence in standards is partly due to the lack of guidance on standards, the pesticides amendment will provide detail on the necessary requirements to suppliers of PAE (para 15).
4. Reduced risk of adverse impacts on the environment from reduced usage of PPP (plant protection products i.e. pesticides) is discussed in the EC' s IA (2004) which presents the following causal impact:

Consequently for unintended emissions of PPP to the environment the following general causal chain can be established:



Source: EC IA, BiPRO

In addition the health impact from exposure to pesticides is evident when considering the most recent HSE Pesticides Incidents Report which reports 33 confirmed/likely cases of ill health in 2009/10. Improved application of pesticides through higher standards on PAE will reduce the risks of adverse health impacts.

5. To this end, the agreed amendment introduces additional essential environmental protection requirements for new pesticide application equipment. These include requirements that machinery for pesticide application be designed and constructed:
 - such that it takes into account the results of the risk assessment so that machinery can be operated, adjusted and maintained without unintended exposure of the environment to pesticides.
 - to facilitate precise filling and complete and easy emptying of pesticide, while preventing spillage and avoiding water source contamination
 - to ensure pesticide is deposited on target areas and where appropriate an even and homogenous deposition.
 - to prevent losses while the pesticide applications function is stopped.
 - to facilitate cleaning

- to facilitate the changing of worn parts; and
 - to facilitate inspections by being able to connect the necessary measuring instruments.
6. In addition to this, the responsible person (i.e. manufacturer/importer) must perform appropriate tests on machinery, nozzles, filters and strainers must be marked as well as indication of pesticide in use by fitting a mounting on which the name of the PPP can be added, and detailed instructions must be provided, for example, in relation to precautions to be taken by users, and restrictions on pesticides to be used with the equipment.
 7. The amendment is in the form of a Directive to amend the Machinery Directive (Directive 2006/42/EC). Directive 2006/42/EC sets out the essential health and safety requirements that machinery must meet before it can be placed, and/or put into service, on the Community market. Directive 2006/42/EC was transposed into UK law by the Department for Business, Enterprise and Regulatory Reform (BERR) Statutory Instrument (SI), The Supply of Machinery (Safety) Regulations (SI 2008, No.1597). This SI from 23rd June 2008 and was accompanied by a full Impact Assessment (IA). Pesticide application equipment (PAE) is already covered by the essential health and safety requirements of the Machinery Directive, any additional administrative burdens from extending the essential requirements of PAE to include environmental protection was negotiated such that they should be minimised.
 8. This IA for the amendment to the Machinery Directive on the application of Pesticides, updates an initial IA from December 2008, whereby option 2 in this IA was considered least cost option. The analysis suggested the alternative option to include PAE within Annex IV of the Machinery Directive would have imposed greater cost and administrative burden to users of PAE due to requirement of external conformity assessment, relative to amending existing text as it stands (presented as option 2 in this IA). A consultation with stakeholders provided support for Option 2 in this IA. The impetus for intervention now is driven by timelines determined by EC legislative processes.

POLICY OBJECTIVE

9. The pesticides amendment for the Directive on Machinery for Pesticide Application has the objective of reducing risks to the environment and human health by introducing least cost essential requirements for environmental protection in connection with the design and construction of new machinery for pesticide application equipment.
10. Removal of “non-tariff” barriers by providing a legislative framework in which businesses and consumers can conduct their transactions on a ‘level playing field’, foster positive impacts on efficiency through increased competition with potential knock on benefits from innovation, and subsequently, on growth. This is in line with BIS's departmental priority number 3: Stimulate exports and inward investment by promoting open and fair global markets
11. The amendment supports Defra’s structural reform priority number 2: Help to enhance the environment and biodiversity to improve quality of life - to enhance and protect the natural environment, including biodiversity and the marine environment, by reducing pollution, mitigating greenhouse gas emissions, and preventing habitat loss and degradation.

RATIONALE FOR INTERVENTION

a) Negative externalities: associated with unregulated use of pesticides

12. The social costs to the environment and of health and safety impacts from over use of pesticides can exceed the private costs, this provides one rationale for Government intervention in the area of machinery for the application of pesticides.
13. In relation to pesticide application equipment (PAE) specifically, the rationale for the amendment is that well designed, constructed and maintained machinery for pesticide application plays a significant role in reducing the risk of adverse impacts on the environment and human health. The negative externalities from pesticides and the trans-boundary nature of these with respect to the environment mean that the social costs of pesticide use can exceed the private costs.

b) 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’.

14. The EU product directives set out requirements for some specific products in the internal Market. These 'New Approach' Directives of the European Union aim 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'. 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. The removal of such non-tariff trade barriers is necessary to foster positive impacts on efficiency, innovation, and subsequently, on growth.

c) Information failures: associated with uncertainty about the scope and requirements of PAE risk assessment.

15. Lack of detail on what the risk assessment of PAE for manufacturers is more likely to lead to differing of interpretation across and within Member states. This has contributed to the phenomenon of PAE being produced to differing standards across countries, with an impact on the functioning of the internal market for PAE.

DESCRIPTION OF OPTIONS CONSIDERED

16. For this final IA two options have been considered:

- Option 1: Do Nothing: That is to retain existing text on PAE in the Machinery Directive (Directive 2006/42/EC). The current text still requires self-certification of equipment by manufacturers.
- Option 2: Amendment to the Machinery Directive on Pesticide Application Equipment: Amending text on PAE in the Machinery Directive (Directive 2006/42/EC) which includes provision of clearer guidance on design and construction requirements of PAE to reduce risk of endangering the environment and health of those that could be exposed. In addition the amendment establishes an "even playing field" across member states and an effective functioning of the internal market in PAE through a common framework for the marketing of products and harmonisation of scope. This will reduce barriers to trade and reduce uncertainty around requirements.

17. An **alternative to regulation** considered is providing guidance to manufacturers in order to allow them to pursue voluntary agreements to comply with EU standards. Although it is likely that companies will adopt EU standards regardless of whether the UK enforces the amendment in option 2, it may leave some UK companies at a competitive disadvantage in the internal market in PAE if compliance to EU standards aren't adopted. In addition the UK would face reputational risk and risk of infraction proceedings for not implementing EU legislation.

COSTS AND BENEFITS OF EACH OPTION

18. The Full Impact Assessment (IA) for the Machinery Directive considered the benefits of the Machinery Directive as being in terms of protection and promotion of the Internal Market in machinery; health and safety benefits to those coming into contact with machinery; and welfare benefits to domestic animals where machinery is involved. These benefits were compared to costs in the form of design and build, additional requirements on conformity assessment, information provision; familiarisation and training, and reporting costs as a consequence of the requirements of the new Directive.

19. The Machinery Directive applies to new pesticide application equipment (PAE) as it applies to any other new machinery within its scope. This means that some of the estimated benefits and costs of the Machinery Directive already cover PAE, and in particular *"..with respect to the protection of the health and safety of users of such machinery and other persons exposed to risks due to its operation."* (Explanatory Memorandum to the Proposal (Page 3) - European Commission).

20. However, the Commission's IA (2004) notes that divergent national requirements for environmental protection specifically in relation to PAE can act as a barrier to free trade in the Internal Market for this type of machinery. In addition, it can also lead to environmental damage, which because of its trans-boundary nature can mean a member State damaging the environment of another member State, but this not being considered by the Member State when the machinery is put into use and/or placed on the market.

21. The amendment thus introduces *"..essential environmental protection requirements.."* (OJ of the EU, Directive 2009/127/EC) for PAE. These requirements are intended to bring benefits in the form of greater protection and promotion of the Internal Market for this type of machinery, and in

terms of enhanced environmental protection across Europe. The costs associated with the Amendment are expected to be in the form of additional design and build costs, and additional tooling and production costs to manufacturers.

OPTION 1: Do Nothing

Costs

22. The “do nothing” scenario does not impose additional costs to users / manufacturers from the additional requirements on the self assessment of PAE. However, there may be some non-monetised costs, when compared to option 2, as noted below.
23. There will be a greater risk of adverse impacts on human/animal health and the environment from more pesticide being deposited than is necessary and increased risk of some product not being deposited on target. Machinery which applies product at an incorrect rate might damage a crop, either through over-exposure to a chemical or because there is an insufficient amount to control the pest, weed or disease. The reduction in yield or need to carry out additional treatments would result in additional costs for users. In addition to this, inefficiencies with the application of pesticides is likely to increase costs to users, as more PPP will need to be purchased. A resulting higher cost base could have adverse implications on UK competition.
24. Furthermore failure to amend UK legislation to take account of changes to the Machinery Directive agreed at a European level would lead to a risk of infraction proceedings against the UK.

Benefits

25. No benefits are envisaged from the do nothing option.
26. However, there will be no additional costs to manufacturers from the additional requirements associated with design and construction of PAE to meet higher standards.

OPTION 2: Implementation of amendment to Machinery Directive relating to pesticides application equipment

Costs

Transition Cost: Adaption of designs / production cost

27. The costs are difficult to quantify because it is unclear exactly what type and what volume of new machinery will be affected specifically, and to what extent this machinery will need to be modified to meet requirements set out in the amendment. Manufacturers may see a one of cost increase as equipment which is found to not conform with the Amendment would need to be re-designed. It is difficult to ascertain the extent to which such re-design would be needed. There is limited evidence on the number of manufacturers that already meet minimum requirements, and therefore would not incur additional costs and those that may need to raise standards as well as the cost of becoming compliant.
28. Industry consultation on compliance with the new requirements, suggests that manufacturers are already doing most of what is required by the amendment. In which case there will be minimal impacts on manufacturers. There is already a voluntary UK test scheme for PAE which covers 90% of equipment in use and uses an EU standard as its basis.
29. In order to monetise one off transition costs it has been assumed that the proportion of non compliant PAE range from 20% (high), 10% (best) and 0% (low). Production costs for the PAE sector are derived using input output tables (ONS, 2008) where the ratio for intermediate consumption to total output for the “agricultural manufacturing” sector is used as a proxy to estimate the proportion of production costs for the PAE sector. This proportion (75%) is applied to the sales value of the PAE industry (PRODCOM data) to estimate production costs. Therefore, production costs equate to around 75% of the total sales value of PAE. The proportion of PAE's assumed to be non compliant, 10% for best scenario, are assumed to represent 10% of production costs. Based on an increase in production costs of 1% to 5% (range is derived by looking at historical trends in production costs), transition cost which is only incurred in year 1 is

estimated at £0 (for 0% non compliance), £0.03m (for 10% non compliance) to £0.3m (for 20% non compliance).

*Transitional costs 2012 (for 'best' scenario) = (((£40m x 75%) x 10%) x 1%)

* totals may differ slightly due to rounding.

30. Although the market is considered to be competitive, it is likely that some of these costs will be passed on to users of PAE.

Conformity Assessment

31. As noted in para 28, self-certification of PAE by manufacturers already takes place because PAE is within the scope of the existing Machinery Directive. Manufacturers are thus already testing PAE, undertaking risk assessments, producing Declarations of Conformity and Technical Files, and applying the CE mark in accordance with the Machinery Directive. The amendment is not expected to have any significant additional cost impact on manufacturers of PAE in terms of them demonstrating adherence to the essential requirements in relation to environmental protection. It is therefore assumed that there are no additional conformity assessment costs.
32. For new PAE that is tested from December 15th 2011 the costs of conformity assessment are not annual costs. Rather they apply in the context of the Machinery Directive for a period of five years when the Directive requires the type approval certificates to be reviewed. This corresponds to the review period for harmonised standards giving a presumption of conformity to the Machinery Directive.

Costs to Public Sector – Monitoring and Enforcement

33. This enforcement of the amendment would be undertaken by the HSE, the Northern Ireland HSE, and by Local Authorities. These bodies already enforce the Machinery Directive in the UK (transposed into UK law by the UK's Machinery Regulations).
34. Enforcement provisions in the existing regulations will not need to change in relation to PAE. HSE will extend their enforcement role to PAE as to be set out in a MOU between enforcement bodies; HSE, EA and SEPA. No additional enforcement costs are expected. PAE is a relatively small proportion of total machinery. In addition, the CE marking of PAE which will take into account additional requirements are expected to make enforcement somewhat easier as non-conforming equipment could be easier to spot. This could result in a level of efficiency gains in relation to enforcement. However, any such gains are difficult to quantify at this stage, and may only become apparent once the amendment is actually in place. Actual costs will depend on the level of complaints, and/or European-wide surveillance projects that may be instigated under the European Commission's New Legislative Framework (NLF) Regulation (EC No. 765-2008).
35. Regulation 5 revokes regulation 16(10) of the 2008 Regulations. This is the provision which requires the SoS to publish a list of UK notified bodies. Instead a link to the Commission's webpage showing all notified bodies under the Machinery Directive will be provided on a non-statutory basis – this will reduce the public sector admin requirement.

BENEFITS FROM OPTION 2

36. The benefits of the amended Directive on machinery for pesticide application equipment (PAE) are difficult to quantify given that these are intended to be in the form of benefits to the environment, health and safety of humans/animals and the operation of the Internal Market in PAE. Health benefits and efficiency savings in PPP for users of PAE are monetised.

Internal Market benefits

37. As noted in para 3 above "*essential environmental protection requirements*" that the amendment is to apply to new PAE are intended, in this context, to prevent divergent environmental requirements or standards across member States restricting the free movement of such equipment within the Internal Market.
38. The final Impact Assessment (IA) for the UK's Regulations transposing the Machinery Directive (<http://www.legislation.gov.uk/ukxi/2008/1597/contents/made>) provided indicative estimates of the potential Internal Market benefits to the UK from the Machinery Directive in the range of £2-£12 million per annum. It was acknowledged in this IA that estimating such Internal Market benefits is fraught with difficulty, particularly given the wide ranging scope of machinery covered by the new

Directive, and the fact that the new Directive was modernising and rationalising the existing Machinery Directive.

39. PAE is only a small proportion of the total machinery within the scope of the new Machinery Directive. In addition, the BiPRO Report (Beratungsgesellschaft für integrierte Problemlösungen, 2004) estimates that the UK uses only some 1.5 per cent of the total number of sprayers estimated to be used in the European Union (EU) as a whole.
40. However, the amendment will impact on trade in PAE 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 PAE from the amendment. The amendment may also have positive impacts on the quality of PAE, as well as bringing possible reductions in the price of such equipment through increased competition, both of which would be of benefit to UK businesses importing PAE, and subsequently to UK consumers purchasing goods from the use of such equipment. But again, such benefits are difficult to quantify.
41. It is thus difficult to quantify any potential benefits from the Amendment in relation to protection and promotion of the Internal Market. However, given the relatively small volume of PAE within 'total machinery', and the relatively small use of such equipment in the UK compared to the rest of the EU (~2%), any potential impact to the UK are expected to be somewhat limited.

Environmental and health benefits

42. Ensuring that that pesticide application equipment (PAE) “..does not endanger the environment unnecessarily..” (Explanatory Memorandum to the Proposal (Page 3) - European Commission) is a key objective to the amendment.
43. The Commissions IA does not provide monetary estimates of the environmental benefits of the Amendment, noting *It is generally recognised to be extremely difficult to quantify many of the actual adverse effects resulting from the use of pesticides and even more difficult to attribute monetary values to them.* Rather, it uses its estimates of the tonnage of pesticide to be saved from the Amendment as an indication of the environmental benefit (estimated to be between 500 and 1000 tonnes of pesticide).
44. The Commission's IA assessment is that “...in the long run it will have positive impacts on human health and the environment via the expected decrease in exposure to pesticides...” The benefits from reduced rate of illnesses linked to pesticide exposure are based on the two most recently published [Pesticides Incidents Reports;](http://www.hse.gov.uk/agriculture/resources/pesticides.htm) (<http://www.hse.gov.uk/agriculture/resources/pesticides.htm>). There is no evidence of PAE being the direct cause of incidents which require medical attention, as a simplifying assumption it is assumed that half of the incidents reported as requiring some sort of medical attention and that are classified as confirmed or likely cases are the result of PAE that do not meet the new requirements. For illustrative purposes this equates to between 8 and 17 people incurring mild or moderate suffering per annum due to PAE application of pesticides. It is assumed the amendment prevents these injuries from occurring. HSE estimate that £150 (mild injury) to £350 (moderate injury) is cost avoided per injury. The numbers of injuries avoided vary as noted in table below according to level of compliance assumed. The low scenario which reflects 100% compliance includes a low level of health benefit (as opposed to none) as it is assumed that additional conformity requirements could slightly improve targeting of PPP. Therefore the benefit from health costs avoided is estimated at ~£3000 on average per year ('best' scenario). Total health benefits over the 10 years are estimated to be £0.03m.

Number of injuries avoided due to amendment:

IA scenarios	mild (pain, grief and suffering minor non-reportable)	moderate (requiring GP/hospital)	Reference (~1/2 of incidents reported)
Low	5	3	2008/09 PIAP
High	15	2	2009/10 PIAP
Best	10	3	Rounded average of high and low

45. It should be recognised that a reduction in pesticides is not the end objective as in some cases this would be detrimental to aggregate welfare. The impact of this amendment should be considered in the context of Pesticides already being controlled by existing and separate legislation in the UK. It is a requirement of UK law that pesticides can only be sold, supplied, used, stored or advertised in the UK after they've been approved. The responsible Departments are: the Department for Environment, Food and Rural Affairs (Defra); the Department of Health; the Scottish Executive Environment and Rural Affairs Department; the National Assembly for Wales; and the Department of Agriculture and Rural Development, Northern Ireland.
46. In addition to this, the Health and Safety Executive's Chemicals Regulation Directorate - an Agency of the HSE, deals specifically with the approval of agricultural pesticides (plant protection products' (PPP)). The Plant Protection Products Regulations (PPPR) control PPP in the UK, and implement European Directive (91/414/EC) on PPP. The use of pesticides is also regulated by the Control of Substances Hazardous to Health (COSHH) Regulations.
47. All of this means that PPP are already regulated in terms of being able to be placed on the UK market, so there are no unacceptable risks to human health or the environment if used in the right way.

Reduced consumption of PPP (plant protection products):

48. Improved PAE will increase the efficiency with which PPP is applied and minimise overall consumption. 2009 data from the crop protection association reported that just over 23,700 tonnes of PPP was put on the UK market in 2009 at a value of just under £600 million. Assuming the price of PPP has risen in line with general inflation, implies that PPP costs on average, in the region of £27,000 per tonne today.
49. Of total PPP used in the UK, some 85 per cent is used by the agricultural sector. Assuming this is applied by equipment within the scope of the Machinery Directive, and assuming that the level of PPP used in the UK today is similar to that used in 2009 implies a figure of ~20,000 tonnes of PPP applied by PAE in the UK currently. In addition to this it's possible that some application equipment used in industrial amenity and forestry may fall into the scope of this amendment e.g. quadbikes / ATV's. The impact is not considered here as it is expected to be negligible given PPP used accounts for approximately 3% of all PPP on the market.
50. The amendment covers only new pesticide application equipment (PAE) and so will only affect PPP applied by this new machinery. It is assumed that the average life of PAE is some 12 years. For an estimated 38,000 pieces of equipment on the UK market currently this implies that the PPP covered by the Amendment is that used in an estimated ~3,200 new machines per annum. A simplifying assumption that PPP is used uniformly in quantity across PAE in turn implies that the Amendment applies to some 8% of total PPP on the market per annum. This IA assumes PAE are already compliant at a ratio of 90% (central estimate) with sensitivities of 80%-100% (see para 29).
51. It is assumed that additional requirements in the Amendment lead to a reduction in the use of PPP by 7.5% by PAE. This assumption is based on the BiPRO Report (EC IA, 2004) which contains assessments of a range of options in relation to the certification and control of PAE. These assessments include estimates of savings in the use of PPP (pesticides) from enhanced certification and control of new PAE. BiPRO estimate savings from the use of PPP under the EC IA's option of mandatory certification of new PAE as being in the range of 12-24 million euros, or some £11-£22 million per annum. This is calculated from a reduction in the use of PPP of some 500-1000 tonnes per annum, with PPP estimated to cost in the region of some 24,000 Euros per tonne. These estimates are based on the estimate that *"..the average PPP use reduction potential resulting from regular control is estimated to range from 5 to 10%."* (BiPRO, page 222).
52. The mid-point of range assumed in the EC's IA (7.5%) to estimate savings in PPP from improved PAE in the UK. Assuming 90% of PAE already comply, this implies a saving in PPP of 7.5% (or 13 tonnes) of the total PPP used by previously non-compliant PAE (167 tonnes) p.a. due to the amendment. Based on above assumption there will be a benefit to users of PAE due to less wastage in PPP. The savings for users are estimated at ~£400,000 on average per year ('best' scenario). Total savings due to reduction in PPP consumption over the 10 years is estimated at £4m.

Summary Table: Total Costs and Benefits from 2012 to 2021 (assuming 90% compliance)

constant prices	Costs (£/m)
Transitional	
Redesign and construction	0.03
Reoccurring	
	0

Total	0.03
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	Benefits
Transitional	
	0
Reoccurring	
Health	0.03
Reduced consumption of PPP	3.92

Total	3.95
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SUMMARY AND PREFERRED OPTION WITH DESCRIPTION OF IMPLEMENTATION PLAN

53. Option 2 is the Government's preferred option. The UK implemented the wider EU legislation (Directive 2006/42/EC) of the Machinery Directive under the Supply of Machinery (Safety) Regulations 2008. The amendment on the application of pesticides requires transposition into UK law by 15 June and enters into force from 15.12.11. Given the legal basis of the amendment the UK has little discretion when implementing the pesticides amendment.
54. This IA estimates the costs and benefits of the implementation of the pesticides amendment to the Machinery directive.
55. Although it has not been possible to quantify all the impacts of the amendment, the analysis shows that the reduction in human injuries as well as the efficiency gains from reduced consumption of PPP is likely to outweigh the costs of redesign and construction of PAE to meet requirements for manufactures of PAE, over the counter option of doing nothing.
56. The main benefits as noted are expected to be in terms of reduced risk of environmental costs and health and safety risks to the public. In addition to this the legislation will contribute towards a level playing field for businesses to operate in the internal market which may facilitate growth in this sector. The costs arising from the legislation compared to option 1 are expected to be small.

ASSUMPTIONS

57. The monetised costs and benefits are sensitive to assumptions noted below:

- The number of new PAE on market per annum that are affected by the amendment; this is based on BiPRO report which estimates of the number of machines on the UK market and the average lifespan of these machines.
- Equal usage of PPP across all PAE on market; this is a simplifying assumption due to lack of evidence.
- Value of pesticide per tonne; this is based on sales value of PPP from Crop Protection Association. Assumed projected real cost of PPP does not change from 2009 levels.
- Volume of pesticide used; this is based on market data of PPP from Crop Protection Association. Assumed that volume of PPP used does not change into the future (up to 2021).
- Existing compliance rate of PAE at 80%, 90% and 100%
- Agricultural manufacturing inputs to outputs used as a proxy to estimated production costs in PAE sector.
- Cost of health care due to injury based on HSE estimates of £150 for treatment of mild injury and 350 for moderate injury.
- Pesticides Incidents Report (HSE) estimates of illness caused by pesticides from 2008/9 and 09/10 – 50% of incidents reported as mild and moderate that were likely or confirmed assumed to be caused by PAE which don't meet new requirements of Amendment.
- The PAE sector is estimated to equate to the PRODCOM categories noted in below table.

PRODCOM CATEGORY 2009	Sales (£)
Portable mechanical appliances with or without a motor, for projecting, dispersing or spraying liquids or powders, for agricultural or horticultural use EXCLUDING: - watering appliances	2,417,000
Sprayers and powder distributors designed to be mounted on or drawn by agricultural tractors EXCLUDING: - watering appliances	6,383,000
Agricultural or horticultural appliances for projecting, dispersing or spraying liquids or powders EXCLUDING: - watering appliances - sprayers and powder distributors designed to be mounted on or drawn by agricultural tractors - portable appliances	28,416,000
Total	37,216,000

Competition Assessment

58. The Government's preferred option is expected to protect and promote the Internal Market for PAE. In this sense, it will have a positive impact on competition in PAE across Europe.

Small Firms Impact Assessment

59. The Governments preferred option is not expected to impose a disproportionate cost to small firms. The additional requirements imposed on suppliers of PAE are not expected to be significant as the rate of compliance is already deemed to be high.
60. Microbusiness Exemption Rule: Under the microbusiness exemption rule whereby regulation exempts organisations of 10 or fewer employees and start-ups, this measure is out of scope because it relates to the EU.

Statutory Equality Duties

61. After an initial screening as to the potential impact of this regulation on race, disability and gender equality it has been decided that there will not be a major impact upon minority groups in terms of numbers affected or the seriousness of the likely impact, or both.

Greenhouse Gas Assessment

62. The regulations are not expected to have any significant impact on Greenhouse gas levels

Wider Environmental Issues

63. The expected decrease in PPP from better quality new PAE is expected to be in the region of 84-167 tonnes. As old PAE become obsolete and are replaced by new PAE this will further enhance the impact – the lifespan of PAE is approximately 12-15 years. If we assume that only new PAE (PAE from Dec 2011 onwards) are on the market from 2030, the tonnes of PPP avoided could equate to around 1000 to 2000 tonnes.
64. This could reduce the level of water pollution from PPP and reduce the cost of water treatment. It is difficult to estimate the scale of the impact as it is the extent to which a reduction in use of PPP will reduce water pollution will depend also on other factors e.g. physical barriers to limit water contamination or spraying in low wind.
65. There could also be a positive impact on biodiversity as better quality PAE will reduce the risk of exposure of pesticides to animals and humans.

Health and Well-Being Assessment

66. After an initial screening of the health and well-being assessment as per guidelines from Department of Health it has been determined that health IA is not required.

Human Rights

67. The Regulations are not expected to have an impact on the rights and freedoms of individuals as set out in the Human Rights Act 1998

Justice System

68. The regulations are not expected to have any material effect on the criminal or civil liberty of those who it affects, and so should not have impact on the justice system in the UK

Rural Proofing

69. Rural communities will benefit from the reduced risk of adverse environmental and health impacts. Pesticides are used mainly for agricultural purposes and therefore applied in rural areas. The amendment will help minimise risks to operators, bystanders and residents from the handling and application of pesticides. The environmental impact of intended spills, leakage and/or imprecise application may lead to greater local impacts (e.g. pollution resulting from spray drift or movement or transport of pesticides over or through the soil may prevent recreational use of water). However, water supplies from rural areas will of course be piped into urban areas for treatment, the impact of pesticide contamination would not therefore be confined to rural areas. The costs are incurred by manufacturers of PAE and so will not be biased towards rural areas.

Sustainable Development

70. As discussed in the wider environmental issues assessment there are expected to be less risk of adverse environmental impacts from the more targeted use of pesticides. However, the regulations are not expected to have a significant impact on sustainable development.

DIRECT COSTS AND BENEFITS TO BUSINESS CALCULATIONS (OIOO)

71. Under the One In, One Out rule a measure of net cost to business (a One In) cannot be implemented unless an equivalent regulation of net cost is removed or simplified (a One Out). However, Regulations which are required to implement EU obligations are not within the scope of OIOO at this time, except any gold-plating of EU obligations, which will require a matching 'OUT'.
72. Direct cost to business include the additional costs to manufacturers from the redesign and constriction cost to ensure PAE produced are compliant, this is estimated at £0.03m which are incurred in year one only. (see para 27)

Gold Plating

73. The proposed legislation does not gold plate because it does not go over the minimum EU requirements. The Machinery Directive amendment on the application of pesticides is a legally binding EU measure which has to be transposed into national law by 15.06.11 and take effect from 15.12.11. Therefore, the legislation is being implemented at the latest possible transposition date.
74. Furthermore, the proposed Regulations revoke regulation 9 of the Supply of Machinery (Safety) Regulations 2008 (SI 2008/1597) which implements the original 2006 Machinery Directive. Regulation 9 prohibits persons who are not "responsible persons", e.g. end users, from placing machinery on the market or putting it into service unless it meets all the essential health and safety requirements of the Machinery Directive and is safe. This in effect places an obligation on users who are not "responsible persons" to satisfy themselves that machinery they have purchased is safe before they start to use it. We now believe that this places a burden on end users which goes beyond the minimum requirements of the Machinery Directive. Revoking regulation 9 of the 2008 Regulations will therefore remove this gold-plating. The impact of the repeal is not accounted for in the NPV calculated for this IA because Regulation 9 largely duplicated a provision in the Provision and Use of Work Equipment Regulations 1998 (SI 1998/2306) and so the duty remains through those Regulations. Further, the provision under the 2008 Regulations was not enforced by the Health and Safety Executive and end-users have probably been unaware of the requirement in regulation 9 and are therefore unlikely to have been complying with it. Therefore there is not expected to be any impact.

Annexes

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

Annex 1: Post Implementation Review (PIR) Plan

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

<p>Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review, or there could be a political commitment to review (PIR)];</p> <p>This proposal implements an amendment to the EU Machinery Directive and will amend the Supply of Machinery (Safety) Regulations 2008. The existing regulations are to be reviewed in December 2011 on the basis of a non-statutory commitment to review (PIR) - this will be too early to review the amendment which is due to enter into force in December 2011. This proposal inserts a duty to review into the existing regulations. In accordance with this proposed review requirement the amendment will be reviewed at the same time as the parent regulations in December 2014.</p>
<p>Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]</p> <p>To ensure that the legislation is achieving its aims without undue burden to those obligated by it</p>
<p>Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]</p> <p>Canvassing stakeholder views through their representative organisations.</p>
<p>Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]</p> <p>This is an amendment to existing legislation - the Supply of Machinery (Safety) Regulations 2008 - which forms the baseline.</p>
<p>Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]</p> <p>Achievement of the policy objectives set out in this Impact Assessment. If this is not being achieved, careful consideration would be given to modifying the regulation or providing improved guidance.</p>
<p>Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection of monitoring information for future policy review]</p> <p>We already have good communications with the representative organisations for the manufacturers of the equipment covered by the proposed legislation. We will continue to work with them to ensure that the objectives are being met and we are informed of any problems.</p>
<p>Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here]</p> <p>N/A</p>