

<p>Title: Transposition of the recast of Directive 93/15/EEC (Directive 2014/28/EU) – Explosives for Civil Use (Civil Uses Directive) - Impact Assessment</p> <p>IA No: HSE0092</p> <p>Lead department or agency: Health and Safety Executive</p> <p>Other departments or agencies: Department for Business, Innovation and Skills</p>	Impact Assessment (IA)		
	Date: 26 February 2015		
	Stage: Consultation		
	Source of intervention: EU		
Type of measure: Secondary			
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Summary: Intervention and Options		RPC Opinion:	

Cost of Preferred (or more likely) Option

Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Two-Out?	Measure qualifies as
-£0.28m	-£0.17m	£0.01m	No	N/A

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

A number of Directives, including the Civil Uses Directive, have been amended or 'recast' to strengthen and modernise market surveillance of products first placed on the market. This measure was adopted and published in the Official Journal of the European Union on 29 March 2014. Under EU law the UK has a legal obligation to implement the recast of the Civil Uses Directive (Directive 93/15/EEC) into domestic legislation.

What are the policy objectives and the intended effects?

The objective is to meet the UK's obligation to implement EU Directives and to ensure that the implementation of the changes is clear, coherent and easy to understand and does not place a disproportionate burden on industry, regulators and other stakeholders. Successful transposition of the changes will ensure the continued alignment of GB with other EU Member States providing a consistent approach to regulating the placing on the market of civil use explosives.

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

Only one option is explored in this IA as viable:

Option 1 - to transpose the recast Directive by an amending SI to the Explosives Regulations 2014 (ER2014), as this meets the UK obligation to transpose EU Directives

Options to produce guidance only or to maintain the status quo have not been considered viable, as neither would deliver our obligations under EU law.

Will the policy be reviewed? It will be reviewed. If applicable, set review date:

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro Yes	< 20 Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: N/a	Non-traded: N/a	

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

Signed by the responsible SELECT SIGNATORY: _____ Date: _____

Summary: Analysis & Evidence

Policy Option 1

Description: Transposition of the recast

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2016	Time Period Years 10	Net Cost (Present Value (PV)) (£m)		
			Low: £0.27m	High: £0.29m	Best Estimate: £0.28m

COSTS (£m)	Total (Constant Price)	Transition Years	Average (excl. Transition)	Annual (Constant Price)	Total (Present Value)	Cost
Low	0.1	1	0.0			0.3
High	0.1		0.0			0.3
Best Estimate	0.1		0.0			0.3

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

Manufacturers bear around 85% of the monetised costs to business, mainly because of changes in requirements for conformity attestation, which will cost around £126k. The other monetised costs to business are familiarisation costs for manufacturers, importers, and distributors. The costs to government are to the notified body and the regulator. The notified body would have to undergo accreditation at an estimated cost of £106k, and the regulator will have one-off training costs.

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

Non-monetised costs are expected to be small and mainly relate to packaging requirements for manufacturers and importers, and procedures that manufacturers, importers, and distributors would have to follow if they come across non-compliant products.

BENEFITS (£m)	Total (Constant Price)	Transition Years	Average (excl. Transition)	Annual (Constant Price)	Total (Present Value)	Benefit
Low		Nil	Nil			Nil
High	Nil	1	Nil			Nil
Best Estimate	Nil		Nil			Nil

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

No benefits have been monetised.

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

The main benefits are potential improvements of overall safety standards. The equivalence of notified body standards also ensures a level playing field across the EU for manufacturers.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5

As it is still early days in the implementation process, issues may arise that cause a departure from the implementation approach and/or the need to revise estimates, and estimate additional costs. It is not possible to estimate the magnitude of potential changes at this stage. There is also uncertainty around how many civil-use explosives will be developed down the line, as this could decrease with an increasing defence budget (and therefore greater demand for defence-related explosives)

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0.01	Benefits: 0	Net: 0.01	No	N/A

Evidence Base (for summary sheets)

1 Problem under Consideration

1. The EU regulates the placing on the market and supervision of explosives for civil uses by way of Directive 93/15/EEC known as the Civil Uses Directive. This is implemented within Great Britain (GB) through the Explosives Regulations 2014 (ER2014). The European Commission has, as part of the 'New Legislative Framework'¹(NLF), recast this Directive (Directive 2014/28/EU) alongside eight others:
 - Low Voltage Directive: Directive 2014/35/EU
 - Electromagnetic Compatibility Directive: Directive 2014/30/EU
 - ATEX Directive: Directive 2014/34/EU
 - Lifts Directive: Directive 2014/33/EU
 - Simple Pressure Vessels Directive: Directive/29/EU
 - Measuring Instruments Directive: Directive 2014/32/EU
 - Non-automatic Weighing Instruments Directive: Directive 2014/31/EU
 - Pyrotechnic Articles Directive: Directive 2013/29/EU (The Pyrotechnic Articles Directive) was adopted early and will come into force summer 2015).
2. The aim of the recast of these Directives is to strengthen and modernise the conditions for placing a wide range of industrial products onto the European market. UK Government intervention is required to amend ER2014 to fully transpose the Directive into GB law by 20 April 2016. Implementation of the Pyrotechnic Directive is assessed in another Impact Assessment (IA) prepared by the Department for Business, Innovation and Skills (BIS). BIS is also assessing the other seven Directives together in a forthcoming IA.
3. With regards to the Civil Uses Directive, the transposition will mean some amendments to the existing regime for anyone who places such an explosive on the EU market for the first time. The key changes are as described starting in paragraph 13.
4. Civil use explosives are those explosives which have been or would be classified in accordance with the United Nations Recommendations as falling within Class 1.² They do not include:

¹ New Legislative Framework http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/new-legislative-framework/index_en.htm

²'Class 1' means Class 1 in respect of explosives or the classification of dangerous goods as set out by the United Nations Recommendations <http://www.unece.org/fileadmin/DAM/trans/danger/publi/manual/Rev5/English/ST-SG-AC10-11-Rev5-EN.pdf>

- i. Ammunition (which is regulated in GB by way of the Firearms Acts 1968 to 1997, a non-exhaustive list of which can be found in Annex 1 of the Directive)³;
 - ii. Any explosive which it is shown is intended for lawful use by the armed forces or the police of any country;
 - iii. A pyrotechnic article, such as fireworks.
5. The "New Legislative Framework"⁴ was adopted in the European Council on 9 July 2008 and published in the Official Journal on 13 August 2008.⁵ The measures are designed to help the internal market for goods work better and to strengthen and modernise the conditions for placing a wide range of industrial products on the EU market.
6. The package builds on existing systems to reinforce the application and enforcement of internal market legislation and aims to:
 - Improve market surveillance rules;
 - Boost the quality of conformity assessment of products;
 - Clarify the meaning of CE marking⁶ and;
 - Establish a common legal framework for industrial products.
7. In the NLF the European Council states that:

“(They) believe that a significant number of products on the market do not fulfil the requirements set out by the directives. Some actors simply affix the CE marking to their products although these products do not fulfil the conditions for being CE marked. Importers and distributors do not all carry out the necessary verifications to ensure that they are only supplying compliant products. Member States are also imposing different obligations on importers and distributors when it comes to ensuring that products meet the applicable requirements. Furthermore, the actions that national authorities are taking vis-à-vis non-compliant products (e.g.

³Articles considered in the relevant United Nations recommendations to be pyrotechnic or ammunition: European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR 2015) This is a 'paid for' document and is available at:
http://www.unece.org/trans/publications/dg_adr_2015.html

⁴ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC;

Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.

⁵ <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=OJ:L:2008:218:TOC>

⁶ The CE mark, or formerly EC mark, is a mandatory conformity marking for certain products sold within the European Economic Area (EEA) since 1985. The CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC directives, as it confirms that a notified body verified that the product conforms to the relevant European standard and meets essential safety requirements,

prohibitions of marketing, withdrawals, etc.) sometimes differ from one Member State to another.”

The Directive looks to remove this inconsistency of compliance across Member States, and places obligations on manufacturers, importers and distributors.

8. There is currently no significant work undertaken on ensuring that civil use explosives in the UK meet the essential safety requirements. This has not been a focus of HSE’s market surveillance programme due to other articles (pyrotechnics) being identified as higher priority. To this end, it is difficult to confirm the rate of compliance by using HSE enforcement data as a primary source.
9. The Department for Business, Innovation and Skills (BIS) has the lead in the UK in implementing the overall NLF work. BIS will be holding a full public consultation across all eight Directives, in relation to market surveillance, including the Civil Uses Directive. This includes enforcement, penalties for non-compliance, and approval and continuous assessment of notified bodies.
10. As the Civil Uses Directive concerns the regulation of explosives within HSE’s remit, it is the responsibility of HSE to implement it, and to consult on the proposed implementation. Rather than duplicate the BIS consultation, HSE will in addition consult on technical matters within the recast [and not included in the market surveillance] by way of a working group representing the civil uses sector. .
11. The recast Directive 2014/28/EU replaces the Civil Uses Directive 93/15/EEC, which entered into force on 1 December 1993. The Placing on the Market and Supervision of Transfers of Explosives Regulations 1993 (POMSTER) implemented this Directive in GB. POMSTER has now been revoked and those provisions have been incorporated into ER2014⁷, which came into force on 1 October 2014. ER2014 consolidated existing explosives legislation, the main elements of which were:
 - Explosives Act 1875 (EA)
 - Control of Explosives Regulations 1991 (COER)
 - Placing on the Market and Supervision of Transfers of Explosives Regulations 1993 (POMSTER)
 - Marking of Plastic Explosives for Detection Regulations 1996
 - Manufacture and Storage of Explosives Regulations 2005 (MSER)
 - Identification and Traceability of Explosives Regulations 2013 (ITOER)
12. The Directive also repeals Directive 2004/57/EC which provided indicative information on the identification of pyrotechnic articles and ammunition.

⁷ The Explosives Regulations 2014 <http://www.legislation.gov.uk/ukxi/2014/1638/made>

2 Key Changes

13. The key changes will have an impact on the economic operators (manufacturers, importers, and distributors) and on the notified body⁸, and the regulator.
14. Manufacturers will see changes in the conformity attestation process, and changes in what details manufacturers must attach to explosives. These changes aim to reinforce existing safety standards. The Directive also allows manufacturers to appoint 'authorised representatives' by written mandate, enabling a person to act on their behalf when placing products on the European market.
15. All economic operators will now also be under the obligation to recall or withdraw products from the market if they pose a risk.
16. Under the Recast, notified bodies will have to be accredited and continuously assessed.
17. The Government would see the extension to HSE inspectors of powers under the Regulation on Accreditation and Market Surveillance (RAMS), so that they are able to recall products.

3 Rationale for intervention

18. The rationale for the transposition approach takes full account of the Government's Guiding Principles for EU Legislation. The key focus is to ensure that economic operators operating within the UK are not disadvantaged within the European Market by unnecessary burdens placed upon them. The Government's preferred approach is to use 'copy-out' for transposition where possible. We do not intend to 'gold plate' any of the Directive's minimum requirements and will incorporate the changes into existing legislation, ER2014. Where necessary, we will elaborate some of the Directive's requirements by way of guidance to ensure that they are clear to industry and to maintain consistency with the current regulations and thereby ensure that there are no additional costs. HSE provided support to negotiations on the recast Directive, to ensure that the impact on GB business was minimised where possible.

4 Policy Objectives

19. The UK policy objectives are to fully transpose the recast Directive requirements into domestic legislation by 20 April 2016 in a way that:
 - minimises the impact of any changes on the explosives industry and UK interests;
 - embeds the new requirements so that they further enhance GB's current explosives regulatory regime;

⁸ The notified body assesses the conformity of civil use explosives.

- is open and transparent and ensures consistency with current regulations;
 - improves the mechanism for the control over the supply of non-compliant products to consumers.
20. Successful transposition of the changes will enable GB to continue to align with other EU Member States, providing a consistent approach to regulating products placed on the market.

5 Options considered

21. There is only one option explored in the impact assessment, as it is the only viable option.
22. **Option 1:** To transpose the Directive into GB law by an amending Statutory Instrument (SI) to ER2014. Failure to implement in law would be incompatible to the UK's treaty obligations under EU law and would open up the UK to infraction proceedings. HSE propose to amend the ER2014 to ensure the Directive is fully transposed by 20 April 2016. The Directive will be transposed in the form of copy-out in line with UK Government policy.
23. While some requirements under the current Directive are implemented under the ER2014, these will be replaced with new and expanded provisions. New duties will also be added.
24. A do nothing option has not been considered as a viable option, as it would pose risk of infraction and would not deliver the GB's obligations under EU law. However, it constitutes the notional baseline against which we compare the costs and benefits of option 1.
25. An option to produce guidance only has not been considered as a viable option as it would also not deliver the obligations under EU law.

6 Research undertaken to inform the IA

26. HSE economists have conducted a series of interviews with stakeholders to estimate the likely costs of implementation, to inform estimates for the impact assessment. We interviewed five manufacturers, a distributor, the regulator, and the notified body (NB), during December 2014 and January 2015.
27. The interviews focused on the impact on manufacturers, as there are more changes in the recast for requirements on manufacturers, than on distributors. This was considered a proportionate approach for this consultation stage IA as most changes discussed apply to manufacturers of explosives. The 5 manufacturers interviewed represent around half of the manufacturers of civil use explosives in the UK.

28. The interviews provided the primary evidence for the assumptions used in the cost and benefit appraisal below. These assumptions will be tested and refined during consultation. We will work alongside the industry working group to ask for specific feedback on the assumptions and expected impacts. We will also ask for feedback from a wider stakeholder group during the public consultation process.
29. We also used the interviews as an opportunity to ask about expected time spent on familiarisation. This was possible because the same industry group has recently had to familiarise themselves with ER2014. We first asked them to recall the time spent on familiarisation with ER2014 (in terms of time spent reading the regulations, understanding their implications and translating them into company policy). Then we asked for their expectations on how much time they would spend familiarising with changes in the Recast, based on the scale of changes in the Recast, compared to ER2014.

7 General Assumptions

7.1 Cost of Time

30. We assume a working week of 37.5 hours with 7.5 hours in a working day.
31. The following analysis will cost the time of workers based on the Full Economic Cost (FEC) model. That is, it is assumed that the cost to an organisation of any activity carried out because of the transposition of the Recast Directive will be the lost productive output of that time.
32. For the costs to manufacturers, one hour of a production or compliance manager's time is assumed to cost around £100. This cost of time is based on feedback from the interviews we had with stakeholders, where we explained the reasoning behind the FEC model and asked for estimates from the respondents.
33. For the costs to distributors and importers, one hour of a functional manager's time is also assumed to cost around £100. However, this is based on just one interview with one distributor, and will be refined during consultation, to ensure it is not an outlier.
34. We obtained the full economic cost of an HSE inspector from HSE's Ready Reckoner. It is given as around £557 per day, assuming 7.5 hours in a working day. This is equivalent to around £74 per hour.

7.2 Time Horizon and Discounting

35. We assume an appraisal period of 10 years, applying a discount rate of 3.5% per annum, consistent with the Green Book⁹.
36. We assume that one-off costs and cost savings are borne in the first year of the appraisal period (Year 0). We also assume that on-going costs and cost savings are borne each year from Year 0 to Year 9, unless otherwise stated.

7.3 Size of the explosives sector

37. The impacts discussed in this IA will be borne by:
- manufacturers of civil use explosives;
 - importers of civil use explosives (any person who places explosives on the market from a third country);
 - distributors of civil use explosives (any person in the supply chain, other than the manufacturer or importer, who makes explosives available on the market);
 - the notified body (NB) which assesses the conformity of civil use explosives, and;
 - the regulator.
38. The estimated numbers of the economic operators in the UK are indicated in Table 1.
39. We calculated the numbers for distributors based on the EU numbers in the EU Impact Assessment¹⁰ for the recast. In the EU as a whole there are an estimated 500 dealers and distributors of civil use explosives. We used Eurostat Prodcom data on the production of explosives and found that in 2012 around 6% of the civil use explosives sold in the EU were sold in the UK. We used this proportion to estimate the number of distributors and dealers in the UK. According to the EU IA, most of the distributors are small or medium size businesses.
40. We obtained the numbers for importers from the validation stage IA on ITOER 2013, which were based on HSE's knowledge of the sector. We will seek to confirm that this is still accurate during consultation.
41. We obtained the numbers for manufacturers from the HSE licencing team, as HSE manages the licencing of manufacturers.¹¹ In GB manufacturers tend to be SMEs, and there are now no large manufacturers.

⁹

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/220541/green_book_complete.pdf

¹⁰ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2011:1376:FIN:EN:PDF>, page 60

¹¹ Do note that currently duty holders are required to hold a licence/certificate to acquire and keep, manufacture, store and transfer explosives, though this does depend on the types and quantity of explosives under consideration. The licencing activity is undertaken by a range of bodies, including the HSE, Police Authorities in England and Wales, the Office for Nuclear Regulation (ONR), and Local Authorities.

42. We are aware that some manufacturers are also importers of civil use explosives, but not all manufacturers import, and not all importers manufacture. For this reason, we have calculated the costs borne by them separately. This may introduce some double counting of familiarisation costs, which implies that familiarisation costs may therefore be overestimated by around half a day to a full day for some businesses.
43. The analysis will assume that the number of operators within the UK will remain the same after 20 April 2016, and for the full ten-year appraisal period. It also assumes that the number of products manufacturers seek to conformity attest per year will remain constant. This is a simplifying assumption. We have received mixed messages from businesses about the expected growth or decline of the civil explosives market. During interviews, some businesses implied that because of a shrinking defence budget they are looking to expand into civil explosives. Conversations between business and HSE policy colleagues have however indicated that the civil explosive market is shrinking, with manufacturers looking towards expansion into explosives for defence purposes. We understand that the market is constantly changing, but expect that a clearer understanding of future expectations will be available during consultation, possibly accompanied by a clarified defence budget.

Table 1: Estimated number of economic operators within the UK

Operator	Number within the UK
Manufacturer	13
Importer	15
Distributor	30

8 Analysis of costs and benefits

8.1 Costs to business

8.1.1 Manufacturers

44. As shown in Table 1, the Recast will affect around 13 manufacturers of explosives.
45. The full economic cost of time (FEC) for production or compliance managers, as obtained from three out of the five manufacturers interviewed was around £100 per hour. It is the FEC used for manufacturers in this IA.
46. Changes in the recast directive that could affect manufacturers are changes in the conformity attestation procedures, in packaging and safety information requirements, and risk procedures. There would also be familiarisation costs.

47. Although specific duties for record keeping may impose a cost in the other Directives in the NLF (BIS is currently assessing these in a separate IA), they do not pose an additional cost in the explosives sector, as the requirement in the recast to keep records for 10 years is a pre-existing requirement in ER2014. This also applies to other economic operators.

Conformity Attestation

48. Manufacturers must ensure that each explosive is examined and appropriate tests are carried out in order to verify its conformity with the relevant requirements set out in the directive. There are a number of tests available, but the requirements for all but one have not changed. The Module B test (for EC type examination) has changed slightly.

49. Under the current Directive, the assessment of the conformity of the explosives under Module B (EC type examination) is determined in the following way: the manufacturer will test their explosive; they will then submit technical documents including test results to a notified body (NB) of their choice. The manufacturer must also make a sample available to the NB if required for carrying out the test programme and agree with the NB where the testing will take place.

50. However, under the recast, the manufacturer will *also* have to provide documentation that includes adequate analysis of the risks; details of the harmonised or technical standards used and, where these have not been applied, reasons why not and details of solutions adopted to meet the essential safety requirements. The documentation must also include details of all tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on its behalf under their responsibility. The manufacturer must draw up a Declaration of Conformity and affix the CE marking (once an explosive has been successfully conformity attested by the NB).¹²

51. During the interviews, manufacturers were asked whether the modification to the Module B assessment would have any impacts on their businesses in terms of one-off costs and/or on-going costs.

52. Based on interview responses, we expect that there would be no one-off costs incurred because of the changes in Module B as any relevant company procedures or guidance would not require changing.

53. We identified on-going costs to business. The additional requirements for documentation following Module B assessment under the recast may require additional hours per product tested, but not all manufacturers would be testing products under Module B.

¹² For more details on the conformity assessment procedures please refer to Annex iii of the recast directive.

54. During the interviews, two companies said they do not expect to test any products under Module B. One company said they expect to test around one product a year. Another company said they expect to test between one and two products a year. The other manufacturer said they expect to test between three and six products. We understand that these assumptions could change due to uncertainty of future market opportunities (as explained in paragraph 43).
55. We therefore assume that around 40% of manufacturers (around 5) will not test any products under Module B, another 40% will test an average of 1.5 products per year, and the remaining 20% (around 3) would test an average of 4.5 products per year.
56. We estimate that the additional time required to test each additional product would be around 1 day, or 7.5 hours. This is based on the average additional time estimated by manufacturers during the interviews.
57. Based on the assumptions in paragraphs 55 and 56 and an FEC of around £100 per hour, we estimate that:
- 40% of manufacturers will not incur any additional annual costs as they do not test products under Module B;
 - 40% of manufacturer will incur an annual cost of around £1.1k each, as they test around 1.5 products each under Module B every year;
 - The remaining 20% of manufacturers will incur an annual cost of £3.4k each, as they test around 4.5 products each under Module B every year.
 - The total annual cost across the 13 manufacturers in the sector is therefore around £14.6k.
58. The estimated total ten-year present value cost is around £126k.

Packaging

59. The current Directive and its daughter Directive 2008/43/EC (for track and trace explosives for civil uses) specifies that as soon as is practicable after manufacture and before explosive leave the site, manufacturers must ensure that all explosives within scope of the Directive 93/15/EEC are marked in a specific way. They must be marked with:
- the name of the manufacturer;
 - the two letters identifying the European Economic Area state (place of production or import onto the market);
 - the three digits identifying the site of manufacture;
 - the unique product code;
 - logistical information designed by the manufacturer, and;
 - a part which can be read electronically in barcode or matrix code format, or both, which relates directly to the alphanumeric identification code.

60. For those explosives currently excluded from the scope of the traceability requirements in ER2014 the recast requires manufacturers to include their name, registered trade name or trademark, and the address at which they can be contacted on the product, or where that is not possible, on its packaging, or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.
61. It is expected that these requirements do not pose a significant burden on manufacturers. The interviews in fact indicated that most companies would not incur any additional costs because of changes in the recast around packaging. This is because the manufacturers already provide all required details.
62. However, we will continue to engage with industry during consultation to verify whether the estimate of no additional costs is reasonable.

Translation of Safety Information

63. The requirement, in the recast, to provide instructions in a language easily understood by end-users and consumers is expected to impact those businesses that transfer or export their explosives to countries where English is not considered 'easily understood'. This is because the interviews revealed that most manufacturers do not currently provide a translated version of safety information and instructions in their transferred or exported products. It must be noted, however, that some Member States have in the past been content with details provided in English.
64. We have an estimate from an interviewee of around £1k per product, per language to translate a product's safety information into another language. This is based on the cost of translating and proofreading one technical document of about 5000 words, at the cost of £200 per 1000 words. However, we are currently not able to estimate the number of firms that export to the countries in question, the number of products they export, and to how many countries they do so. As such, we are unable to estimate costs at this stage but will seek to obtain an estimate during consultation with industry.

Procedure when products pose a risk

65. The recast requires manufacturers to inform market surveillance authorities where their products pose a risk, and to withdraw products from the market if the market surveillance authorities request them to do so.
66. In terms of the requirement to inform authorities when products pose a risk, interviews with manufacturers revealed that no procedures would have to change in light of changes in the recast. This is classified as business as usual and no costs would be necessary to implement or set in place any additional procedures.

67. However, as the requirement to notify HSE is a new legal requirement, manufacturers would bear a cost of notification and following up any subsequent action requested by the Market Surveillance Authority. We have not quantified the costs, as inspectors' and manufacturers' knowledge of the sector indicates that the likelihood that products pose a risk is low. The costs would be the time cost of the phone call made to HSE for notification, and any costs that may develop from that around checking products and any subsequent action.

68. We assume that the likelihood that products pose a high enough risk to require recall or withdrawal is even lower. Furthermore, based on our knowledge of the market, we will assume here that, currently, if a product were to pose such a risk, manufacturers would withdraw it voluntarily. Therefore, in effect, this new requirement would not lead to any additional recalls. We will work with stakeholders during consultation to validate this assumption.

Familiarisation

69. Based on the method described in paragraph 25 it is estimated that between around one and two days would be required to read and understand changes and translate this into company policy. The best estimate is around 1.5 days.

70. Based on 13 firms, an FEC of £100 per hour and 7.5 hours in a working day, this gives an estimated total one-off cost of between around £9.8k and £19.5k, with a best estimate of around £14.6k.

Total Costs to Manufacturers

71. The costs described give a total estimated ten-year present value cost to manufacturers of between around £136k and £145k, with a best estimate of around £141k.

8.1.2 Distributors

72. Table 1 shows that around 30 distributors would be affected by the recast.

73. We are using a FEC of £100 per hour, as mentioned in paragraph 28.

74. Changes in the recast that are likely to affect distributors are additional obligations for checks by distributors, and changes in the required action if products are deemed unsafe or non-compliant. There are also some familiarisation costs.

75. The time and cost estimates used in this section are based on the one interview we had with a distributor. The figures would require refining during consultation, to ensure that they were representative of the sector.

Checking packaging and safety requirements

76. Under the recast the distributor must ensure that manufacturers and importers (where applicable) have complied with obligations in the recast Directive (in so far as they have provided required documents and that the products are CE marked) before making explosives available on the market.
77. Based on the interview we assume that the current procedure to check products received for dispatch will not change, and that no additional costs would be incurred. However, this assumption will be tested during consultation.

Action following receipt of non-compliant products

78. Under the recast, if a distributor believes that an explosive is not in conformity they must not place that product on the market. Furthermore, where it presents a risk, they must inform the importer or manufacturer, and notify the competent authority, providing the competent authority of the member states where they made the explosive available with details, including as to the non-compliance and any corrective action. They must also fully co-operate with the authority at its request on any action taken to eliminate the risk posed by the explosives they have placed on the market.
79. However we have not estimated any additional costs, given the low likelihood that products are not in conformity, pose a risk, or pose a high enough risk to require withdrawal, as described in paragraph 67 and 68 on costs to manufacturers.

Familiarisation

80. We estimate, based on the method described in paragraph 25, that distributors would take between around half a day and a day to familiarise, with an FEC of around £100 per hour. This gives a cost per firm between around £375 and £750, with a best estimate of around £563.
81. Across the 30 distributors, this gives a total estimated one-off cost of between around £11.3k and £22.5k, with a best estimate of around £16.9k.

8.1.3 Importers

82. Table 1 shows that the Recast would affect around 15 importers.
83. We are using an FEC of £100 per hour, as mentioned in paragraph 28.
84. Changes in the recast that are likely to impact importers are changes in packaging and safety requirements and changes in the required action if products are deemed unsafe or non-compliant. There are also some familiarisation costs.

85. The time and cost estimates used in this section are based on the one interview we had with a distributor. The implications of the recast are similar for the importers and the distributors; however, the figures would require refining during consultation.

Checking packaging and safety requirements

86. The current directive does not place specific obligations on importers, but no product can be placed on the market unless all essential safety requirements (including conformity attestation) have been complied with.

87. Under the recast directive, the importer must ensure that the manufacturer has drawn up all technical documentation and that all instructions and safety information are present, and that this information accompanies the explosives or articles.

88. It is understood that the current procedure to check whether products received for dispatch are compliant will not change, and that no additional costs would be incurred.

89. Under the recast, importers must also annotate the explosives with their details, but the impact has not been estimated, as we have not interviewed any importers. The cost of this requirement will be explored during consultation, and quantified if proportionate.

Action following receipt of non-compliant products

90. Under the recast, if an importer suspects the essential safety requirements have not been met they must make arrangements for the explosive to be withdrawn or recalled from the market and take corrective action to ensure its conformity. If it presents a risk, importers must notify competent authorities (in the state they have placed them on the market) and notify them of any corrective measures taken.

91. However we have not estimated any additional costs, given the low likelihood that products are not in conformity, pose a risk, or pose a high enough risk to require withdrawal, as described in paragraph 67 and 68 on costs to manufacturers.

Familiarisation

92. Based on the method described in paragraph 25, we estimate that importers would take between around half a day to a day to familiarise, with an FEC of around £100 per hour. This gives a cost per firm between around £375 and £750, with a best estimate of around £563.

93. Across the fifteen importers, this gives a total estimated one off cost of between around £5.6k and £11.3k, with a best estimate of around £8.4k.

8.1.4 Total Costs to Business

94. Keeping in mind the assumptions and limitations of the assessment to date, this gives a total estimated ten-year present value cost to business of between around £153k and £179k, with a best estimate of around £166k.

95. This is broken down as follows:

- To manufacturers, between around £136k and £145k, with a best estimate of around £141k
- To importers, between around £5.6k and £11.3k, with a best estimate of around £8.4k
- To distributors, between around £11.3k and £22.5k, with a best estimate of around £16.9k

8.2 Costs to Government

8.2.1 Notified Body

96. Within GB there is currently only one NB, the Health and Safety Laboratory (HSL), which is part of HSE. As HSL is a public body, the costs described in this section are classified as costs to government.

97. The function of a NB is to verify the compliance of a product by conducting a conformity assessment. It also ensures that the technical documentation sufficiently supports product compliance. If the NB is involved in the production control phase, its identification number will follow the CE marking. A fee in respect of the work to be undertaken is agreed with and paid by the manufacturer to the NB. When the notified body is convinced of product compliance, a certificate of conformity that confirms this will be issued. The manufacturer will then draw up the Declaration of Conformity (DoC) to declare that they are solely responsible for the product's conformity to the Directive.

98. The changes in the recast that impact the NB are slight modifications in the description of Module B (as described in the costs to manufacturers), and the cost for accreditation under BS EN ISO/IEC17065:12 and continuous monitoring against that standard.

99. Do note that under the NLF one of the measures also intended to ensure the quality of work performed by NBs (not just those in the civil explosives sector) are specific requirements for notifying authorities (the national authorities in charge of the assessment, notification and monitoring of NBs). BIS will be assessing the impact of specific requirements on notifying authorities, in their forthcoming IA covering the other seven directives in NLF.

Conformity Attestation

100. The interview with HSL revealed that no additional time would be required by the notified body to review additional information received for CE marking of products. The reason why no additional time would be required is that HSL believe that manufacturers already supply all of the information that the Recast Directive indicates as a requirement. During consultation, we will ask for further feedback from manufacturers to clarify the extent of the changes.

Accreditation

101. In order to attain accreditation as notified body for explosives, HSL would need to be approved by the United Kingdom Accreditation Service, UKAS.¹³ UKAS have estimated that this would require two pre-assessment visits, for which HSL would be charged £7.5k each. There would then be a final assessment visit, charged at £15k. This gives a total estimated one-off cost of around £30k.

102. Thereafter, UKAS would undertake an annual inspection visit, which would be charged at around £10k. This annual cost will be borne from Year 1 to Year 9 and gives an estimated ten-year present value cost of around £76k.

103. Thus the total cost incurred by HSL to attain and maintain accreditation over the 10 year appraisal period, is around £106k. This includes the one-off cost in Year 0, and the cost of the annual inspection visits borne from Year 1 to Year 9.

104. It is likely that HSE would pass on all of this cost to manufacturers.

105. HSL have indicated that they would incur additional costs in terms of their own time and resources to comply with the accreditation process, but that they are unable to estimate them at this stage.

Familiarisation

106. As HSL are the only notified body, and they already have a clear understanding of the implications of the Recast on their business, we estimate that they will not incur any familiarisation costs during the appraisal period.

8.2.2 Regulator

Extension of Powers Under RAMS

107. Changes in the Recast mean that HSE inspectors would require a power to recall products. Currently, when products pose a risk, HSE inspectors could use powers under the Health and Safety at Work Act

¹³ Notified Bodies can choose one of two routes for accreditation appointment: one is through the accreditation authority, and the other is a direct route through the National Authority to the Commission. They chose the former.

(HSWA) to issue enforcement or prohibition notices to firms; however, they do not have the power to recall or withdraw the product.

108. The extension to HSE inspectors of powers under the Regulation on Accreditation and Market Surveillance (RAMS) would require some additional training of the twenty-eight inspectors. The HSE Explosives Inspectorate has estimated that the training would take about half a day and would be delivered internally. Based on the full economic cost of an inspector of around £557 per day, this gives an estimated total one-off cost to Government of around £7.8k.

Tightening of the safeguard clause

109. The tightening on the safeguard clause means there are now obligations on importers and distributors to notify relevant enforcement authorities when there are unsafe explosives. This means that HSE may receive notification of unsafe products more often from other EU authorities. This may increase the amount of information made available to HSE and HSE could therefore incur additional costs of acting on the information, and taking any relevant enforcement action. Given the low likelihood of receipt of unsafe explosives, this cost is deemed low, and its estimation is therefore not considered proportionate.

8.2.3 Total Costs to Government

110. Keeping in mind the assumptions and limitations of the assessment to date, this gives a total estimated ten-year present value cost to government of around £114k.

8.3 Benefits under the recast

111. It has not been possible to quantify and monetise any of the following benefits at this stage, but further work will be undertaken with the industry group and through consultation to do so for the final stage IA, if proportionate to do so.

8.3.1 Improvement of Safety Standards

112. Any product that poses a risk under the recast would be withdrawn from the market regardless of where it is in the supply chain, as all economic operators will have responsibility for the safety of the explosive and any risk posed throughout the supply chain. This would allow for a more rapid identification of such products and their swifter withdrawal, thereby limiting the scope for risks to human health and safety. However, the high level of existing standards and the extent to which such monitoring is already standard practice is expected to limit the extent of this benefit.

113. End users will have explosives that satisfy all current essential safety standards and are clearly marked accordingly, and receive safety

instructions in a language that is easily understood to enable them to use the explosives safely in the correct manner and environment. This is expected to minimise situations wherein users are unclear of the risks or correct uses for the product due to sub-standard packaging. However, as above, the high level of existing standards is expected to reduce the scope for such benefits.

8.3.2 Equivalence of Notified Body Standards

114. The recast provides a common legal framework across the EU, which in turn creates a level playing field for all economic operators who will be obliged to comply with the Directive. Continuous assessment of NBs will ensure standards of assessment and impartiality are maintained. Assessments of conformity undertaken by notified bodies should be of similar standard throughout the EU, including those products imported from third countries. This is expected to reduce the scope for manufacturers to seek attestation of conformity through an NB in the EU that may apply a lower standard than does HSL, as well as the scope for products entering the British market from outside the EU to fail to be assessed to the intended standard. This would thereby limit the scope for unsafe products to reach the British market.

8.3.3 Authorised Representatives

115. Under the recast, manufacturers can authorise or appoint an authorised representative by written mandate to place a product on the EU market. This person is neither the manufacturer nor an importer but acts on behalf of the manufacturer for the purposes of, for example, record keeping. As this is a new role and not mandated (a permissive change), it is for the manufacturer to decide to make such an appointment and any benefits to the manufacturer would at least be equal to the costs, or the manufacturer would not engage such a representative.

8.3.4 Benefits in enforcement and detection

116. Under the tightening on the safeguard clause that ensures the relevant enforcement authorities are informed about explosives that are non-compliant and that the equivalent response will be acted upon by all other Member States, HSE may receive notification of unsafe products more often from other EU authorities. This may increase the amount of information made available to HSE as regulator and allow for cross-border enforcement to be undertaken with greater regularity and at lower cost.

117. Notification to HSE from economic operators of any explosives that pose a risk would allow HSE to quickly identify the manufacturer, importer or distributor and ensure they take the appropriate action to have that product removed and/or recalled from the market until such time that it is compliant with the requirements under the Directive.

9 Proportionality Approach

118. As explained in paragraph 27 the research carried out was considered proportionate for the consultation stage IA given the scale of expected changes on the various economic operators, and the size of the sector.

10 Risks and Assumptions

119. We expect that the approach to implementation, and the changes described throughout the IA, will remain the same and will continue to apply. However, it is still early days in the implementation process, and issues may arise that cause a departure from the implementation approach and/or the need to revise estimates, and estimate further costs.

120. The costs to manufacturers are also sensitive to expectations about future markets, as explained in paragraph 43.

121. We described the key assumptions in section 7. These covered the cost of time, time horizon and discounting, and the size of the explosives sector.

11 Direct Costs and Benefits to Business Calculations

122. This IA calculates the costs borne by business and government from the transposition of a European directive. No gold plating takes place. It is therefore not in scope of OITO.

123. The direct costs to business are calculated based on the costs estimated between pages 10 and 17.

124. The EANCB in 2009 prices is estimated to be around £0.01 million.

12 Wider Impacts

125. Wider impacts have been considered and no impacts have been identified for;

- Statutory Equality Duties;
- Human Rights;
- Justice System;
- Rural Proofing;
- Social Impacts;
- Environmental impacts; and
- Sustainable development.

126. We have considered the criteria for wider competition and health and wellbeing impacts and do not consider that there is anything that needs to be addressed other than what is addressed in the main body of the IA.

127. The civil uses explosives sector is mainly made up of a number of small businesses, some of which were interviewed as we were calculating the main costs of the IA. The impacts on these businesses are therefore identical to those described in the main body of the IA. Also, note that there is no small business exemption due to the high hazard nature of explosives.

13 Small Business Exemption

128. There is no small business exemption due to the high hazard nature of explosives.

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14 Summary

129. Table 2 summarises all quantified costs and benefits to business and government.

Table 2: Summarised quantified costs (£ thousands)

	Low	Likely	High
Manufacturers			
Conformity Attestation	126	126	126
Procedure when products pose a risk	Nil	Nil	Nil
Familiarisation	9.8	14.6	19.5
Total costs to manufacturers	136	141	145
Distributors			
Checking packaging and safety requirements	Nil	Nil	Nil
Familiarisation	11.3	16.9	22.5
Total costs to distributors	11.3	16.9	22.5
Importers			
Checking packaging and safety requirements	Nil	Nil	Nil
Familiarisation	5.6	8.4	11.3
Total costs to importers	5.6	8.4	11.3
Total costs to business	153	166	179
Government			
Regulator			
Extension of RAMS	7.8	7.8	7.8
Notified Body			
Conformity Attestation	Nil	Nil	Nil
Accreditation	106	106	106
Familiarisation	Nil	Nil	Nil
Total costs to the NB	106	106	106
Total costs to Government	114	114	114
Total costs	266	280	293

Note: Figures are ten-year present values, in thousands, and totals may not sum due to rounding.

130. In addition, some impacts have yet to be quantified in this consultation stage IA, and some assumptions require further refinement. Further work will be undertaken during consultation to estimate the likely impact of these. Each component is discussed above but they are collected in Table 3 for reference.

Table 3: Summary of areas requiring further research for the final stage IA

Area	Likely scale of change	Further work to be undertaken
Full Economic Cost estimate for distributors and importers (Paragraph 28)	This may be revised down or up depending on the feedback received	Given that it is a one-point estimate we will seek feedback from the working group, and during consultation about whether the estimate of £100 per hour is appropriate.
Additional time spent on conformity attestation by manufacturers (Paragraph 52)	The current cost estimate is expected to be narrowed	Following feedback from HSL that the conformity attestation procedure hasn't changed significantly we will seek to refine the additional time estimated by manufacturers that would be required. The requirements are likely to become more clear during consultation which will facilitate additional time estimates
Changes in packaging requirements for manufacturers (Paragraph 56)	Small increase in costs, if any at all	We will engage with industry to verify that the estimate of no additional cost is reasonable.
Changes in requirements for manufacturers on language of safety information (Paragraph 60)	Some transition costs to business expected, with smaller ongoing costs	We will engage with industry during the consultation process to get a better picture of which countries they trade with, and how many products would require translated safety information.
Importer annotation of explosives with own details (Paragraph 85)	Negligible	We will engage with importers during consultation stage to estimate this cost, if proportionate to do so
The time that the notified body must spend on preparing for the accreditation process and visits by UKAS (Paragraph 98)	Several hours	We will engage with HSL to obtain an estimate of how much time their staff would need to spend on the accreditation process.