

Title: Impact assessment for the transposition of the Seveso III Directive into UK Law through the COMAH Regulations 2015
IA No: HSE 0082

Lead department or agency:

Health and Safety Executive

Other departments or agencies:

Environment Agency

Scottish Environment Protection Agency (SEPA)

Natural Resources Wales (NRW)

ONR

Department for Communities and Local Government and the devolved administrations

Impact Assessment (IA)

Date: 28th October 2014

Stage: Final

Source of intervention: European

Type of measure: Secondary Legislation

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Summary: Intervention and Options

RPC Opinion: Green

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
-£40.23m	-£39.30m	£0.1m in-scope of OITO (£3.69m overall)	Yes	IN

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

European member states currently regulate establishments with major accident potential through Directive 96/82/EC, more commonly known as the "Seveso II Directive". This is implemented in Great Britain (GB) through the Control of Major Accident Hazard (COMAH) Regulations 1999 as amended and land use planning legislation. Northern Ireland and Gibraltar have corresponding legislation. Due to changes in the EU system of classifying chemicals (on which the Seveso Directive is based) the European Commission (EC) has replaced the current Seveso Directive with a new Directive (Seveso III). At the same time, the Commission took the opportunity to modernise the Directive in line with other environmental legislation. UK Government intervention is required to implement new COMAH Regulations 2015 (COMAH'15) to fully transpose the Seveso III Directive into law in Great Britain by 1 June 2015.

What are the policy objectives and the intended effects?

The UK policy objectives are to ensure that implementation of the changes is clear, coherent and easy to understand and does not place a disproportionate burden on industry, regulators or other stakeholders. Successful transposition of the changes will ensure continued high levels of protection for human health and the environment are maintained.

What policy options have been considered, including any alternatives to regulation?

To comply with our legal obligations, the UK will implement COMAH'15 and relevant legislation to implement land-use planning requirements in Great Britain and the equivalent in Northern Ireland and Gibraltar to ensure the Directive is fully transposed by 1st June 2015. The vast majority of the Directive will be transposed in the form of copy-out in line with UK Government policy. During negotiation of the Directive, the UK successfully narrowed down the amount of prescription in the original proposal and was instrumental in achieving agreement that an EU Expert Group should be established to share good regulatory practice. This will help to ensure consistency of approach and a level playing field for businesses across member states. The limited areas where it is proposed to go further than the requirements of the Directive are where there are already similar measures in existing UK law or where there are strong public safety or public information arguments/benefits to do so. The options considered in the Impact Assessment (IA) are Option 1, to maintain the status quo, and Option 2 (the preferred option), to implement the Directive. Emergency responders' involvement in emergency plan testing is an area of gold plating and the source of the small 'IN'; however, the majority of responders to the public consultation supported this proposal. The consultation stage IA considered options built around who should pay for the emergency responders' involvement in testing emergency plans (business, local government or the emergency services themselves). HSE now considers that a decision on charging/cost recovery for the involvement of emergency responders is beyond its remit and is a matter for local democracy - under Option 2 in this IA, Local Authorities may choose how and whether to recover costs.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: June 2020

Does implementation go beyond minimum EU requirements?			Yes		
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 Minister : _____ Freud _____ Date: _____ 2/3/2015 _____

Summary: Analysis & Evidence

Policy Option 1

Description: Status quo

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2014	Time Period Years 10	Net Cost (Present Value (PV)) (£m)		
		Low: Nil	High: Nil	Best Estimate: Nil	

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

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

There are no costs associated with this option as it maintains the status quo. This option has been included as the baseline against which the other options are assessed.

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

There are no costs associated with this option as it maintains the status quo.

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

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

There are no benefits associated with this option as it maintains the status quo

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

There are no benefits associated with this option as it maintains the status quo

Key assumptions/sensitivities/risks

Discount rate (%)

3.5

Under this scenario, COMAH'99 would no longer function as they would be linked to Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP) which from 1 June 2015 will be superseded by the Classification, Labelling and Packaging Regulation (CLP). This would mean that there would be no basis in regulation for defining establishments as in or out of scope of COMAH as such the existing COMAH regime could no longer function.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: Nil	Benefits: Nil	Net: Nil	N/A	N/A

Summary: Analysis & Evidence

Policy Option 2

Description: Full implementation of the Seveso III Directive through COMAH'15, with Local Authority discretion as to the charging for Category 1 (Cat 1) responder testing of emergency plans

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2014	Time Period Years 10	Net Cost (Present Value (PV)) (£m)		
			Low: £18.2	High: £62.3	Best Estimate: £40.2
COSTS (£m)	Total Transition (Constant Price, PV) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)	
Low	£17.5	2	£0.4	£20.9	
High	£59.3		£1.0	£67.4	
Best Estimate	£38.4		£0.7	£44.1	
Description and scale of key monetised costs by 'main affected groups'					
<p>The main costs to industry represent work undertaken to become compliant with the new COMAH Regulations (COMAH'15). Greatest among these are the costs of updating safety reports (around £20.9m over ten years), redacting safety reports (around £11.4m over ten years) and managing public information (around £2.9m over ten years). The Competent Authority would cost recover a further £1.9m over ten years to cover its work managing public information and assessing the information provided by new and existing establishments. The cost of requiring emergency responders to attend external emergency plan tests at Upper Tier (UT) COMAH establishments has been estimated at around £1.6m in present values over ten years, of which around £1.1m would fall on business. As this is gold plating, it is in scope of OITO and brings an 'IN' of around £0.1m EANCB in 2009 prices.</p>					
Other key non-monetised costs by 'main affected groups'					
<p>Additional smaller areas of gold plating concern HSE specifying COMAH establishments must use its IT platform (database) to submit notifications and host public information, the cost of which is expected to be insignificant. Table 10 shows areas of gold plating, including where current health and safety standards are being maintained at no additional cost. Other non-monetised costs include possible (but unlikely) upward revisions to the estimates of the number of sites in scope of the Regulations due to the inclusion of alternative fuels and substances in pipelines in notifications and a very small ongoing cost to HSE to verify establishments' public information.</p>					
BENEFITS (£)	Total Transition (Constant Price, PV) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)	
Low	£0	1	£0.3	£2.8	
High	£0		£0.6	£5.1	
Best Estimate	£0		£0.5	£3.9	
Description and scale of key monetised benefits by 'main affected groups'					
<p>The main savings arise from an expected net decrease in the number of establishments in scope of COMAH. This results in direct ongoing savings to business and reduced ongoing cost recovery by the CA for some activities. COMAH'15 maintains the existing environmental and human health standards already in place under COMAH'99.</p>					
Other key non-monetised benefits by 'main affected groups'					
<p>Pre-existing gold plating from COMAH'99 will be removed in respect of allowing a longer period to submit an internal emergency plan in line with the Directive. The additional time allowed is small, but some savings might be made by industry in scope of OITO. It has not been possible to estimate this, but HSE considers the impact very slight. New duties on COMAH establishments to identify and share information with non-COMAH neighbouring establishments that are particularly vulnerable to major accidents may allow the escalation of major accidents to be mitigated were they to occur. This would have benefits for the environment, human health and the economy. However, the frequency of such events is so small that HSE is unable to reliably quantify the impact of this. The benefits, if quantified, would be unlikely to outweigh the costs.</p>					
Key assumptions/sensitivities/risks				Discount rate (%)	3.5

Many of the costs and savings discussed are based on estimates of the number of establishments in scope of COMAH'15 and a great deal of research has been undertaken to produce these. Further refinements to these estimates were considered during consultation, but were not considered proportionate given the level of work already completed. The analysis of the costs of requiring emergency responders to attend external emergency plan tests at UT COMAH establishments, where invited, assumes that LAs and emergency responders will choose to divide costs as they do now, with business bearing around two-thirds. Should this proportion rise, however, so, too, would the costs to business and so the size of the 'IN'. However, as business already bears two-thirds, it would be unlikely to rise by much.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: £0.1	Benefits: £0.0	Net: £0.1	Yes	IN

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1. Problem under consideration

1. The Seveso Directive was first adopted in 1982, following a major accident in Seveso, Italy, and is the main piece of European Union (EU) legislation that deals specifically with on-shore major accident hazards involving dangerous chemical substances. The aim of the Directive is to prevent major accidents which involve dangerous substances and limit the consequences to people and the environment of any accidents which do occur.
2. The Directive is based on a three-part strategy:
 - Identification of major hazard establishments by reference to either named substances or categories of substances e.g. toxic or inflammable above certain threshold quantities;
 - Prevention and control of major accidents by technical, procedural and organisational measures and to demonstrate these in a safety report prepared by the operator and submitted to the regulator for assessment, and
 - Mitigation of the consequences of a major accident by emergency plans and land use planning controls.
3. The European Commission (EC) has replaced the Seveso II Directive (96/82/EC) with a new Directive (Seveso III 2012/18/EU) which came into force on 13th August 2012. Seveso II was replaced because the hazard-based classification system for chemicals which is implemented through the Chemicals (Hazardous Information and Packaging for Supply) (CHIP) Regulations 2009 is being replaced by a new EU Regulation on the classification, labelling and packaging (CLP) (EC 12 72/2008) Regulation. Industry was influential in the introduction of the CLP Regulations and supportive of their implementation because of the international trade benefits they bring through improved integration. The scope of Seveso II was determined by CHIP so the move to CLP meant that Seveso II would no longer function unless there was a link to CLP. The Commission took this as an opportunity to modernise the Directive in line with other environmental legislation.
4. CLP has strong links to REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) which came into force on 1st June 2007 and replaced a number of European Directives and Regulations with a single system. REACH applies to substances manufactured or imported into the EU in quantities of 1 tonne or more per year. It applies to all individual chemical substances on their own, in preparations or articles. Certain substances are excluded e.g. radioactive substances. Businesses that manufacture or import (from outside the EU) 1 tonne or more of any given substance each year are responsible for registering a dossier of information about that substance with the European Chemicals Agency. Substances in articles may also count towards this manufacturing or importation total.
5. REACH defines the content of the label on the products put on the market and the description of hazards and precautions in the safety data sheet. Information produced within the framework of the REACH provisions must be used for the classification of the product.¹

¹ Further information about REACH can be found at <http://www.hse.gov.uk/reach/index.htm>

6. The original Seveso Directive has been revised on a number of occasions. Seveso II is implemented in Great Britain by the Control of Major Accident Hazards (COMAH) Regulations 1999 (as amended) and separate land use planning legislation which is the responsibility of the Department for Communities and Local Government (DCLG) and the devolved administrations. Northern Ireland and Gibraltar have corresponding legislation. The COMAH regulations are enforced by a Competent Authority (CA) comprising HSE and the Environment Agency (EA) in England², Natural Resources Wales (NRW)³ in Wales and the Scottish Environment Protection Agency (SEPA) in Scotland. The Agencies lead on the environmental aspects of the legislation.
7. Seveso and COMAH work on a number of principles, the first of which is that establishments come into scope if they have dangerous substances at or above the threshold quantities in Schedule 1 of COMAH'99. There are two tiers of regulatory control, known as Top Tier and Lower Tier (LT), depending on the quantity of dangerous substances present. Top Tier will be renamed Upper Tier (UT) in COMAH'15.
8. Other principles of both the COMAH 99 and COMAH'15 regimes include land use planning controls and a programme of inspection by the CA. COMAH operators must:
 - take all necessary measures to prevent major accidents and limit the consequences for people and the environment of any that do happen;
 - notify specified information to the CA;
 - prepare and implement a major accident prevention policy (MAPP);
 - plan for emergencies;
 - notify major accidents to the CA.
9. In addition operators of UT establishments must:
 - prepare external emergency plans and review, test and where necessary revise them at least every three years.
 - produce and submit to the CA a written safety report which sets out the main risks presented by the establishment, the ways in which these risks are controlled and the means of mitigating the consequences of any failure that might occur. The safety report must be reviewed at certain times and revised as necessary to reflect changes at the establishment. It must be fully reviewed at least every five years. The CA must examine the safety report and communicate conclusions to the operator and designate 'domino groups' i.e. groups of sites within sufficiently close proximity such that an incident at one may trigger an event at another.
 - provide information to people and establishments liable to be affected by a major accident about the major accident hazards and the safety measures that are in place. The information has to be reviewed at least every three years.
10. Since 1999 the CA is required by Government to recover from establishments the costs of the regulatory activities that fall to the CA as a result of the COMAH regulatory regime. Additionally, for UT establishments costs are also recovered for work in ensuring compliance with other health and safety legislation. The system of cost recovery is based on the amount of resource used by the CA in

² Since 2013

³ Since 2013

performing its duties under COMAH and, for HSE, other relevant regulatory functions in relation to any particular establishment.

Effectiveness of the Seveso II Directive

11. A study⁴ was undertaken in 2008 on behalf of the European Commission to assess the level and quality of implementation of the Seveso II Directive and its impact on the competitiveness of the EU. The report concluded that:
- the Directive had led to a “recognizably higher level of safety in comparison to non-Seveso establishments”;
 - it is effective in achieving its aims to prevent major accidents and limit the consequences of any accidents that do happen;
 - the two-tier approach (referred to in paragraph 7) which implements the proportionality principle was seen as appropriate, although the report also concluded that certain effective aspects of the Directive could additionally be applied to LT establishments;
 - industry recognised that the requirements have to be implemented and the safety costs are financially beneficial in the long term as opposed to the potentially huge cost of a major accident.
12. Informal consultation with industry during 2013 bore out the fact that industry appreciates the level of detail in the current COMAH regime and the clarity that the regulations provide.

Gold Plating

13. Gold plating is proposed in eleven areas (see Table 10 on page 52) and is described in the relevant paragraphs of this assessment. These areas were tested during informal and public consultation with little or no negative feedback from stakeholders at each stage; or were suggested by the consultation itself. Seven of the areas of gold plating are where there is a higher standard in GB legislation and a failure to retain those standards would constitute an overall reduction in safety standards. These have not been costed as their costs are included in the baseline, hence no new additional costs will occur. One area in relation to safety reports and maintenance of the 5 year review cycle was supported by some operators during public consultation. It will not result in any increased costs to business and would in fact reduce costs relative to copying out the Directive – this is demonstrated in paragraphs 85 to 97.
14. The remaining three areas of gold plating are described in more detail in this IA. In summary they are:
- A requirement that Category 1 responders (‘Cat 1s’, as defined in the Civil Contingencies Act 2004⁵) must, by law, be included in the testing of emergency plans for UT establishments (No. 7 on Table 10). This proposal stems from views of a range of stakeholders (e.g. industry, emergency planners, emergency responders) during informal consultation. This measure will ensure that external emergency plans are properly tested (which is not always the case at present) and provide public assurance that Cat 1 responders are engaged

⁴ http://ec.europa.eu/environment/seveso/pdf/seveso_report.pdf

⁵ Cat 1s include the ‘blue lights’ emergency services, accident and emergency services, local council, Primary Care Trust, local health board, port authority and appropriate agency for the environment.

with the emergency response procedure for the establishment. Research was undertaken during the consultation period to establish the extent to which Cat 1 responders currently participate in the testing of external emergency plans, who pays for their involvement and how much their involvement costs. Further details about this research is available at paragraphs 143 to 156.

- The other two areas relate to electronic communication. HSE proposes to provide the means by which the operator can make the public information permanently and electronically available and comply with the notification requirements through an HSE database (No. 2 and 8 on Table 10). This will help to reduce costs to industry and is in line with the Government's strategy 'Digital by Default'. The costs of this (if any) will be minimal. Further details can be found in paragraphs 111 to 112 and 126.

2. Rationale for intervention

15. UK Government intervention is required in order to comply with the Seveso III Directive. The UK is required to fully transpose the Directive (2012/18/EU into law by 1st June 2015 and will do so by implementing new COMAH Regulations and legislation to cover the land use planning elements⁶. Effective implementation will ensure the UK avoids infraction proceedings and associated costs for failure to fully implement the Directive. In addition, the superseding of the CHIP classification regulations by CLP will mean that from 1st June 2015 there would be no basis in regulation to define sites as in scope or not of the COMAH'99, so COMAH'15 is necessary as they will reflect the CLP classifications and continue to ensure high levels of protection to people and the environment from major accidents involving dangerous substances.
16. HSE's objective throughout transposition of this Directive is to ensure high levels of protection are maintained in line with the Directive whilst minimising the costs to business and not compromising their competitiveness in Europe. We have also sought to add clarity to the requirements wherever necessary.
17. During negotiation of the Directive, the UK successfully narrowed down the amount of prescription in the original proposal and was instrumental in achieving agreement that an EU Expert Group should be established to share good regulatory practice. This will help to ensure consistency of approach and a level playing field for businesses across member states. Throughout the transposition of the Directive itself, HSE has sought to reduce regulatory burdens on business by:
 - working closely with the Better Regulation Executive on findings from the recent Focus on Enforcement Review so that the draft COMAH Regulations take into account the outcome of that work;
 - working closely with stakeholders during informal consultation who have good knowledge and experience of the current COMAH regime and have been able to advise HSE on the development of the new regime.

3. Policy objectives

18. The UK policy objectives to implement the Directive are to ensure that:
 - implementation of the changes is clear, coherent and easy to understand;

⁶ Implemented by DCLG and the devolved administrations

- they do not place a disproportionate burden on industry, regulators or other stakeholders;
- high levels of protection are maintained and further improved in line with the Directive, for human health and the environment;
- a 'level playing-field' for the major hazards industry is maintained.

4. Description of options considered

19. Three broad options were considered in the development of this IA;

- Do nothing. This was not a viable option because:
 - the Directive must be transposed into law by 1st June 2015 or risk infraction proceedings;
 - industry's desire for an integrated world-wide chemical classification system would not be realised;
 - the COMAH'99 Regulations will fall on 1st June 2015 by virtue of them being based on a, by then, non-existent classification system (CHIP), and this would result in unacceptably lower levels of protection.
- Use non-legislative means. This option would leave the UK open to infraction proceedings by the EC, as it would not deliver the certainty of risk reduction that legislative means can deliver.
- Transpose the Directive into UK law through implementation of new COMAH Regulations.

20. Since a) and b) are not viable options, in accordance with Better Regulation guidance on IAs⁷ they have not been analysed any further in this IA. The negotiation process effectively considered and ruled out other options for implementation. In reality, there is only one viable option, which is c) above, to transpose the Directive into law through implementation of new COMAH regulations.

21. Three policy options were put forward in the consultation stage IA in relation to who would bears the cost for the involvement of Cat 1 emergency services⁸ in emergency response plan testing – industry or local authorities. The options were as follows:

- Option 2: the Local Authority bears the cost
- Option 3: the COMAH establishment bears the cost
- Option 4: the Local Authority has discretion whether to pass the cost onto the COMAH establishment

22. Following consultation and the further research undertaken by HSE it is now proposed that Option 4 (now referred to as Option 2 in this IA as the other two options have been removed) will go forward i.e. the Local Authority can decide whether or not to pass the cost on to industry or not as HSE believes this is a matter for local democracy and not within HSE's remit to decide. The proposed regulations allow for cost recovery and it is a matter for local democracy to decide

⁷ See the Better Regulation Impact Assessment Overview document : https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/31606/11-1110-impact-assessment-overview.pdf

⁸ As defined in the Civil Contingencies Act – see paragraphs 122 to 137

whether any costs incurred by the Cat 1 responders should be recovered from the establishments.

23. As explained under a) above, the 'do nothing' option is not viable. However, in order to appropriately reflect the additional costs and benefits of the new COMAH'15 regulations they must be compared to a baseline. The baseline used in this IA is the scenario whereby the COMAH'99 regulations (Seveso II) continue into the future. This allows comparison of the additional costs that will result from COMAH'15 compared to the current situation, which is the relevant comparison for decision-making purposes. This is referred to as Option 1 in this IA.

5. Preferred Option

24. The preferred option is Option 2 i.e. full implementation of the Seveso III Directive through COMAH'15, with Local Authority discretion as to the charging for Cat 1 responder testing of emergency plans. This will ensure that the Directive is fully transposed into UK law and will protect the UK from infraction proceedings by the EC. It will also satisfy the policy objectives whilst continuing to ensure that high levels of protection are maintained and further improved for human health and the environment.
25. HSE proposes wherever possible to retain the current safety standards in the COMAH regime, since not to do so could pose an increased safety risk. This means that in those areas where the current standards are being maintained there will be no additional costs to business. Instances where existing standards which are not required in the Directive have been retained are highlighted in this IA with accompanying justification. They are also summarised in Table 10.

6. Consultation, Analysis and Further Research

26. In the consultation stage IA there were some areas where we were unable to quantify costs for a variety of reasons (see Table 9). However, we committed to cover those costs in the final stage IA unless there were valid reasons not to do so, such as no further information being available, in which case we have dealt with them qualitatively. This final stage IA takes account of the information gathered through the public consultation, the analysis of responses and, where necessary, further research undertaken.

Public consultation

27. The 8-week public consultation on the proposed changes to COMAH'99 concluded on 27th June 2014 but responses were accepted for another week to allow for late submissions.
28. A link to the consultation was issued to subscribers to the Seveso III e-bulletin (approx 24,000 email addresses) and to HSE's consultations e-bulletin (approx 27,000 email addresses). It was also sent to approximately 80 key COMAH stakeholders. The link was also published on the HSE twitter feed (approx 36,000 followers).
29. The consultation document was downloaded 4,532 times and 145 individual responses were received; these included trade associations, operators, representatives of local authorities and emergency services and members of the public.
30. Overall, the responses were positive and generally supportive of the proposals. Issues raised were mainly ones that had been anticipated and previously raised at informal consultation events. Formal consultation responses have been

reflected in the analysis where appropriate and are addressed in the relevant sections of the IA.

Data on scope and compliance costs

31. In 2010, HSE commissioned ORC International, a research agency, to carry out a survey of all UK COMAH establishments with two main aims: firstly to identify what substances they were holding and secondly to gather information about the cost of compliance with COMAH'99. More information about this survey and the analysis of the data is available in Annex 2 and Annex 3. The survey received a 25% response rate and enabled the Health and Safety Laboratory (HSL) to estimate the number of sites that might move in or out of scope of COMAH'15 and the number of sites that might move between tiers in the regime. In addition to this survey evidence, data on around 6,000 substances has been made available via the European Chemicals Agency (ECHA) CLP inventory database⁹, including substances with an EU harmonised classification under CLP and notifications under REACH. Account was also taken of the named substances in the final published text of the Seveso III Directive. HSL used this data to further refine their estimates of the number of establishments affected by the change in scope. The entire analysis was subject to specialist peer review and the rigour involved allows reliance to be placed on the estimates of establishments changing scope and compliance costs in this IA. Full details of how scope is changing and the estimated impacts of such are provided in paragraphs 47 to 114.
32. In addition to the large scale quantitative survey, some qualitative work was undertaken to triangulate the findings. ORC research consultants used industry focus groups and in-depth interviews with industry to discuss the cost estimates with them, particularly whether these had changed over time, and to identify whether there were certain kinds of establishments or duty holders who incur different cost burdens for the same COMAH duty. This qualitative work did not identify any issues which would make us question the statistically robust cost estimates obtained from the quantitative survey work.

⁹ CLP Inventory Database, <http://echa.europa.eu/information-on-chemicals/cl-inventory-database>

Data on cost impacts of other key themes

33. HSE organised a research group comprising eleven representatives from industry and three representatives from trade associations (British Aerosol Manufacturers' Association; Chemical Business Association (CBA) and Chemical Industry Association (CIA)). The potential implications of the proposed COMAH'15 regulations and the cost impacts were discussed. There were some notable areas where impacts could not be quantified, but the research group helped to highlight these areas and they have been described qualitatively in this IA. Analysis of the research group findings is provided within this IA in the appropriate sections. The research group did not include many small companies because it can be difficult for them to spare the time to attend a workshop. Therefore, in order to capture their views, three small companies were contacted via telephone and the same questions asked of them as in the research group. Their answers are included in the summary analysis. When this IA refers to this analysis as a source of evidence, it will be referenced as 'the research group.'

Data on testing external emergency plans

34. In order to gather information to assess the costs of requiring Cat 1s to attend external emergency plan tests at UT establishments when invited, HSE commissioned HSL to undertake a series of interviews with eighteen LAs, thirteen emergency planners and five metropolitan fire brigades to answer three key questions:
- To what extent do Cat 1s currently participate in the testing of external emergency plans?
 - Who currently pays for this attendance?
 - What is the cost of this attendance?
35. The interviewees selected were chosen because of the range of UT establishments in their jurisdiction, which allowed the research to gather data on the experiences of around one-third of all UT sites from these eighteen interviews. Further detail of the results is given in paragraphs 143 to 156.

7. Costs and Benefits

36. The costs and benefits of the proposal have been considered. Although many of the key themes in COMAH 99 remain the same in the proposed COMAH 15 Regulations, there have been some key changes in the classification system and, as a result of modernising the Directive, an increase in access to information for the public. There have also been a number of other smaller changes. The best way to capture these is to analyse the impacts under five key headings:
- The change in scope as a result of the changes in the classification system and knock on effects to existing establishments
 - Notifications and safety reports
 - An increase in requirements to provide access to information for the public
 - Changes to the emergency planning system
 - Other changes including the streamlining of information provision to the CA

8. Risks and Assumptions

37. All costs and benefits are appraised over a period of 10 years. It is understood that the Commission will report to the European Parliament by September 2020 (5 years after COMAH'15 comes into force) and every 4 years thereafter. If in 2020 it is identified that Seveso III needs updating, then negotiations on Seveso IV will begin. It is unlikely that a new Seveso IV Directive would be in place before 2024, which takes us to a period of 10 years from the time of writing (and 2014 being the first year of the appraisal period).
38. The IA includes costs and benefits that extend into the future. Consequently, it is important that any monetised impacts are expressed in present values, to enable comparison over time. The discount rate used to generate these present values is defined in the Green Book¹⁰ as 3.5% for any appraisal period of less than 30 years.
39. Costs are in terms of opportunity and financial costs. Where market values are not available, costs are expressed in terms of the best proxy value where relevant. For instance, for any compliance activities that take up the time of a worker or duty holder, there is a cost of that time. The best proxy for the value of this time is what they could have produced during that time if they were not required to perform these compliance tasks. It is assumed that the worker's productivity is best reflected by the true cost of employing that person (they create as much value as they are paid). In reality this could be conservative for some occupations and staff, but is the best estimate available and is recommended by Government in the HM Treasury Green Book (see footnote 10). The true economic cost of employing the person is assumed to be their gross hourly wage rate inflated by 30% to reflect the non-wage costs of employment (such as employer tax and NI contributions, employer contributions to pension and overheads).
40. Based on discussions with the research group, it has been ascertained that in large businesses, most of the compliance work would be undertaken by a science professional. Using ASHE 2013(p)¹¹, the gross hourly wage rate of a Science, Technology and Engineering professional is £20.93 an hour.¹² The true economic cost of the employee's time is £27.21¹³ an hour and this is used in the IA for large businesses unless stated otherwise. For small and medium sized businesses, the research group discussed that the compliance tasks would mostly be undertaken by senior management or Board-level Directors. Using ASHE, the gross hourly wage rate for Corporate Managers and Directors in 2013 is £26.71¹⁴. The true economic cost of this time is therefore £34.72 an hour and this is used in this IA for the cost of small and medium sized companies' time, unless otherwise stated.
41. It was necessary to estimate what proportion of affected businesses are small, medium and large. The survey of COMAH establishments described in paragraph 32 shows that of the establishments surveyed, 47% were small (1- 49

¹⁰ Available at: http://www.hm-treasury.gov.uk/d/green_book_complete.pdf

¹¹ Annual Survey of Hours and Earnings, available at:

<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcM%3A77-328216>

¹² Based on ASHE 2013(p), Table 14.5a, SOC Code 21: Science, research, engineering and technology professionals

¹³ The gross hourly wage rate is inflated by 30% to reflect the true cost of employing that person (employer tax, pension, NICS etc).

¹⁴ Based on ASHE 2013(p), table 14.5a, SOC Code 11: Corporate managers and directors

employees), 33% were medium sized (50 - 249 employees) and 21% were large (250+ employees). However, most establishments (72%) stated they are part of an organisation with other establishments rather than being the sole establishment. Some genuinely small businesses are likely to be COMAH establishments: applying the rationale that 72% of the 47% of small establishments had operations at multiple sites, then it can be assumed that just 13% of all establishments were genuinely small. Applying the same rationale, 9% of all establishments would be genuinely medium sized. The remainder, or 78% are assumed to be large companies. These proportions are used throughout the IA for both tiers of COMAH establishment when estimating the cost of time and which wage rates to use, unless otherwise stated. These percentage shares of small, medium and large companies are assumed to be the same in both UT and LT, and for those establishments changing tier. This gives an average cost of time per hour of £28.89. There are assumed to be 7.5 hours in a working day.

42. The estimated numbers of COMAH establishments in the countries of Great Britain as at summer 2014 are given in Table 1:

Table 1 Estimated number of COMAH establishments in GB

	Number of COMAH LT Establishments	Number of COMAH UT Establishments	Grand total
England	451	264	715
Scotland	113	63	176
Wales	32	24	56
Grand Total	596	351	947

43. Ranges are calculated around all estimates to reflect uncertainty in the estimates. The range is either that specified by industry or if a point estimate was provided, a range of +/-10% is added around the estimate. When calculating costs for each impact, where there is a range around more than one variable (e.g. the number of establishments and the amount of time taken) then all combinations of cost have been provided and the lowest and highest estimate from those combinations is quoted. Best estimates are then the average of these high and low estimates.

44. A description of how the establishment estimates are interpreted and used for each cost impact relying on establishment estimates (other than scope) is given in Annex 4.

45. The analysis assumes that the number of establishments within LT and UT that are in scope after 1st June 2015 will remain so for the next 10 years. So while there could be establishments that might reduce tier or move out of scope as a result of business decisions, or from ceasing to operate, it is assumed that an equal number might move into scope or increase tier. Thus, the annual compliance costs are assumed to continue for the next 10 years. There is no sound basis on which to make an alternative assumption about how businesses might change their operations, and so to make an alternative assumption would introduce more uncertainty than assuming a static number of firms. HSE experts on the operation of the COMAH regime agreed this assumption was the most reasonable.

46. The land use planning controls in the Directive are a devolved matter and will be implemented through separate legislation in England, Scotland and Wales.

Separate IA procedures will be undertaken by DCLG and the devolved administrations for implementation of the land-use planning requirements of the Directive.

9. Scope

47. Scope is one of the key areas of change in the Seveso III Directive to be carried into the new COMAH 15 regulations. The scope of the Directive is given in terms of categories / named dangerous substances and their quantities at or above the threshold levels stated in COMAH'15. This determines whether an establishment is classified as an LT or a UT establishment or is out of scope. The categories / named dangerous substances and quantities in COMAH'99 are based on the CHIP Regulations 2009. A more thorough description of the reasons for the change in scope is provided in Annex 1.
48. Seveso III is aligned to CLP rather than CHIP so there are some differences in terms of what substances and quantities are in scope of Seveso III compared to Seveso II (and so in scope of COMAH 15 compared to COMAH 99). In order to understand these differences, some significant research was undertaken: see reference in paragraphs 32 and 33 and further details in Annex 2. The analysis produced two sets of estimates, which reflects the fact that there is uncertainty in the analysis. The first is based on HSL analysis verified by a peer review and partial corroboration with the European Chemicals Agency (ECHA) database (Estimate A). However, following this comparison and peer review, it was thought the estimates in the original analysis would now perhaps be a possible underestimate. This is because the peer review, which only looked at substances identified as being in the area of interest (i.e., that the original work assessed would be likely to change classification under CLP) and assessed that some of these would not in fact change at all. It was not possible to carry out a review against the ECHA data on all the substances, as this would have required disproportionate resource. However, it is possible that such analysis would identify further substances and hence lead to the conclusion that more UK establishments would in fact change their COMAH status than this peer reviewed analysis concluded. The estimates (A) are therefore considered to be a minimum estimate. An alternative and comparator estimate (B) has been provided by HSL, being their original analysis, unadjusted for the peer review analysis and cross-checked to the ECHA data. It is not the case that one of these estimates is more appropriate than the other, but they provide two alternatives between where it is probable the true number of establishments will lie. The projections are shown in Table 2 below.

Table 2: Analysis of impact on the number of establishments due to change in scope to align COMAH 15 with CLP Regulations plus other technical amendments¹⁵ – survey results extrapolated over 937 major hazard establishments in GB at time of writing.

Movement	Estimated impact on establishments in scope – estimate A	Estimated impact on establishments in scope – estimate B
Upper Tier to Lower Tier	12	21
Lower Tier to out of scope	24	30
Lower Tier to Upper Tier	1	8
Not in scope to Lower Tier	5	14
Not in scope to Upper Tier	<1	3
Net movement UT	-11	-11
Net movement LT	-7	-2
Net movement into scope	-18	-13

N.B Totals may not sum due to rounding

49. Overall the changes are predicted to result in total net movement of establishments of a decrease of between around 13 to 18 establishments in scope. There is expected to be a net decrease in establishments at UT by about 11, and a net decrease in establishments at LT of between 2 and 7.

50. It should be noted that these estimates are subject to uncertainty due to incomplete data received from industry about the toxicity of the substances they store and the complexity of the task of analysing the data (see Annex 2), along with the inherent error introduced as a result of extrapolating survey results over all establishments. However, analysis and conclusions have been peer reviewed by an HSL toxicologist and the ranges provided are thought to encapsulate this uncertainty.

51. In addition, under Seveso III (and so under COMAH'15), for the purpose of application, any quantity of dangerous substance in a pipeline within the

¹⁵ As well as the alignment of Seveso III with CLP, there are technical amendments that have been made to the annex, regarding Flammable Aerosols, Sodium Hypochlorite, alternative fuels and biogas. HSL have predicted that 4 sites storing sodium hypochlorite will move into scope at LT and 8 sites storing flammable aerosols will move from LT to out-of-scope. It is also estimated that there could be a movement of one flammable aerosol site from UT to LT. HSL considered it unlikely that the inclusion of alternative fuels and biogas would lead to changes in scope or tier. Table 2 shows the total movements expected based on CLP alignment plus these technical amendments.

boundary of an establishment will be included in the inventory and could therefore affect whether the site comes into scope of the regulations or changes tier. In COMAH'99 dangerous substances in a pipeline were only taken into account if the establishment stored any other dangerous substances which were subject to the COMAH regulations. This was not taken into consideration in the work by HSL analysing how many establishments will move into or out of scope as a result of the Seveso III Directive, or how many might change tier. It is expected that the effect of the measures might be to bring some additional sites into scope or to cause a slight increase in the number of establishments moving from LT to UT.

52. HSE investigated this further during consultation, in conjunction with HSL and a trade body to see what the extent of this effect might be and concluded that the impact would be small, while acknowledging that some establishments may be affected. The main reason for this is that the quantity of dangerous substances in pipelines is expected to be small and that those establishments that do have large volumes in pipelines are likely to have large volumes stored elsewhere and so likely to already be in-scope or UT.
53. With this in mind, HSE considered whether it was proportionate to commission HSL to carry out further research to refine the estimates given in Table 2. However, it emerged that it was not possible to refine the work already carried out by adding the pipeline quantities without considerable effort, if at all. HSE therefore concluded that it was not proportionate to carry out the further refinement as best indications show this to be a marginal issue for industry, it would therefore seem bureaucratic and burdensome on industry to conduct a formal and wider consultation exercise on the matter. This final stage IA therefore acknowledges that the figures in Table 2 may overestimate slightly the new movement out of scope of COMAH, but considers that this overestimation is small and not appropriate to refine.

9.1 Cost impacts of changing scope

54. The total cost impacts of changing scope depend on the estimated annual costs of compliance with the COMAH'99 regulations and the one-off costs of moving into scope for the first time. For those establishments moving out of scope or from UT to LT, they would experience some savings from a reduction or removal of regulatory duties. They may incur a small one-off cost in terms of updating procedures, but this is expected to be part of the process of familiarisation, described in paragraphs 194 to 199, and also to be part of the ongoing business-as-usual cost of reviewing procedures.
55. The estimated costs of changing scope are based on the current or baseline compliance costs with COMAH'99. There are some additional costs of compliance expected for all establishments (new and existing) as a result of certain changes, for example to public information requirements, but these are considered separately and include all establishments i.e. also new establishments brought into scope as a result of alignment. Keeping the two issues separate allows the reader to understand both the costs to business changing scope or tier because of the alignment of COMAH with CLP and the other changes separately before seeing the net position.

56. The method for estimating the compliance costs is described in full detail in Annex 3. Annex 2 includes an explanation about the way in which HSE has estimated how many sites are affected by each category of the proposals. The annual compliance costs are based on the research work performed by HSL and ORC International, involving a survey of all major hazard establishments which included high level questions on the cost of compliance with COMAH'99. The survey was sent to all registered COMAH establishments at the time of testing (around 1,100) and received a 25% response rate. The findings from the survey data were also corroborated qualitatively using focus groups and in-depth interviews. The establishments provided estimates in terms of time taken to comply, and these estimates have been converted to costs using wage rate data as a proxy for the cost of that time. From the time estimates provided by industry it has been estimated that annual costs for an UT establishment are between around £24 thousand and £29 thousand, with a best estimate of around £27 thousand. For LT establishments, the estimated annual costs are estimated to be between about £9 thousand and £11 thousand, with a best estimate of around £10 thousand.
57. The one-off costs of compliance (i.e. the costs when sites move into scope for the first time) were not captured by the survey. However, based on work HSE has been undertaking with the main trade associations, including a survey of chemical business sites, it is estimated that the one-off costs for an establishment moving from out-of-scope to LT will be between around £15 thousand and £23 thousand, with a best estimate of around £20 thousand. This is predominated by the costs of a Major Accident Prevention Policy (MAPP) and HSE charges for regulator activity.
58. The costs for an out-of-scope establishment moving into scope at UT from drafting a safety report have been estimated to be between £100 thousand and £135 thousand, with a best estimate of around £118 thousand. There could be costs for new UT establishments on top of this estimated cost of drafting a safety report, but these are difficult to predict in the aggregate, as they depend on where the establishment is located (emergency planning arrangements include Local Authorities and so their experience of UT establishments will affect the total cost of those planning arrangements) and whether the operator has other establishments which are at UT or not. Therefore, the one-off cost to UT establishments estimated at between about £100 thousand and £135 thousand is likely to be an underestimate, but the additional costs that may be omitted would only be small.
59. For those establishments moving from LT to UT, their one-off cost is estimated to be equal to the £100 thousand to £135 thousand for a wholly new UT site, minus the £15 thousand to £23 thousand that they have already expended becoming compliant at LT. This is because the work they have already undertaken to become compliant at LT is expected to account for some of their duties in UT.
60. A summary of the estimated cost of compliance is provided in Table 3 below.

Table 3 Summary of average costs of compliance per COMAH establishment

	One-off costs (£ thousands)	Annual Costs (£ thousands)
Lower Tier establishments	15 - 23	9 - 11
Upper Tier establishments	100 - 135	24 - 29

61. Establishments that move into scope at either UT or LT for the first time will incur these one-off costs (assumed in the first year of the appraisal period) and then annual costs over the remainder of the 10 year appraisal period. However, those establishments that see their scope decrease (or totally removed) will experience cost savings. It is assumed that they will not experience any savings against the one off costs if they are already in scope (as these costs will be classed as sunk costs), but over the 10 year appraisal period they will save annual costs.

62. The following table summarises the total estimated costs and savings as a result of the change to scope, using the estimated annual costs of compliance and one-off costs as described above, applied to the estimated number of establishments changing scope detailed in Table 2 and Annex 2. Following the method described in paragraph 43, the 'A Estimate' of cost in Table 4 is calculated using the 'A Estimate' of the number of establishments changing scope and tier in Table 2 combined with the lower cost estimates in Table 3. The 'B Estimate' in Table 4 represents that 'B Estimate in Table 2 and the higher cost estimates in Table 3.

Table 4: Analysis of impact on establishments due to changing scope – based on 947 major hazard establishments in GB at time of writing

Movement	<i>Changes including CLP alignment and technical amendments</i>	
	Estimated cost impact– estimate A (Total 10-year present value £m)	Estimated cost impact - estimate B. (Total 10-year present value £m)
<i>COST SAVINGS</i>		
Upper Tier to Lower Tier	1.2	2.6
Lower Tier to out of scope	1.4	2.1
<i>Total cost savings</i>	2.6	4.7
<i>COSTS</i>		
Lower Tier to Upper Tier	0.09	1.7
Out-of-scope to Lower Tier	0.4	1.3
Out-of-scope to Upper Tier	0.08	0.8
<i>Total costs</i>	0.55	3.9
Net costs	-2.0	-0.8
<i>Best estimate net cost</i>	-1.4	

N.B. Totals may not sum due to rounding

63. In comparing the current scope with that proposed under COMAH'15, the **estimated present value of the net impact on industry over 10 years** will be cost savings of between around £0.8 million and savings of £2.0 million with a **best estimate of savings of around £1.4 million.**

64. To return briefly to the pipelines issue discussed in paragraphs 51 to 53, HSE estimates that it would take between approximately 5 and 20 establishments being brought into scope or changing tier due to substances held in pipelines to negate the net savings presently estimated from the changes in scope due to the movement from CHIP to CLP. This is under the assumption that the sites brought into scope or changing tier as a result of the pipelines issue are of the same characteristics as those moving into scope or moving up into UT in Table 2, i.e. that the same proportion of additional establishments would move from LT to UT, from out-of-scope to LT and from out-of-scope to UT. In reality, this might be an underestimate (i.e. it might require more than 5 to 20 establishments being

affected by the pipelines measures to negate the net savings under scope) as it is less likely that the amount of substances in pipelines alone would be sufficient to bring a site all the way from out-of-scope to UT. As such, HSE considers it unlikely that the inclusion of substances in pipelines would cancel out the savings from the changes from CHIP to CLP.

9.2 Reviewing inventories to determine scope

65. Nearly all establishments currently in scope of COMAH'99 will have to review their inventories and determine whether the changes to Annex 1 of Seveso III will have any implications for their establishment (i.e. will move them from UT to LT or vice versa, or out of scope completely). This will enable the new CLP Regulation to be fully implemented. Sites currently not in scope of COMAH'99 but storing quantities of dangerous substances will also have to review their inventories against the changes to determine whether they might move into scope for the first time.
66. Discussion with the research group indicated that the time taken to review inventories could be between 1 and 2 days for most establishments. However, HSL provided some expert input to the analysis on this matter. Based on expert judgement about the analysis required for substances, they concluded that it could take between 1 – 2 hours per substance to fully understand the classification of that substance under the new CLP regulations and develop the physical property and hazard data to put in the safety report.
67. Based on the analysis of survey responses on substances, HSL has estimated the following relationship between the number of substances stored and the number of establishments storing those substances:

Table 5 Percentage of establishments storing different quantities of substances

Number of substances changing scope	Percentage of current COMAH establishments
0	39
1	24
2	12
3	9
4	5
5	3
6	3
7	1
8	2
9	1
10	0.5
15	0.5

68. Using the suggested time of 1-2 hours to review each substance, and the estimated current number of COMAH establishments of 947, the total estimated number of hours to review all substances for all current establishments is between about 1,600 and 3,200 with a best estimate of about 2,400. Excluding those establishments with no substances changing scope, this gives an average time spent per site of between around 3 and 6 hours. This is approximately half the time estimated by the research group. Given the results of the survey summarised in Table 5 that around 75% of establishments would have no more than two substances changing scope, this assumption appears reasonable.
69. Using the assumption of an average per hour cost of £28.89 (see paragraph 41), the total cost of this time to industry is estimated to be between £47 thousand and £93 thousand one-off cost, with a best estimate of £70 thousand.
70. HSE does not know how many other establishments just outside of scope of COMAH will also have to review their inventories to ascertain whether they are affected by the changes. However, HSL has estimated that between 5 and 17 sites will move into scope of COMAH for the first time, (see Table 2 and Annex 2). Using the same assumptions as above, the total estimated time to review the substances for those sites moving into scope for the first time is estimated to be between around 9 and 57 hours with a total cost of between £270 and £1.7 thousand per site, with a best estimate of around £1 thousand.
71. The total **estimated present value cost** of reviewing inventories for all current establishments and for all expected to move into scope of COMAH'99 is between around £47 thousand and £95 thousand with a **best estimate of around £71 thousand**. There could be other sites that are outside of scope, who remain outside of scope but who still have to review their inventories. This would lead to these costs being higher than estimated. As these sites are not known to HSE and will remain unknown to us, it is not possible to estimate how many there could be, but it is very likely that there will not be as many as the current number of COMAH establishments. At the same time, it is assumed that the time required for the newly-in-scope establishments to review their inventories would be the same as for those already in scope, which is probably not the case. Their present inventories do not bring them into scope of COMAH'99, which indicates that they are likely smaller and have fewer substances in stock than the average. This would lead to these costs being lower than estimated. We will assume that these two factors broadly balance each other out.
72. However, even in the unlikely event that the number of establishments affected or the time required in our calculations was to double, the total cost would still be less than £200 thousand for all establishments, which is less than 1% of the total likely costs of the rest of the changes to the COMAH regulations. This gap in our knowledge is not therefore going to change significantly the total cost estimates and so no further research in this area was conducted during consultation.

9.3 Safety reports and Notifications

9.3.1 Updating safety reports

73. Due to the changes in Annex 1 and the classification of scope from CHIP to CLP, it is anticipated that nearly all establishments will have to update their safety reports, but the extent of the changes will depend on what substances the establishment stores and therefore how significant the changes are for that establishment. Industry representatives did not express any disagreement with

the view that the majority of safety reports would need to be updated in order to comply with COMAH'15.

74. It is estimated that there are currently 351 UT establishments. It is also estimated that between 12 and 21 establishments will move out of UT to LT status, and no establishments will move from UT out of scope completely (see Table 2). Thus, the estimated number of present UT establishments that will remain as UT following the implementation of COMAH'15 will be between 330 and 339. These establishments will need to update their safety reports. There will of course be costs to establishments moving into UT status for the first time, but these are already captured in the scope section above, see paragraphs 54 to 63.
75. Between 330 and 339 establishments are therefore expected to incur costs associated with amending and updating safety reports, at least for the new classification of the dangerous substances they store. From the research group discussions, it was agreed that to complete a safety report from scratch it could take between 4 months and 1 year with a best estimate of 6 months. An independent consultant working for HSL who reviewed around 12 safety reports in detail (which is a substantial piece of work) estimated it could take 3 to 4 months for establishments needing to update their report. Therefore, the consultation stage IA assumed the time taken would be between 3 months and 1 year.
76. However, responses to the public consultation indicated that the lower bound of 3 months was too low and that the actual average time would likely be closer to the upper bound of 1 year. Given that the majority of these responses came from industry, who will have a greater collective experience of writing and updating safety reports than the HSL consultant, HSE thought it appropriate to raise the lower bound. Therefore, the estimated time to undertake a full safety report update is between around 6 and 12 man-months, with a best estimate of around 9 man-months. That is, between around 1,365 and 2,730 working hours per establishment, with a best estimate of around 2,050 working hours.
77. The research group also indicated that a proportion of the time required to update the report would be accounted for by consultants rather than staff. The group was unable to estimate this proportion at the time and so this was assumed to be nil in the consultation stage IA, but with the caveat that further evidence would be sought. During consultation, HSE contacted members of a trade body and sent follow-up questions to members of the research group on this point. What emerged was a patchy picture: for the most part, consultants seem either to not be involved at all or to do all (or nearly all) of the update themselves – there were very few responses in the middle. Given this range, the final stage IA assumes that consultants would account for around half of all the time necessary to update safety reports. This estimated proportion is indicated by the quantitative estimates HSE received and also fits with the qualitative responses from informal consultation.
78. This means that where safety reports require a full update, taking between 6 and 12 man-months, the time will be accounted for half by a staff member at an average full economic cost of £28.29 per hour (see paragraph 41). The other half would be accounted for by a consultant at a charge-out rate of between £135 and £165 per hour, as suggested by the research group, with a best estimate of £150 per hour. This gives an average cost of time of between £81.65 and £96.65 per hour, with a best estimate of £89.15 per hour.

79. The precursor to updating the safety report is the review of inventories, which has been costed separately in paragraphs 65 to 71 above. The remainder of the time taken to update the document will depend on the extent of the changes proposed. In order to try to estimate the proportion of UT sites that would need to undertake a full update of their safety report (the remainder only needing to make a smaller update), further evidence was sought from an expert working for HSL who has been researching this area. He looked through twelve safety reports in detail and worked on a case study for a site. He noted that the work involved included:

- classifications needing to be updated to align with CLP; and
- for each substance listed, the hazards from each and the risk to be analysed in the report.

80. While the ECHA databases will help with the classification, there are four of these and it will be time consuming for each substance held. For establishments storing and producing mixtures and preparations, the process of determining the classification for the safety report will be more complicated and could require the assistance of an external consultant.

81. Based on the HSL consultant's work, HSE anticipates that the majority of establishments will not have to make significant changes to their safety reports and the cost of these minor changes will be just business as usual, under the general duty of COMAH on UT establishments to ensure on an on-going basis that their safety report is up to date. If an establishment only has to make changes to express CHIP to CLP classifications and those changes do not impact on their safety report the operator will just need to reflect this in their notification. The CA will append the notification to the safety report which will have a negligible cost only and is viewed as business as usual.

82. However, for companies storing or using a large number of substances and complicated mixtures and compounds, a significant amount of time could be required to update their safety report. From the review of safety reports by the independent consultant working for HSL, the best estimate is that 20% of existing UT establishments will fall into this more complex category requiring updates to their safety reports. As there is uncertainty in this percentage, a range has been assumed between 20% and 40% to provide a conservative approach. Comments were sought on this assumption in consultation and it met with broad agreement with very few compelling arguments against.

83. To summarise these assumptions:

- Between 330 and 339 current UT establishments would need to update their safety reports
- Between 20% and 40% would need to undertake a full update
- The remainder would make small amendments, which are considered negligible costs and business-as-usual
- For each establishment undertaking a full update, the time taken would be between 1,365 hours and 2,730 hours, with a best estimate of 2,050 hours
- The cost of time would be between £81.65 and £96.65 per hour, with a best estimate of £89.15 per hour.

84. Based on these assumptions, the **total estimated present value cost** of updating safety reports in 2015 (Year 1 of the appraisal period) is between around £7.1 million and £34.7 million with a **best estimate of around £20.9 million**.

Gold Plating – maintaining the five-year review cycle for safety reports

85. Under COMAH'99 and COMAH'15 there is a requirement to update safety reports for a variety of reasons e.g. following a major accident. In any event, a safety report must be reviewed and updated every five years and sent to the CA. The Directive does not specifically indicate what effect this should have on the five-year review cycle, but it has been interpreted by HSE as requiring UT sites to undertake a full review at the point of submitting an updated safety report for COMAH'15 compliance by 1st June 2016, with subsequent reviews every five years – this would 'reset the clock' for existing UT sites. However, HSE proposes to enact an interpretation of the Directive whereby the existing five-year review cycle is maintained as this will reduce burdens on business.

86. As described in paragraph 73, it is expected that the majority of UT operators who already come under the COMAH regime will need to update their safety reports by 1st June 2016. One of the outcomes of the public consultation was a view expressed by some operators that the five-year-review cycle should be maintained from COMAH'99. The COMAH'15 regulations take this on board. For operators, this means that the 'one-off' updating of safety reports by 1st June 2016 will not impact on their 5 year review cycle currently established under COMAH'99.

87. The estimates in Table 6 and Table 7 indicate that maintaining the current review cycle in this manner would be less costly for industry than resetting it, and therefore would represent a zero net cost.

88. Although HSE's legal advice is that this is technically gold plating (No. 11 on Table 10), this deviation from copy out of the Directive will not result in any additional costs for operators over and above the baseline, and will actually serve to minimise costs to business. HSE's legal advice is that this does not pose an infraction risk.

89. Presently, there are 351 UT establishments. Following the implementation of COMAH'15, it is estimated there will be between 1 and 11 establishments that will enter into UT, either from LT or as sites which had previously been out of scope (see Table 2); their costs of five-year reviews are captured under the ongoing costs of being in scope at UT in paragraphs 54 to 63.

90. To estimate the costs of five-year reviews, we have used the current 351 UT establishments less the 12 to 21 current UT establishments that will move to LT under COMAH'15, whose cost savings from moving out of UT are captured in paragraphs 54 to 63. This gives between 330 and 339 UT sites whose current five-year review cycle will be maintained.

91. Based on a survey conducted by one of the industry bodies, the cost to UT sites of conducting a five-yearly safety report review is estimated at around £66 thousand for each review conducted.

92. Based on HSE data for current five-year reviews, maintaining the present cycle following implementation of COMAH'15 would lead to the following timetable of

UT reviews and associated costs, which are captured in the baseline and therefore not additional, as summarised in Table 6.

Table 6: Summary of baseline five-year reviews

	Proportion of UT sites undergoing five-year review	UT sites = 330		UT sites = 339	
		Number of reviews	Cost (£m)	Number of reviews	Cost (£m)
2014*	N/A	N/A	N/A	N/A	N/A
2015	13%	43	£2.8	44	£2.9
2016	19%	62	£4.1	64	£4.2
2017	26%	86	£5.7	88	£5.8
2018	26%	87	£5.7	89	£5.9
2019	16%	53	£3.5	54	£3.6
2020	13%	43	£2.8	44	£2.9
2021	19%	62	£4.1	64	£4.2
2022	26%	86	£5.7	88	£5.8
2023	26%	87	£5.7	89	£5.9
Present Value (£m)	-	-	£33.6	-	£34.5

*2014 is prior to implementation and no change is expected

93. Maintaining the five-year review cycle for existing UT establishments would maintain a present value cost of between around £33.6 million and £34.5 million.

94. Table 7 summarises the same number and cost of reviews based on the five-year review cycle being reset in 2016 for all UT establishments.

Table 7: Summary of five-year reviews if reset in 2016

	Proportion of UT sites undergoing five-year review	UT sites = 330		UT sites = 339	
		Number of reviews	Cost (£m)	Number of reviews	Cost (£m)
2014*	N/A	N/A	N/A	N/A	N/A
2015	13%	43	£2.8	44	£2.9
2016	100%	330	£21.8	339	£22.4
2017	0%	0	£0.0	0	£0.0
2018	0%	0	£0.0	0	£0.0
2019	0%	0	£0.0	0	£0.0
2020	0%	0	£0.0	0	£0.0
2021	100%	330	£21.8	339	£22.4
2022	0%	0	£0.0	0	£0.0
2023	0%	0	£0.0	0	£0.0
Present Value (£m)	-	-	£40.2	-	£41.3

*2014 is prior to implementation and no change is expected

95. Resetting the five-year review cycle by requiring all UT sites to perform a review in 2016 and every five years thereafter would bring forward several UT establishments' five-year reviews and lead to present value costs of between around £40.2 million and £41.3 million.
96. Therefore, deviating from copy-out would maintain the current review-cycle for these 330 to 339 UT sites at no additional cost. However, resetting the five-year cycle in 2016 would lead to additional present values costs of between around £6.6 million and £6.8 million.
97. Based on this analysis, the deviation from copy-out is estimated to be beneficial for business relative to a strict copy-out and maintains the baseline at **no additional cost**.

Gold Plating – Retaining pre-existing UK health and safety standards for safety reports

98. There are two areas in relation to safety reports where it is proposed to retain present health and safety standards that go beyond the Directive. The first is the requirement that a safety report for new COMAH establishments must be produced at both the pre-construction (if applicable) and pre-operation stages (No. 3, Table 10). This goes beyond the Directive, which requires a safety report be produced at either the pre-construction or pre-operation stages. There would be no need for a new report at each stage, only amendments or additions would be necessary. Most responses to the public consultation saw the value in this and there was little or no negative feedback from stakeholders during informal consultation. Pre-construction/Pre-operation safety reports afford operators early access to the CA's opinion on the design and controls of new establishments early in the process. Information from Principal Inspectors in HSE's Energy Division is that following consideration of a pre-construction safety report, HSE has given advice that would have had a monetary benefit to the operator, examples include:

- **Pre-Construction:** LNG import terminal project - the CA identified that the COMAH operator planned to construct the plant to functional safety standards that did not meet relevant good practice. This meant the plant was to be built with key safety systems that did not provide the level of risk reduction required, did not provide adequate redundancy in case of system failure and did not provide sufficient system reliability. Intervention at the pre-construction stage allowed the plant design to be changed to incorporate safety systems that met relevant good practice and provided adequate prevention against major accident hazards. If this issue had only been identified and rectified after the plant had been built it would have had huge cost implications for the operator.
- **Pre-Operation:** underground salt cavity gas storage project - the CA identified that the operator planned to pressure-test the well casing connecting the underground gas cavities to the above ground plant to a lower standard than was recognised good practice. Pressure testing is used to prove the integrity of the well casing. Loss of well integrity is a known major accident hazard and testing to the standard planned by the operator would not have properly tested the well casing. Identification of this issue at the pre-operation stage meant the CA could ensure an adequate standard of testing was applied before the plant was commissioned. If the required standard of testing had been applied after the plant was operational it would have had significant cost implications for the operator.

99. This measure retains the current standard in the COMAH'99 so no additional impact on business or familiarisation costs would be incurred.

100. The second area of gold plating relates to a requirement on the operator to inform the CA in writing (No. 4, Table 10) when a safety report has been reviewed but does not require updating. This goes beyond the Directive, which only requires notification if the safety report does need updating. Safety reports have to be reviewed every five years unless there have been certain changes at the establishment. This should only affect a small number of cases where no revision is necessary. This measure also retains the current standard in COMAH'99 therefore no additional impact on business or familiarisation costs would be incurred. There was little or no negative feedback from stakeholders on this during informal consultation.

9.3.2 Notifications as a result of scope changes

101. Operators are required to notify the CA if their establishment comes under the COMAH regime. For the COMAH'15 regulations there are three groups of establishments to consider in terms of impact:
- **Existing establishments** - we anticipate that all establishments currently within scope of COMAH'99 (existing establishments) will have to re-notify the CA under COMAH 15 because of the change from CHIP to CLP classification, so there will be an additional cost to consider in this IA. These establishments will have one year from 1st June 2015 to notify.
 - **New establishments coming into scope purely because of the changes to Annex 1** - the cost of notification will also be a relevant additional cost but is already captured in the paragraphs 54 to 63 on the compliance costs resulting from the change in scope.
 - **New establishments coming into scope as a result of a business decision** (e.g. they begin to use a new hazardous substance) – these establishments will incur costs of notification but not as a result of the change to the Seveso III Directive and so the costs are not relevant to this IA.
102. Therefore, it is only the re-notifications of the existing 947 COMAH establishments that we need to cost here. Discussions with the research group indicated that the time taken to re-notify would depend on the extent of the changes for the establishment.
103. Those for whom there are not significant changes could take between 0.5 days and 1 day to re-notify. However, for existing establishments that end up changing tier, the costs of re-notification could be higher. For existing sites changing from LT to UT, this has already been captured in the one-off costs of compliance in paragraphs 54 to 63. But for those 12 to 21 establishments moving from UT to LT, it is estimated that this higher cost of re-notification could range between 1 day and 2 days.
104. This translates to between 21 and 12 establishments taking between 1 and 2 days to re-notify and between 926 and 935 establishments taking between 0.5 days and 1 day to re-notify. Based on there being 7.5 hours in a working day, this gives a total of between around 3,630 and 7,193 hours, with a best estimate of around 5,420 hours.
105. If we cost these hours at the average full economic cost of £28.89 per hour (see paragraph 41), this gives an **estimated total present value one-off cost** in Year 1 of the appraisal period of between around £101 thousand and £201 thousand, with a **best estimate of around £151 thousand**.
106. There is also a new requirement that notifications should include, where available, details of neighbouring establishments which would include establishments that fall outside the scope of the Directive, and could increase the risk or consequences of a major accident. HSE explored this issue at consultation and gathered further information from the research group. This follow up showed that, while the burden of gathering this information and adding it to the notification would not be great, establishments would need to keep their

information up to date on an ongoing basis to take account of any changes to their neighbours or to their processes.

107. Based on these responses, HSE estimate that each COMAH establishment would spend between 1 and 2 days per annum gathering and updating information about their neighbouring establishments, with a best estimate of 1-and-a-half days. Across the 929 to 934 COMAH establishments expected to be operating within COMAH'15 each year, this gives between around 7 thousand and 14 thousand hours per annum, with a best estimate of around 10.5 thousand.
108. Costed at the average cost of time of £28.89, this gives an average annual cost of between around £201 thousand and £405 thousand, with a best estimate of around £303 thousand.
109. Borne from Year 1 to Year 9 of the appraisal period, this gives a **present value cost to business** of between around £1.5 million and £3.1 million, with a **best estimate of around £2.3 million**.
110. It is not necessary to estimate the cost of the neighbouring non-COMAH sites participating in or assisting the COMAH establishments in gathering this information as the new Regulations would not place a duty on them to do so. If they chose to engage with the COMAH establishment, this would be their own business decision and this analysis assumes that they would only do so if they assessed that the benefits at least equalled the costs.

Gold Plating

111. It is proposed that all notifications will be sent to the CA via the HSE database (No. 2, Table 10). This is an example of gold plating, in that the Directive allows for greater flexibility in the mode of submission. However, the proposal for an electronic system to submit re-notifications will ease burdens on business. For this proposal there was little or no negative feedback from stakeholders during informal consultation and the vast majority of responses in the public consultation supported this.
112. If there is any additional cost in relation to this specification, it will depend on the methods currently employed by COMAH establishments to notify and whether these are any more or less onerous than the proposed HSE database. However, for those establishments who may prefer to notify by some other means (by post, for example) it is not anticipated that the additional effort to submit it to the database would be much beyond a simple 'copy-and-paste'. Although the notification process has been costed above in totality, it is expected that some small component of this cost will represent the cost of this gold plating.

Gold Plating – Retaining pre-existing UK health and safety standards for Notifications

113. Operators will be required to send a notification to the CA within a reasonable period of time prior to the start of construction and operation of an establishment (but they only have to send notification prior to the start of operation if any details have changed from their pre-construction notification) (No. 1, Table 10). The Directive requires notification prior to the start of construction *or* operation. This requirement in the COMAH'15 regulations retains the pre-existing standards in

the COMAH'99 regulations so there will be no additional impact on business or familiarisation necessary.

9.3.3 Changes to requirement of when to notify including notification of decrease in quantity of dangerous substances

114. There is a new requirement that establishments should notify the CA of a decrease in quantity of dangerous substances in advance. Based on discussions with industry, the cost per establishment is not expected to be substantial but we cannot quantify the total cost because it is not possible to predict how many establishments this will affect in the future. On the basis of proportionality, no further evidence has been sought in this area.

10. Public Information

115. The public information requirements in the Seveso III Directive are another key area of change to be carried into COMAH'15. This is because the Directive has been brought in line with the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice on Environmental Matters¹⁶. Article 14 requires UT establishments to regularly send every person likely to be affected in the event of a major accident clear information on safety measures and what to do in the event of a major accident at the establishment. This is currently a requirement in the COMAH'99 and is known as the Public Information Zone (PIZ). Article 14 also requires that the safety report and inventory of dangerous substances is made available to the public upon request. Annex V of the Directive requires certain information regarding all major hazard establishments and their hazards to be made permanently and electronically available to the public and for the information to be kept up to date. The CA will host a database which operators will use to upload the relevant information which will then be accessible to the public.

10.1 Annex 5 requirements

116. Both UT and LT establishments will have to provide information as set out in Annex 5 part 1 of the Directive. This includes:

- the name / trade of the operator and full address of the establishment;
- confirmation that the establishment is subject to the regulations;
- confirmation that the notification and safety report have been submitted to the CA;
- a simple explanation of the activity or activities undertaken;
- the hazard classification of the relevant dangerous substances involved at the establishment that could give rise to a major accident, with an indication of their principal dangerous characteristics in simple terms;
- general information about how the public concerned will be warned and what to do in the event of a major accident;
- date of last site visit, and where more detailed information about the inspection and related inspection plan can be obtained upon request;

¹⁶ www.unece/fileadmin/DAM/env/pp/documents/cep43e.pdf

- details where further relevant information can be obtained.
117. Making all of this information available is a new requirement for LT establishments; UT sites are already required to do this under COMAH'99.
118. Annex 5 part 2 requirements are in addition to those in Part 1 but are for UT establishments only. The new additional requirements not contained in the COMAH'99 are:
- to provide a summary of major accident scenarios and the control of measures to address them; and to
 - indicate whether the establishment is close to the territory of another Member State with the possibility of a major accident with trans-boundary effects.
119. As this information needs to be made available electronically and kept up to date, any costs will include both one-off costs to ensure initial compliance and then ongoing monitoring costs.
- UT establishments: evidence provided by the research group suggests that UT establishments already provide most of this information, although not in an electronic format.
 - LT establishments: evidence provided by the research group indicated that most LT establishments do not currently make this information available.
120. It is proposed that a template will be provided to industry by the CA for them to use to ensure they are compliant with the public information requirements in Regulation 17(1) and (2) of COMAH'15. Operators will be required to complete the template and upload the information onto the database.
121. There are expected to be around 340 UT establishments following implementation of the Directive (current 351 less the expected net decrease in UT establishments of 11). Initial thoughts by HSE were that it could take between 2 and 3 days to complete the information. However, clarification from the research group revealed this could be more like from 10 person-days up to 60 person-days. Whilst the drafting process may only take 2 – 3 days of time, the research group explained that this was a gross underestimate of the time because the information would be subject to close scrutiny throughout the organisation, as it would be going into the public domain. Based on the average cost of time of £28.89 per hour, **the estimated present value one-off cost** of producing the public information in year 2015 (Year 1) is between around £711 thousand and £4.3 million with a **best estimate of around £2.5 million**.
122. The public information will need to be updated on a continual basis as and when matters change. The marginal cost of updating the information compared to the cost of updating the establishments' internal information is thought to be small. HSE's best assumption based on its own expert experience is that it will take at most 0.5 hours a month per top tier establishment, or 6 hours per annum. Based on the previously outlined estimates of the cost of time to small and medium and large businesses, the **total estimated present value cost** of the time to review is estimated to be between around £403 thousand and £493 thousand, with a **best estimate of around £448 thousand**.
123. The proposal to provide a database and the use of templates was supported by industry during stakeholder events and the majority of responses to the formal consultation were in favour. The template approach should reduce the burden on

industry as opposed to designing the information styles themselves. It is planned that a representative group from industry will test the database.

124. Early indications of the total cost (excluding VAT) to the CA to host the database to provide the public information requirements might be in the region of £360 thousand to £440 thousand, with a best estimate of around **£400 thousand in one-off set up costs** and that this cost would not be recovered from industry. This is currently the preferred option and will require industry to provide the information and ensure the information is kept up to date.

125. There could also be ongoing monitoring costs to the CA to ensure those submitting the information onto the database are bona fide. However details about the HSE process to do this are still being considered but it is likely to be a small cost and may be included as part of ongoing 'business-as-usual' contact between HSE and COMAH establishments. The information uploaded to the database will be checked for accuracy as part of the CA inspection process. HSE assesses that any cost here would be small and does not consider it proportionate to attempt to monetise it.

Gold Plating

126. It is proposed that COMAH'15 will specify that public information should be stored and made available on the HSE database (No. 8, Table 10). This ensures a consistent formatting of the relevant data and is in-keeping with the Government's Digital Strategy. This is an example of gold plating because the Seveso III Directive itself is not so prescriptive. However, we believe that this will help businesses as they will not have to consider how to do this and will instead just need to focus on the information they will have to provide. The vast majority of responses in the public consultation supported this. If there is any additional cost in relation to this specification, this will depend on the methods that COMAH operators would otherwise use to publish their information online (such as on their own website) and whether these are any more or less onerous than the proposed HSE database. However, this is expected to be very small – once the information had been gathered, any efforts required to publish it on the HSE database over and above that necessary to post it on one's own website would amount to a simple 'copy-and-paste'. Although the public information process has been costed above in totality, it is expected that some very small component of this cost (if any) might represent the cost of this gold plating, but this is not considered proportionate to monetise separately.

Gold Plating – Retaining pre-existing UK health and safety standards for the provision of information to persons likely to be affected by a major accident

127. There is an area where HSE plans to retain a requirement from COMAH'99 in relation to providing information to people likely to be affected by a major accident. This is the requirement that the operator must consult the local authority when preparing the information (No. 9, Table 10). Retaining this requirement from COMAH'99 will ensure that the PIZ information aligns with any other emergency information held or provided by the local authority and ensures that there would be no additional impact on business or familiarisation costs. For this proposal there was little or no negative feedback from stakeholders during informal consultation and the vast majority of responses in the public consultation supported this.

10.2 Making safety reports available to the public by UT establishments

128. Article 14 (2)(b) requires that safety reports are made available to the public upon request unless there are issues of commercial confidentiality or national security. In such cases in the UK an assessment under the Environmental Information Regulations (EIR) 2004 would be carried out which may result in a redacted version being provided.

129. COMAH'99 requires the CA to make safety reports available to the public via a public register and provides that operators can apply for information which is commercially confidential to be excluded. Since the USA terrorist attacks of 11th September 2001 this requirement has been protected by a Secretary of State (SoS) Direction which has prohibited the disclosure of safety reports. The SoS Direction will fall on 1st June 2015. From that date under COMAH'15 each request for a COMAH safety report will be dealt with on a case-by-case basis but unless there are commercial confidentiality or national security issues the CA will be required to provide the full safety report.

130. To facilitate the release of safety reports to the public under COMAH'15, operators will be required to identify issues relating to national security or commercial confidentiality when they submit their information to the CA. COMAH'99 contained the same requirement but the SoS Direction meant that operators did not have to do this. Following the fall of the SoS Direction the system to release safety reports in COMAH'15 would be the same as currently under COMAH'99. This represents an additional cost over and above this IA's notional baseline of the 'status quo'. As discussed in paragraph 23, because CHIP will be superseded by CLP, COMAH'99 would not be able to apply after 1st June 2015. Therefore, in the 'do nothing' option, even when the SOS Direction fell on 1st June 2015, this requirement would not apply.

131. In requiring operators to identify parts of the report that would require redaction in advance of any requests from the public the report will be virtually ready to give to a member of the public upon request. This will require the redaction of all safety reports in preparation for public release. However, the research group said this could be a relatively high cost for industry.

132. There would be both the costs of identifying areas of redacting to be submitted to the CA and a lot of industry time required to explain which aspects of the report can and cannot be put into the public domain (areas which are commercial in confidence, for instance).

133. In terms of the CA's costs, there are two scenarios for redacting the safety reports (based on past precedents):

- either use a Band 3 inspector for around between around 273 and 330 hours, with a best estimate of around 300 hours, or;
- use a Band 6 administrative officer for between around 150 and 225 hours, with a best estimate of around 188 hours, plus a Band 3 inspector review estimated to take between 7.5 and 22.5 hours, with a best estimate of around 15 hours

134. This evidence is based on limited experience of redacting safety reports in HSE and the difference in times reflects the size and complexity of the safety reports in question. It was not possible to find any further examples during consultation, but wider sense checking of the estimate within HSE did not present arguments for revising this estimated time.

135. Which of the two scenarios for CA time spent redacting safety reports would be more likely would depend on the size and complexity of the safety report in question. This analysis is unable to make that judgement, and so it is assumed that the average time spent will be an average of these two scenarios. Based on the estimated true economic cost of employing these staff of £155 per hour for a Band 3 Inspector¹⁷ and £19.48 per hour for a Band 6 administrative officer¹⁸, it is estimated that the cost of redacting a safety report would be between around £23 thousand and £30 thousand, with a best estimate of around £26 thousand. This would be cost-recovered from industry.

136. There would also be costs to industry to identify these commercial and security sensitive areas. It is difficult to say what these costs to industry could be, but if they were of similar magnitude to the costs of getting clearance for the public information (between 10 person-days – 60 person-days with the same estimated average cost of time of £28.89 per hour), then the cost per report would be between around £2 thousand and £13 thousand with a best estimate of around £8 thousand.

137. If all safety reports were to be redacted in the first year of the appraisal period, then based on there being between 333 and 339 reports to redact (between 330 and 339 existing UT establishments plus between less than 3 and less than 1 new UT establishments) the **estimated present value total one-off costs** would be between £8.4 million and £14.4 million with a **best estimate of around £11.4 million**.

138. Over the last eight years, two reports have been redacted. However, once the Secretary of State's (SoS) Direction falls there may be an increase in the number of requests from the public, particularly from those with a specific interest. There are no plans for the SoS Direction to be renewed, not least because of the EC's desire for a far more open regime.

10.3 – Local Authorities to inform population likely to be affected following major accident

139. COMAH'15 will implement a new requirement on Local Authorities that following a major accident in their area they must inform those likely to be

¹⁷ Based on the COMAH cost recovery rate

¹⁸ HSE Ready Reckoner

affected about the accident and where relevant advise them about any mitigatory measures taken. A major accident would not only be an event as high-impact as the 2005 Buncefield fire, for example it could be a major accident which is contained within the site. COMAH'15 defines a major accident as "an occurrence such as a major emission, fire or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by these Regulations, and leading to serious danger to human health or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substances." So while some major accidents, such as Buncefield, may have a large impact on the local population, those that only affect the site itself may go unnoticed by local residents and businesses and this requirement will ensure that those likely to be affected are informed. HSE estimate that there are presently between around 10 and 14 COMAH major accidents in the UK per year.

140. HSE estimates that the cost of putting this information together would be minimal as it would already be collected in some form for the CA or for internal procedures and so is estimated to impose little additional cost. The most effective method of delivering this information would be via the LA web-pages, which would be a negligible cost, plus perhaps a mail shot to addresses in the affected area. The size of this area would depend on the type and scale of the accident; as an upper estimate it might contain several thousand addresses. In some cases, LAs might already undertake this work (particularly with larger accidents), meaning that the duty under COMAH'15 would impose no additional cost, however HSE is unable to estimate in how many instances this might be the case. Consultation with the Royal Mail indicates that a mail shot of this size would only cost a few hundred pounds, so this analysis estimates that this duty would impose a **small ongoing cost on Local Authorities**, but HSE does not consider it proportionate to monetise it given its small size relative to the other costs in this IA.

11. Emergency Plans

11.1 Testing of external emergency plans for UT establishments

141. The Civil Contingencies Act (CCA) 2004¹⁹ is UK legislation that establishes a framework for emergency planning and response. COMAH'99 emergency planning pre-dated the CCA, which identifies Cat 1 responders. They are core responders and include the 'blue light' emergency services as well as NHS hospital and primary care organisations, public health and environment agencies. Cat 1 responders ('Cat 1s') are a slightly broader group than the current COMAH definition of 'emergency services', as more health organisations are included.

142. The Seveso III Directive requires emergency plans to be tested. COMAH'15 requires 'designated authorities' which includes Cat 1 responders (as detailed in the CCA) to take part in the testing of external emergency plans for UT establishments when requested to do so by the local authority (LA). At present, local authorities have a duty to test the off-site emergency plan and take reasonable steps to arrange for the emergency services to participate. There is currently no specific duty on emergency services (or other Cat 1 responders) to take part. Through informal consultation HSE has been made aware that in some parts of the UK key partners fail to take part, but the picture is patchy across the country. However where Cat 1 responders fail to co-operate the

¹⁹ <http://www.legislation.gov.uk/ukpga/2004/36/contents>

effectiveness of tests will be significantly reduced which could have a potential impact on the health and safety of the surrounding population.

Gold Plating

143. The proposal to legally require Cat 1 responders to take part in the testing of external emergency plans stems from views of stakeholders (industry, emergency planners and emergency responders) during informal consultation in 2013. The proposal is gold plating (No. 7, Table 10) as it goes beyond the requirements of the Directive. However HSE believes that to require this through regulation will increase the effectiveness of off-site emergency plans and allow for greater consistency of approach across the country. Recommendation 19 in a report²⁰ of the findings into an explosion and fire at the Buncefield Fuel Depot²¹ in Hemel Hempstead, Hertfordshire, stated that Local Authorities should ensure their revised external emergency arrangements for COMAH sites are tested within twelve months of production. It also recommended that 'all Cat 1 responders should ensure their staff are trained within six months of production to deliver the emergency response'. Legally requiring Cat 1 responders to take part in the testing of external emergency plans will provide public reassurance that these plans are properly tested.
144. The vast majority of responses to the formal consultation supported the proposal although they felt the requirement to attend should be proportionate to the level of testing required, a factor that will be covered in guidance. Those who opposed the requirement did so because they were of the opinion that there was not a problem in their area. This corroborates the fact that attendance by Cat 1 responders at this type of testing is patchy across the country. This means that in terms of impact only a certain percentage will be affected by this new legislative requirement (please see paragraph 150).
145. In order to estimate the costs of legally requiring Cat 1 responders to take part in the testing of external emergency plans, an understanding of the baseline is important. This proposal was therefore fully tested during consultation through a research project with the Health and Safety Laboratory (HSL), commissioned by HSE, which looked at three questions;
- To what extent do Cat 1 responders currently participate in emergency plan exercises?
 - Who pays for their involvement?
 - How much does their involvement cost?
146. A census survey and in-depth questionnaire of all 351 UT establishments was considered by HSE social researchers to be the most accurate method to gather this information. However, this was not considered practical in the time available and would have placed a disproportionate burden on business. Instead, it was decided that the next best course would be to telephone-interview LA and Metropolitan Fire Brigade (MFB) emergency planners, who would have a good overview of sector and the current arrangements for external emergency plan testing. HSL interviewed thirteen LA emergency planners and five MFBs in May and June 2014. Between them they covered 118 (around one-third of the total) UT COMAH establishment.

²⁰ <http://www.buncefieldinvestigation.gov.uk/reports/>

²¹ 11 December 2005 - caused widespread damage to neighbouring properties

147. The findings showed that:

- The amount of participation by Cat 1 responders in this type of exercise varies. The emergency services appear to take part more regularly than other agencies with certain Cat 1 responders having more of a problem attending due to resource issues. Some agencies attended depending how relevant the test was to their organisation.
- In terms of who pays for Cat 1 attendance, this was dependent on which jurisdiction the emergency arrangements came under, i.e. either the LA or the MFB. For the majority of tests the overall cost falls to the COMAH establishment, although there was some indication that the organiser (i.e. the LA or the MFB) bore the cost if there was a beneficial training element.
- The actual cost depends on the type of exercise e.g. a 'table-top' test would be less expensive than a full test. The research responses presented a range of between £3,700 and £34,000, subject to the type of test.

148. The research confirmed our initial view that there is inconsistency across the country in terms of the emergency services that currently take part in the testing of external emergency plans. There is also inconsistency in terms of whether UT establishments are charged by LAs for their participation. As such, in some areas of the country costs will already be incurred by industry for Cat 1 responder participation and in others, Cat 1 responders may be participating without charging. In addition, in some areas, Cat 1 responders may not be participating at all. Therefore, in some parts of the country, this will not be a new cost to industry or LAs, while in others it might constitute a new cost.

149. It was difficult to estimate a proportion of current external emergency plan tests that Cat 1s already attend based on the HSL interview responses, except to say that it would be quite high. The majority of the respondents reported that Cat 1s attend all tests which are appropriate for them to attend and noted only a few instances where there was presently a shortfall. However, respondents struggled to give an estimated percentage.

150. HSE analysts inferred that those respondents who stated Cat 1s attended 'all' tests that they were expected to meant roughly 100% Cat 1 attendance. Based on expert knowledge of the sector within HSE and on the responses themselves, it was further inferred that for those who said the attendance varied, a percentage of 75% Cat 1 attendance might have been meant. This gave an average, weighted by the number of UT sites that each respondent covered, of around 85% and colleagues within HSE agreed that this was reasonable based on their experience of the sector.

151. It was much clearer from the responses to the HSL interviews what the current cost distribution was between the COMAH establishments, LAs and the Cat 1s themselves. This was because, as described in paragraph 147, the manner in which costs are divided tends to be a matter of policy in each jurisdiction and so respondents were able to describe that policy. This showed that the COMAH establishment bears the cost in around two-thirds of cases. In the remaining one-third, this is estimated to be split fairly evenly between LAs and the Cat 1s.

152. The costs of the tests was estimated by respondents based on two broad scenarios that currently take place – 'full live' tests and 'table-top' exercises. A full live test may be thought of as a fully simulated emergency, to which Cat 1

responders and the COMAH establishment rehearse their response. A table-top exercise may involve only elements of the plan being tested (such as communication links) or something similar to a role play exercise taking place. The average costs were estimated based on the amounts presently cost recovered (where full cost recovery takes place) and are as follows:

- For a full live test, the average cost is between £15 thousand and £18 thousand, with a best estimate of around £16 thousand.
- For a table-top exercise, the average cost is between around £7 thousand and £10 thousand, with a best estimate of around £8-and-a-half thousand.

153. The Regulations require that the emergency plan is tested at least once every three years. The HSL interview responses indicated that tests tended to be full live, table top exercises or a hybrid of the two, depending on the characteristics of the COMAH establishment and the resources of the LA and Cat 1s. As a simplifying assumption, this analysis will assume an even split between the two test types and therefore an average per test cost of between around £8-and-a-half thousand and £16 thousand, with a best estimate of around £12 thousand.

154. Following the changes to the CLP classification scheme in COMAH, there are expected to be between 333 and 339 UT establishments, with a best estimate of 336. As each is required to test its external emergency plan at least once every three years, this gives an average number of tests per annum of between 111 and 113, with a best estimate of 112. Based on the estimate in paragraph 150 that Cat 1s currently attend around 85% of all tests where it would be appropriate for them to attend, this gives between 94 and 96 attended tests per annum, with a best estimate of 95.

155. This gives an average number of tests per annum where Cat 1s might attend, but presently do not, of around 17 per annum. Based on the average cost of involvement discussed in paragraph 153, this gives an additional annual average cost of between around £140 thousand and £276 thousand, with a best estimate of around £207 thousand. HSE attempted to gather information during consultation on how LAs may choose to split the costs of the additional Cat 1 attendance at tests, but was unable to find any reliable evidence. As a simplifying assumption, this analysis assumes that the cost split of the tests will remain as presently. However, it should be noted that if LAs choose to pass on more of the costs to COMAH establishments, the costs to business and so the 'IN' may rise. Based on the proportion split of costs in paragraph 151, these costs would be borne as follows:

- COMAH establishments' average annual cost would be between around £94 thousand and £184 thousand, with a best estimate of around £138 thousand
- Cat 1s' average annual cost would be between around £23 thousand and £46 thousand, with a best estimate of around £35 thousand
- LAs' average annual cost would be between around £23 thousand and £46 thousand, with a best estimate of around £35 thousand

156. Borne from Year 1 to Year 9, this would give a **total present value cost** of between around £1.1 million and £2.1 million, with a **best estimate of around £1.6 million**. Based on the proportion split in paragraph 151, these costs would be borne as follows:

- COMAH establishments' present value cost over ten years would be between around £712 thousand and £1.4 million, with a best estimate of around £1.1 million. These costs would be within scope of OITO
- Cat 1s' present value cost over ten years would be between around £178 thousand and £350 thousand, with a best estimate of around £263 thousand
- LAs' present value cost over ten years would be between around £178 thousand and £350 thousand, with a best estimate of around £263 thousand

11.2 Timescales for the preparation of emergency plans

External Emergency Plans

157. Longer timescales for the preparation of external emergency plans by the local authority are specified in the Directive than are available in the current COMAH Regulations (within 2 years following receipt of necessary information from the operator). Using timescales from the Directive for the preparation of external emergency plans would leave a bigger gap before such a plan is in place which would increase risk. This is particularly an issue for new establishments. COMAH'15 retains the timescales set out in the COMAH'99 for the preparation of external emergency plans. The majority of responses to the formal consultation were in favour of this.

158. No further work was undertaken on the proposal for the public concerned to be allowed the opportunity to comment on external emergency plans. This was because in COMAH'99 the LA is required to consult "such members of the public as it considers appropriate...." Therefore this requirement does not impose any additional cost.

Gold Plating – Retaining pre-existing UK health and safety standards for External Emergency Plans

159. Another element of gold-plating is the retention of pre-existing standards of health and safety currently in place in the COMAH'99 for external emergency plans and the timescales in which they need to be produced by the LA (No. 6, Table 9). This means no additional cost will be incurred and it will provide consistency and certainty for operators.

160. The requirement in COMAH'15 is that external emergency plans must be drawn up within 6 months (or such longer period not exceeding 9 months agreed by the CA in writing) following receipt of the necessary information from the operator. The Directive allows 2 years for this but the shorter period retains the standard in COMAH'99. For this proposal there was little or no negative feedback from stakeholders during informal consultation. The majority of responses to the formal consultation were in favour of retaining this requirement and agreed that two years was too long and posed too a great a risk. Most considered the current timescales were generally realistic and achievable.

Internal Emergency Plans

161. For establishments which move into the COMAH regime or change from LT to UT the timescales for operators to produce an internal emergency plan (IEP) will be changed in line with the Directive i.e. from one year in COMAH'99 to two

years in COMAH'15. In the consultation stage IA, this was described as having the potential to deliver a small saving to business as they would have a slight degree of extra flexibility in the time they have to submit, although it was not costed at that stage.

162. During consultation, HSE looked further into this area to estimate the likely scale of any savings. It was estimated based on follow up feedback with the focus group and from expertise within HSE that an IEP might take at most around 200 hours to produce. Costed at the average cost of time in this IA of £28.22 per hour, this gives around £5.6 thousand.
163. The greatest possible saving would come about if an eligible establishment delayed the writing of the IEP by a full year, generating a saving of just under £200 per establishment. Given that this would only affect those establishments moving into UT, of which there are estimated to be between 1 and 10 (see Table 1), this means that even if every eligible establishment delayed writing their IEP by a full year, the total saving might be no more than between around £200 and £2 thousand. These estimates are rough, but HSE is satisfied that they show that any savings from this change would be small and that it would be disproportionate to spend further resources trying to refine the cost saving. Therefore, this final stage IA considers that, while there may be savings in terms of time or flexibility from the removal of this gold plating, they would be very small and therefore **no quantified savings** have been estimated.

Gold Plating – Retaining pre-existing UK health and safety standards for Internal Emergency Plans

164. It is the intention to retain the consultee list from COMAH'99 (No. 5, Table 10). This is a list of people and certain agencies with whom the operator must consult when preparing the internal emergency plan. Retaining this list will ensure that the emergency planning communities are appropriately involved in the development of the internal emergency plan. This is consistent with COMAH'99, therefore there will be no additional impact on business.

12. Monitoring ageing equipment and corrosion

165. From discussion with the research group it was ascertained that the majority of establishments do this as a matter of business as usual. No circumstances where additional cost might be incurred were provided for existing establishments.
166. This is because section 2(2)(a) of the Health and Safety at Work etc Act (HSWA) 1974 imposes an express duty on employers regarding the provision and maintenance of plant, which is to ensure that they are, so far as is reasonably practicable, safe and without risks to health. So there are no additional costs relating to this issue to consider for this IA.

13. Costs to the Competent Authority

13.1 Impact on the CA of change of establishments in scope

167. Overall it is estimated that there will be cost savings for establishments in scope of COMAH due to an overall net reduction in the number of establishments of between about 13 and 18. Of this total, it is estimated there will be an overall

reduction in the number of both UT and LT establishments. The costs of the change in scope to business are calculated in paragraphs 54 to 63.

168. The impact on the CA will include:
- Small reduction in the number of establishments to inspect.
 - One-off cost of reviewing notifications for establishments moving into scope.
 - One-off cost of reviewing safety reports for establishments moving into scope.
 - Ongoing savings from the overall reduction in the number of safety reports it has to review every 5 years.
169. Inspections: Despite the fact that the number of establishments to be inspected is overall expected to decrease, it is not expected this will deliver a saving in terms of CA time. This is because the maximum reduction possible is only about 2% of the current number of establishments.
170. One-off costs of reviewing notifications for establishments moving into scope for the first time: it is estimated that between 5 and 17 establishments will move into scope for the first time (see Table 2). These establishments will have to notify the CA. The costs of this notification to business are included in the compliance cost estimates summarised in Table 4. However, there will also be a cost to the CA of reviewing these notifications.
171. HSE's best estimate is that it will take a Band 2 specialist inspector 0.25 hours to review each notification, plus 1 hour administration time for each notification.
172. In 2012/13 the hourly cost recovery rate for COMAH activities was £155 an hour²². This includes inspector and administration resource effort directed at COMAH work and is used to cost the 15 minutes of time spent reviewing the re-notification and includes the administration time of one hour.
173. On the basis that there will be between 5 and 17 new notifications the **total estimated present value of the cost** of CA resource to review new notifications is estimated to be between around £210 and £630 with a **best estimate of around £420**. As this work is cost-recoverable, the cost will be borne by industry.
174. One-off review of Safety reports: it is estimated that the gross number of establishments moving into UT for the first time will range between just less than 1 and 10 establishments. The CA will have to review these safety reports as they are submitted.
175. HSE's best estimate is that to review a full safety report, the total assessment time for the CA would be between 25 and 50 days. HSE estimates that one hour of time spent on COMAH-related support activities is valued to HSE at £155 as explained in paragraph 172. The average cost recovery rate for the Environment Agency is £125 per hour and for the Scottish Environment Protection Agency (SEPA) is around to be £136 per hour²³. Assuming the review is split evenly between HSE and the two environmental agencies, then the average cost of time per hour is estimated to be £139. On this basis, the review of new safety reports

²² See explanation of the COMAH cost recovery rate at:

<http://www.hse.gov.uk/charging/comahcharg/comahch1.htm>

²³ See details of rates at: <http://www.hse.gov.uk/charging/comahcharg/comahch1.htm>

in Year 1 of the analysis is estimated to give a **present value cost** between around £20 thousand and £507 thousand with a **best estimate of around £263 thousand**. This is a cost to the CA in terms of time, but will be recovered from industry.

176. 5-yearly costs of reviewing updated safety reports - it is estimated that there will be a net decrease in UT establishments of about 11 establishments. For these establishments there will be ongoing savings to the CA from not having to review their safety reports following the five-yearly updates which establishments are obliged to do. In reality, under the status quo baseline, these 11 establishments could have been due to review their safety report at any point in the first 5 years of the appraisal period. For simplicity and in the absence of further information, it is assumed that the CA would have reviewed 20% of these establishments in each year of the appraisal period (so 100% over 5 years). The direct cost saving to business has already been captured above, in the costs and savings associated with the change in scope. However, the CA will also make a cost saving from not having to review these safety reports.

177. It is assumed that the time taken for the CA to review new safety reports is between 10 – 20 days based on HSE expert knowledge. Using the average hourly cost recovery rate of £139 per hour, the expected **present value of the cost saving** to HSE from not reviewing around 2 safety reports per annum over the ten year appraisal period is estimated to be between around £173 thousand and £355 thousand with a **best estimate of around £264 thousand**. These costs would have been recovered from industry so this is a saving to industry.

13.2 CA costs of reviewing updated safety reports

178. There will also be costs to the CA of reviewing the updated safety reports for those establishments remaining in UT (costs to business calculated in paragraphs 73 to 84). If an establishment only has to make changes to the substances to reflect CLP and those changes do not impact on their safety report they will need to reflect this in their notification, in which case the CA will only need to append the notification to the safety report and will not need to review it until the next review date.

179. HSE will keep the costs down as much as possible in terms of handling updated safety reports and dealing with the notification where there is no impact on the safety report. HSE will not have any extra resource for this work and will therefore absorb costs by reprioritising resources. As such, while HSE estimate an increase in costs recovered from industry in respect of safety reports, savings to industry will be generated elsewhere due to having to divert HSE resources from other cost-recoverable work.

180. HSE experts have estimated that to review updated safety reports could take the CA between 6 and 20 days of time per report, depending on size and complexity. As noted in paragraphs 74 to 84 it is estimated that 20% - 40% of between 330 and 339 establishments will be submitting updated safety reports.

181. On the basis that the average hourly cost recovery rate across the CA is £139 an hour (see paragraph 175) it is estimated that the **present value of the one-off costs** to the CA of reviewing updated safety reports in Year 1 will be between around £398 thousand and £2.7 million with a **best estimate of around £1.6 million**. This cost will be recovered from industry.

13.3 CA cost of reviewing re-notifications

182. There will also be a cost of the CA time spent reviewing the re-notifications. The costs to business are estimated in paragraphs 101 to 110. HSE's best estimate is that it will take an HSE Band 2 specialist inspector 0.25 hours at £155 per hour to review each notification.
183. On the basis that there will be between about 947 re-notifications in Year 1 of the appraisal period (see paragraph 102) the **total present value of the cost** of CA resource to review re-notifications is estimated to be **around £35 thousand**. These costs will be recovered from industry.

13.4 Other costs to the CA

184. Time limit introduced for provision of information on major accidents to the EC - this will be extended from the current 3 year period to 4 years. This could create a saving, but will depend on the frequency of major accidents as to how great that saving is. However, it is thought the saving per establishment will be relatively low, because it is simply diverting costs from year 3 to year 4 where they are valued slightly less. It is also expected that the number of major accidents will be low (based on past experience and the reliance on the Directive as fit for purpose) and so any potential cost savings are also assumed to be low and it would be disproportionate to quantify them.
185. Guidance – the CA will be required to draft guidance for the new regulations, although this will be classed as business-as-usual costs. There could be a cost for industry if they are asked to contribute to drafting the guidance, but they would not be compelled and are assumed only to do so if they assess that the benefits were greater than the costs.

13.5 Summary of costs to the CA

186. It is estimated that the total estimated present value costs to the CA to be passed onto industry will be between around £454 thousand and £3.3 million, with a best estimate of around £1.9 million.
187. The total estimated present value savings to the CA to be passed onto industry are estimated to be between around £173 thousand and £355 thousand, with a best estimate of around £264 thousand.
188. This gives an additional **present value net cost to industry** of between around £280 thousand and £2.9 million, with a **best estimate of around £1.6 million**.
189. As reflected in paragraph 179, HSE aims to limit costs as much as possible in terms of handling updated safety reports and dealing with the notification where there is no impact on the safety report. HSE will not have any extra resource for this work and will therefore absorb costs by reprioritising resources. As such, while HSE estimate an increase in costs recovered from industry in respect of safety reports, savings to industry will be generated elsewhere due to having to divert HSE resources from other cost-recoverable work.

14. Domino Groups and non-COMAH Neighbours

190. The Directive introduces a new duty for members of a 'domino group' to co-operate in informing neighbouring non-COMAH establishments about the domino group and providing suitable information to them as well as providing the local authority with information to help in preparing external emergency plans. The requirement to identify such establishments falls to the CA, although the operator must provide any additional information as requested by the CA.
191. According to data held by HSE, the average number of COMAH establishments that are part of a domino group over the last five years is around 195. It is not clear at this stage how many of these establishments will have non-COMAH establishments nearby, nor how the concept of 'neighbouring' would be defined.
192. Based on follow-up correspondence with the focus group and expertise within HSE, it is estimated that each COMAH establishment in a domino group would need to spend between one and two days managing these requirements each year, with a best estimate of around one-and-a-half days. However, this is already accounted for in the cost of time that COMAH establishments will bear gathering information on neighbouring sites for their notification to the CA, discussed in paragraphs 106 to 110. This would cover the time required to engage with the neighbouring non-COMAH establishments and with the CA.

Gold Plating – Retaining pre-existing UK health and safety standards for Domino effects

193. To retain pre-existing health and safety standards, COMAH'15 will retain the following requirement in COMAH'99 (No. 10, Table 10) i.e. when the CA has identified a group of establishments which could have domino effects it must notify the operators of those establishments which fall within that domino group. This will ensure that establishments are aware of fellow domino establishments and will aid co-operation. The Directive does not link the requirement on the CA to identify domino establishments with the requirement for those establishments to co-operate. As this retains a current requirement in COMAH'99 there will be no additional impact on business or familiarisation necessary.

15. Familiarisation

194. In addition to the activities described above that are undertaken in order to become compliant with COMAH'15, an initial period of time will be required for establishments to become familiar with the changes to their obligations under the new regime from those they currently have under COMAH'99. This would also allow the individual dutyholders to identify the activities necessary to bring establishments into compliance if necessary, such as updating safety reports or reviewing inventories as described above, and to set in motion the work to do so.
195. HSE estimates that this will be achieved by one staff member at each COMAH establishment reading the regulations and guidance. This is expected to take one to two days per establishment and to include both current COMAH establishments and those that would be expected to move into scope. This time assumption was tested with industry during consultation and no argument was found to change it. In line with estimates from the focus group as to who would

undertake this work, we assume that the average cost of time of £28.89 per hour would apply.

196. As the new measures under COMAH'15 do not affect the day-to-day management or control of establishments, it is not expected that efforts will be necessary to familiarise all workers on-site, beyond that which would take place as part of normal ongoing training, so this would not be an additional cost.
197. In addition, for those activities described above where effort is undertaken to bring establishments into compliance with the regulations, such as updating safety reports or reviewing inventories, HSE has interpreted the times estimated by industry to complete the work as including a small allowance to allow the people involved to become familiar with the work and the reasons for doing so. As such, there would not be an additional familiarisation cost for those workers either.
198. As shown in Table 1, there are around 947 current COMAH establishments in GB. As shown in Table 2, the gross figure of currently out-of-scope establishments expected to move into scope is estimated to be between around 6 and 17. This gives between about 953 and 964 establishments needing to familiarise, with a best estimate of about 958.
199. Using the average cost of time of £28.89 per hour, this gives a **total one-off cost to industry** of between about £206 thousand and £418 thousand, with a **best estimate of around £312 thousand**.

16. Summary of Costs to Business, Government and Society

200. The following table summarises the estimated costs and savings which have been quantified.

Table 8: Estimated quantified costs and savings under Option 2 in ten-year present values (£k)

	Low	Likely	High
Costs to Industry			
Scope	£551	£2,229	£3,908
Updating safety reports	£7,132	£20,902	£34,672
Reviewing inventories	£47	£71	£95
Re-notifications	£1,633	£2,457	£3,281
Public information	£1,115	£2,940	£4,765
Redacting safety reports	£8,358	£11,391	£14,423
CA costs recovered	£454	£1,861	£3,268
Testing external emergency plans	£712	£1,051	£1,398
Familiarisation	£206	£312	£418
Total Costs to Industry	£20,206	£43,214	£66,227
Costs to Government			
IT system	£360	£400	£440
Testing external emergency plans	£356	£526	£699
Total Costs to Government	£716	£926	£1,139
Cost Savings to Industry			
Scope	£2,590	£3,648	£4,707
CA savings passed on	£173	£264	£355
Total Savings to Industry	£2,763	£3,912	£5,062
TOTAL COSTS	£20,922	£44,140	£67,366
TOTAL SAVINGS	£2,763	£3,912	£5,062
NET COST	£18,159	£40,227	£62,305
Net Cost to Industry	£17,444	£39,301	£61,166
Net Cost to Government	£716	£926	£1,139

Note: totals may not sum due to rounding

201. Table 9 summarises the unquantified costs and savings.

Table 9: Summary of unquantified costs and savings in final stage IA

Measure	Estimated scale
<p>Internal Emergency Plans (IEP) – timescales to produce a new internal emergency plan – from 1 year to 2 years (see paragraphs 161 to 163)</p>	<p>The extended timescale to create an IEP is expected to yield a small saving for industry. Given that this removes pre-existing gold plating, this saving would be in scope of OITO. However, having investigated this further during consultation, this saving is expected to be very small and so has not been estimated.</p>
<p>Pipelines - quantity of dangerous substances in a pipeline within the boundary of an establishment will be included in its inventory and could therefore affect whether the establishment comes into scope of the regulations or changes tier (see paragraphs 51 to 53)</p>	<p>The inclusion of pipeline quantities within the boundary of an establishment in the assessment of dangerous substances may lead to some businesses moving into scope of COMAH'15 or to increase tier from LT to UT. This would represent a small ongoing cost to industry. HSE investigated this with HSL and a trade body to establish the impact this could have. Although some establishments may be affected, it was agreed the impact would be small. HSE therefore considered it was not proportionate to carry out further research.</p>
<p>Further technical amendments (see footnote 15)</p>	<p>The inclusion of alternative fuels and biogas in the assessment of dangerous substances may lead to some businesses moving into scope of COMAH'15 or to increase tier from LT to UT. This would represent a small ongoing cost to industry. Additional work undertaken by HSL on this indicates there will be little or no impact and so this was not refined further for the final stage IA.</p>
<p>Safety reports – pre-construction and pre-operation safety reports (see paragraph 98)</p>	<p>The retention of the standard whereby businesses must submit a safety report at both the pre-construction and pre-operation stages is expected to maintain a small ongoing benefit to business, although as this retains the current standard this would not be an additional benefit. While HSE has been able to give some examples of good practice, it has not been possible to quantify this benefit. This is because the benefits are often specific to particular projects and it has not been possible to generalise across the sector.</p>
<p>Notifications – regulations specify the means by which operators have to send their notification (i.e. via the database) (see paragraphs 111 to 112)</p> <p>Gold Plating – (No. 2, Table 10)</p>	<p>HSE explored the issue during consultation and found that, while this is likely to impose a small ongoing cost to business in some cases, the cost is very small and has not been quantified.</p>
<p>Public information – costs to CA of verifying information provided by operators for the public information via the</p>	<p>There would be a duty on HSE to verify that the public information submitted to the database was from a bona fide source. As this would be cost recovered, this might impose a small ongoing cost to business. However, when this was investigated further during consultation, it was clear that this</p>

database (see paragraph 125)	could probably be part of the ongoing relationship between HSE and industry and so would be a small or nil impact.
Public information – the format in which such information or revised information is to be provided (see paragraph 126) Gold Plating – (No. 8, Table 10)	By specifying that public information must be hosted on the HSE database will impose a small ongoing cost to industry , but only if businesses wish to also host the information on their own website. In these instances, the additional effort is not expected to be great and would probably constitute a simple ‘copy-and-paste’. As such, it has not been possible to quantify this during consultation.
LAs to inform population likely to be affected following major accident (see paragraphs 139 – 140)	This new duty is expected to impose a small ongoing cost to LAs . Given the infrequency of major accidents in the UK and the small costs of distributing the information (a few hundred pounds) it is not considered proportionate to monetise this amount, and it would be small in comparison to other costs calculated in this IA.

202. Table 10, below, shows a summary of areas of ‘gold plating’ in the transposition of the Seveso III Directive into UK law through the COMAH’15 regulations. Some of these areas maintain the current standards present in COMAH’99 at no additional cost. As well as being summarised in the table, the areas are discussed further in the relevant sections of this IA.

Table 10: Summary of gold plating (including areas maintaining health and safety standards) in COMAH'15

	The EU Directive requires that	COMAH'15	Reason
1	<p>Notifications – Operators submit information about their site <u>either before</u> construction, <u>before</u> operation commences <u>or before</u> a significant modification is carried out.</p>	<p>Notifications - Operators submit information about their site <u>before</u> construction <u>and before</u> operation commences if the information is different.</p> <p>Sites would also have to submit information prior to a significant modification being carried out.</p>	<ul style="list-style-type: none"> • Consistent with COMAH'99 therefore no additional impact on business or familiarisation necessary. • This early engagement is useful for both the regulator and operator. The regulator can start to plan its assessment and inspection programmes and ensure that the operator is making arrangements to fulfil its duties. This can potentially result in savings for the operator later. • Not requiring a new notification at each stage but amendments / additions as necessary. • In line with BRE Focus on Enforcement review that they would notify their intentions at an early stage.
2	<p>Notifications – Operators have to submit information about their site but not in a specific format.</p>	<p>Notifications – Operators are required to use an electronic form that links to the public information database (line 8)</p>	<ul style="list-style-type: none"> • Avoids duplication. • Gives operators clarity about the information to be provided. • Consistent with government's digital strategy to make services online. • The vast majority of responses in the public consultation supported this.
3	<p>Safety Reports – Operators produce a safety report either before construction, before operations <u>or</u> before a significant modification is carried out.</p>	<p>Safety Reports – Operators produce a safety report before construction <u>and</u> before operations commence, providing the information is different.</p> <p>Sites would also have to produce a safety report prior to a significant modification being carried out.</p>	<ul style="list-style-type: none"> • Consistent with COMAH'99 therefore no additional impact on business or familiarisation necessary. • Pro business – gives operators early access to CA opinion, which dutyholders value. • The regulator can engage with designers and operators and provide input on safety critical issues before construction starts potentially resulting in savings for the operator down the line.

			<ul style="list-style-type: none"> • Little or no negative feedback on this point during informal consultation. • Most responses in the public consultation saw the value in this.
4	<p>Safety Reports – Operators review their safety report as appropriate, and at least every five years. If updates are required these should be made and submitted to the regulator.</p>	<p>Safety Reports – Operators who have reviewed their safety report at the five year point and concluded no update is necessary should inform the regulator.</p>	<ul style="list-style-type: none"> • Consistent with COMAH'99 so therefore no additional impact on business or familiarisation necessary. • This facilitates the regulator to obtaining quickly the necessary assurance that risks have been considered by the operator and then follow up as necessary. • It is more cost effective for the operator to inform the regulator. • Should only affect a small number of cases where no revision is necessary in five years.
5	<p>Internal Emergency Plans – The internal emergency plan should be produced in consultation with staff working at the site.</p>	<p>Internal Emergency Plans - The internal emergency plan should be produced in consultation with: staff working at the site, the appropriate environmental agency, the emergency services, the local health authority and the local authority as appropriate.</p>	<ul style="list-style-type: none"> • Consistent with COMAH'99 therefore no additional impact on business or familiarisation necessary. • It sets the duty in a GB context by requiring the operator to liaise with the relevant bodies who may have to respond and therefore helps to produce a fit for purpose plan.
6	<p>External emergency plans - The local authority should produce an external emergency plan within two years of being provided with the necessary information by the operator.</p>	<p>External emergency plans - The local authority should produce an external emergency plan within nine months of being provided with the necessary information.</p>	<ul style="list-style-type: none"> • Consistent with COMAH'99 therefore no additional impact on business or familiarisation necessary. • Industry, Emergency Planning Authorities and emergency responders expressed concern that two years was too long to be without an up to date plan. Other member states have alternatives to bridge this gap. • External emergency plans provide for the response

			<p>to a major accident which could be in a built up area with a significant population.</p> <ul style="list-style-type: none"> • Little / no negative feedback received during informal consultation. • The vast majority of responses in the public consultation supported this.
7	<p>External Emergency Plans – Enhanced co-operation between relevant bodies occurs to ensure proper testing of external emergency plans.</p>	<p>External Emergency Plans – Category 1 responders (emergency services, local hospitals, health trusts etc) will be required to co-operate with the testing of plans as necessary.</p>	<ul style="list-style-type: none"> • Feedback from industry that validity of some tests has been compromised due to some responders not fully co-operating. Testing would be strengthened by legislation securing co-operation. • The vast majority of responses in the public consultation supported this.
8	<p>Public information – Operators must make certain key information “permanently and electronically” available to the public.</p>	<p>Public information – Operators are required to use an electronic form to submit the information to a database provided by the regulator.</p>	<ul style="list-style-type: none"> • A central database provided by the regulator would allow easy public access to information presented in a consistent way. As the information would be provided via the regulator this may promote public trust and increase transparency. • Consistent with the government’s Digital Strategy. • The vast majority of responses in the public consultation supported this.
9	<p>Public Information – People living or working near a major accident hazard site should receive information on safety measures and action they should take in the event of an accident. This information should be supplied regularly and proactively by the site.</p>	<p>Public Information – When preparing the information that they must provide, sites should liaise with the relevant local authority.</p>	<ul style="list-style-type: none"> • Consistent with COMAH’99 therefore no additional impact on business or familiarisation necessary. • It allows best use to be made of local authority expertise in communicating with the public and their local knowledge. The local authority can also perform a co-ordinating role where different operators have sites located close together. • Little / no negative feedback received during informal consultation. • The vast majority of responses in the public consultation supported this.

10	<p>Domino Effects – The regulator identifies sites considered to be domino groups (sites where the nature of their hazards and proximity could trigger or worsen a major accident) The operators then have to co-operate with each other to ensure that their combined hazard is considered for emergency planning and public information.</p>	<p>Domino Effects – Once the regulator has identified a domino group it must notify all the relevant operators and provide contact details of the other members in the domino group.</p>	<ul style="list-style-type: none"> • Consistent with COMAH'99 therefore no additional impact on business or familiarisation necessary. • A duty on operators to co-operate requires them to know who other members are. The proposed text provides this link that is absent in the Directive.
11	<p>Safety Reports - maintaining the 5 year review cycle A safety report must be reviewed and updated every 5 years and sent to the CA. The Directive has been interpreted by HSE as requiring UT sites to undertake a full review at the point of submitting an updated safety report for COMAH'15 compliance by 1st June 2016, with subsequent reviews every five years – this would 'reset the clock' for existing UT sites.</p>	<p>Safety Reports - maintaining the 5 year review cycle HSE proposes to enact an interpretation of the Directive whereby the existing 5 year review cycle from COMAH'99 is maintained, rather than re-set the clock.</p>	<ul style="list-style-type: none"> • Maintaining the 5 yearly review cycle from the COMAH Regulations 1999 will reduce burdens on business relative to copying out the Directive. • This was a view expressed by some operators during the public consultation. • Consistent with COMAH'99 therefore no additional impact on business or familiarisation necessary. • Less costly for industry than re-setting the clock. • Represents a zero net cost

17. Benefits

203. The main benefit of the COMAH regime is the prevention of catastrophic incidents which could cause serious harm to people, the environment and the economy and to provide public assurance that risks which could affect them are effectively regulated. The public acceptance of high hazard industries allows these industries to operate in communities and so provide essential services to society. A financial estimate of this benefit would be very difficult to develop but it is known that major accidents have a significant cost for the company concerned, individuals and government including local authorities. The final report of the Major Incident Investigation Board (MIIB) for the Buncefield incident in 2005 gives the total quantifiable costs as close to £1 billion.²⁴
204. A research project in HSE and HSL has recently been completed²⁵ to estimate the average cost of catastrophic incidents. The initial results show that the costs of the Buncefield incident might not have been exceptionally high relative to other potential major accidents. The average costs in the HSL research are in the region of £100 million for a major accident at a flammable risk site; £150 million at a toxic risk site and; up to around £400 million at certain types of overpressure (explosion) risk sites. The majority of these costs are accounted for by human impacts, including the death or injury of workers and /or members of the public. The COMAH regime (including safety report assessment, inspection, incident investigation, incident reporting, learning from incidents and emergency planning) acts to minimise major accident risks and to focus attention on any emerging issues.
205. The difficulty in quantifying the existing benefits of COMAH 99 in terms of the reduction in the likelihood and impact of major accidents, and how these might change under COMAH'15, stems from not being able to estimate accurately the frequency with which major accidents occur. This is because they are rare events and the circumstances necessary to bring them about are not predictable, nor is it possible to estimate exactly how these circumstances might change with the change in the Regulations, except to say that their likelihood would probably decrease.

17.1 – The new classification system (CLP)

206. The main change introduced by Seveso III is the adoption of the new classification system introduced by the European CLP regulation through the COMAH 15 regulations. This is the Globally Harmonised System (GHS) of classification and is used worldwide. It was brought about as a result of industry desire to have greater integration of packaging and labelling systems and a system which would be world-wide. Having a more common approach will help to reduce burdens on business.
207. The new classification system is also likely to offer benefits in terms of more consistent management of risks between major hazard installations and the transport of dangerous substances. It will also contribute to more comparable incident reports worldwide and so enhance the ability to learn lessons from incidents and improve safety for the public and the environment. CLP and the associated REACH regulation promote the sharing of hazard information about substances and mixtures to maximise the benefits in preventing major accidents. These benefits cannot be quantified in a proportionate manner.

²⁴ <http://www.buncefieldinvestigation.gov.uk/reports/volume1.pdf>, page 24

²⁵ Report not yet published

17.2 - Scope

208. It is important that the substances in scope of COMAH should have genuine major accident potential otherwise regulatory attention will be diluted when it needs to focus on installations with major accident risk. The negotiations of the Seveso III Directive used the HSE/HSL research about the potential for establishments to change scope to influence the alignment between Seveso III and CLP and to include a number of new named substances. This has minimised the impact such that few if any new COMAH establishments are expected to come into scope which do not have major accident potential.

17.3 Domino establishments and sharing information with neighbouring sites

209. Arrangements for providing information to neighbouring sites (e.g. sites which may not fall within scope of COMAH) about accidents and actions to take will have the advantage of allowing these neighbouring businesses to pre-plan their response, in terms of evacuation or shelter indoors, thereby improving the safety of their workers and customers. Such information is already provided to households under COMAH'99.

17.4 Emergency Plans

210. The involvement of all the emergency services in the testing of external emergency plans will ensure the plan is thoroughly tested and the correct emergency arrangements are in place to protect the public and workers in the event of a major accident.
211. Maintaining the current timescales for the development of an external emergency plan will ensure risk to the public is not increased if development of the plan was to be extended over a longer time period.

17.5 Public information

212. The requirement for operators to provide the public with easily accessible information about their establishment will result in a better informed public about the overall operation of the establishment and what to do in an emergency. It will also provide public assurance that risks which could affect them are being effectively regulated.

17.6 Summary of benefits

213. While COMAH'15 is expected to deliver real benefits to business, this analysis considers it unlikely that these unquantified benefits would outweigh the costs of the Regulations. Based on the provisional estimates from HSL (see paragraph 204), the average cost for a major accident is around £100 million. Given that the total net cost for the new COMAH'15 Regulations are estimated at around £40.2 million in present values over ten years, it would require the prevention of around one major accident over two decades to justify the expense. Given the infrequency of major accidents in GB, this scale of incident prevention is unlikely to occur.

18. Rationale and evidence that justify the level of analysis used in the IA (proportionality approach)

214. The evidence collected for this final stage IA is described in detail in paragraphs 26 to 35. In summary, the evidence consists of the following:

- a survey of all 1,100 COMAH establishments in 2010/11 which received a 25% response rate and detailed analysis of the substances they store by the Health and Safety Laboratory (HSL);
- further analysis of substances and alignment using the ECHA data base and detailed peer review of HSL judgements.
- data on costs of compliance collected via the survey of 1000 COMAH establishments.
- informal consultation with industry at the Society of Industrial Emergency Services Officers (SIESO) conference;
- a research group with 11 representatives from industry and 3 from trade associations to discuss cost impacts, with some follow up correspondence during consultation;
- telephone interviews with a sample of smaller businesses;
- telephone interviews with thirteen Local Authorities and five Metropolitan Fire Brigades (covering 118 UT COMAH establishments) to gain an understanding of the extent that Cat 1 responders currently participate in the testing of emergency plans and to explore costs.

215. Considerable cost both in terms of research fees and time of officials has gone into the analysis in this IA. This is thought to be proportionate to the significant impact on industry resulting from Seveso III.

216. The initial analysis based on the survey evidence and HSL scientific input contributed significantly to negotiations in Europe, leading to agreement on scope which would minimise costs to the UK.

217. More effort has been spent in trying to estimate those costs which are likely to have a greater impact on industry (i.e. the evidence base has been informed by survey evidence or discussion with the research group rather than relying on HSE judgement alone) and overall the level of analysis is thought to be proportionate to the changes proposed.

19. Direct costs and benefits to business calculations (following OITO methodology)

218. The total estimated NPV of the costs to society of Option 2 is between around £18.2 million and £62.3 million with a best estimate of around £40.2 million.

219. The total estimated net present value of costs to business are estimated to be between £17.4 million and £61.2 million with a best estimate of around £39.3 million.

220. The Equivalent Annual Net Cost to Business (EANCB) in scope of One In, Two Out (OITO) is estimated to be around £0.10 million in 2009 prices. This is due to the costs of requiring Cat 1 emergency responders to attend external emergency plan tests for UT COMAH establishments, which is gold plating. The

overall EANCB, including both the elements in-scope and out-of-scope of OITO, is around £3.69 million, also in 2009 prices.

221. There are also three much smaller impacts in scope of OITO that have not been quantified, as it was not proportionate to do so. There are two requirements that notifications and public information should be handled through the HSE online systems, which are expected to reduce flexibility and so impose a very small potential cost, if any. There is also the removal of some pre-existing gold plating that gives new COMAH sites more time to prepare an internal emergency plan, which is expected to deliver a small saving. These impacts are expected to be very small, if anything.
222. The proposal is European in origin, except in those areas, summarised in Table 10, where COMAH'15 contains elements of gold plating or maintains current health and safety standards at no additional cost. These areas are within scope of One In Two Out (OITO). Where the gold plating does not maintain current health and safety standards, this will impose a burden on industry within the scope OITO and so deliver an IN.

20. Wider impacts

20.1 Statutory equality duties

223. None has been identified.

20.2 Economic impacts / Competition:

224. The measures under COMAH'15 would affect businesses differently depending on their COMAH tier (UT or LT) and so places a greater burden on some businesses in scope than on others. However, this difference in burdens under COMAH'15 is in proportion to the greater impact of possible failures in control at UT establishments relative to LT establishments and is in keeping both with the measures contained within the Seveso III Directive and the current arrangements under COMAH'99.
225. Under Option 2, LAs would have discretion as to whether or not to charge UT establishments for the participation of Cat 1 emergency responders in the testing of external emergency plans. This reflects the democratic nature of the devolution of powers to LAs, but has the potential to lead to an 'unequal playing field' within GB, wherein UT establishments in some areas must pay while others elsewhere do not.

20.3 Small and Micro-businesses

226. As COMAH'15 will transpose an EU Directive the Regulations will apply to all businesses and the small and medium business assessment (SMBA) does not apply. Due to the nature of the substances handled and stored by COMAH establishments, the risk posed by any loss of containment to the environment or to human health is not proportionate to the number of employees. This is in keeping with the current arrangements under COMAH'99.

20.4 Environmental impacts

227. HSE estimate that the new measures covering mitigation of major accidents, such as those relating to Domino establishments, may deliver an environmental benefit where they allow vulnerable sites close to COMAH establishments to prepare better measures to prevent the escalation of major accidents. Throughout the rest of COMAH'15, the high standards of environmental protection afforded by COMAH'99 have been maintained.

20.5 Health and Well Being

228. As with the environmental impacts, above, where the greater preparedness of Domino establishments is able to prevent the escalation of major accidents, human health and well-being may be protected. Throughout the rest of COMAH'15, the high standards of human health protection afforded by COMAH'99 have been maintained.

20.6 Social impacts

229. It is anticipated that the measures on public information in COMAH'15 would better inform the public and provide assurance that there are suitable measures in place to mitigate or control the risks from major accident hazard sites.

20.7 Human Rights

230. None has been identified.

20.8 Justice System

231. None has been identified.

20.9 Rural Proofing

232. None has been identified

20.10 Sustainable Development

233. None has been identified.

21. Summary and preferred option with description of implementation plan

234. It is estimated that the total quantified net present value of the costs of the proposed COMAH'15 Regulations under Option 2 will be of between about £18.2 million and £62.3 million over 10 years, with a best estimate of around £40.3 million.

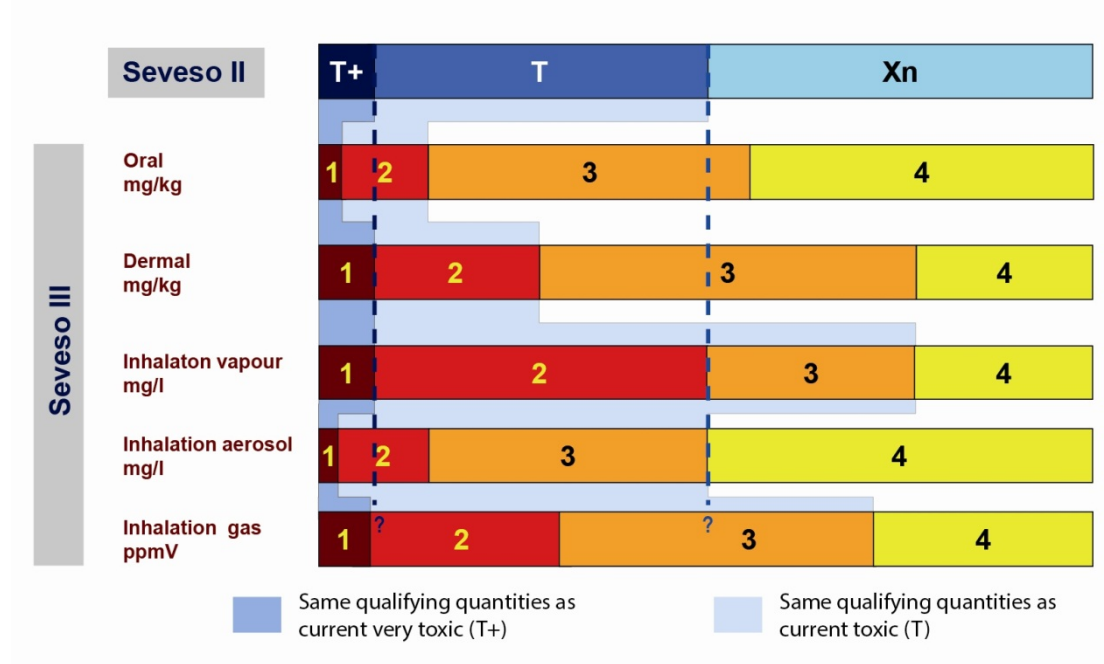
235. The estimated Equivalent Annual Net Cost to Business (EANCB) in scope of OITO is estimated to be about £0.10 million in 2009 prices. The overall EANCB, including both the elements in-scope and out-of-scope of OITO, is around £3.69 million, also in 2009 prices.

236. The Seveso III Directive is being transposed into GB law through 'copy out'. Exceptions are areas of gold plating, the majority of which maintain current health and safety standards at no additional cost, as summarised in Table 10. Operators should be left in no doubt about their legal duties and effective transposition will not reduce the control of major accident hazards as required by the current COMAH Regulations.

Annex 1 - Background to Change of Scope

1. The main reason for the new Seveso III directive is the replacement of the Dangerous Substances Directive (DSD) (EC, 1967) and Dangerous Preparations Directive (DPD) (EC, 1999) with Classification Labelling and Packaging Regulations (CLP) (EC, 2008) which use the Globally Harmonised System (GHS) of classification of chemicals. The scope of the Seveso II Directive (EC, 1996) as amended, which is implemented in GB by the COMAH'99, was linked to classifications in the DSD/ DPD, which determine the qualifying quantities of dangerous substances for establishments to be UT or LT. The scope of the Seveso III Directive will instead be linked to GHS classifications. The major effect of the classification changes is a result of the change of classification for acute health effects.
2. The DSD/DPD define two categories for acute toxicity which align with Seveso II threshold quantities. These are 'toxic' (T) and 'very toxic' (T+). In addition, there is a 'harmful' (Xn) category which is out of scope of Seveso II. However, CLP uses the GHS acute toxicity categories 1, 2, 3 and 4 which do not completely correspond to the previous two categories they replace, i.e. Toxic (T) and very toxic (T+) which have different cut off values for lethal doses. For both systems, categories can be defined according to the lethality response for the oral, dermal or inhalation exposure routes.
3. Figure 1 shows ranges of toxicity from left to right, with higher toxicity on the left. It also shows the different exposure routes considered by the GHS system adopted in the CLP Regulation from top to bottom. The dark blue and light blue shading show the GHS categories which are aligned with the current EU DSD classifications of very toxic (T+), toxic (T). Harmful (Xn) was not in scope of Seveso II.
4. The diagram shows the comparison between the EU (DSD / DPD) and GHS acute toxicity categories. The fact these two classification systems do not align is evident from the diagram. How best to align the two classification systems to minimise the change in scope was the subject of lengthy negotiations in Europe. The outcome of the negotiations (shown in dark and pale blue shading on the diagram below) was agreed by the UK to be the best compromise, so that impacts to business are minimised while maintaining Health and Safety standards.

Figure 1 Alignment option for Annex 1 of Seveso III



5. The diagram shows that:

- some substances in the Oral and Dermal category 3 will drop out of scope (i.e. under the T category they were in scope but under the new alignment they will not be in scope);
- substances in Inhalation vapour category 3 will come into scope of the Directive (i.e. under the T category they were out of scope but under the new alignment they will be in scope).
- there should be no change for the inhalation of aerosols; and
- some substances in the Inhalation gas category 3 will come into scope (i.e. under the T category some substances were out of scope but under the new alignment they will be in scope).

6. In order to achieve the alignment between DSD/DPD and the new GHS, the qualifying threshold quantities in Annex 1 of the Directive for the relevant substances have been changed appropriately to achieve the scope in the diagram above.

Annex 2 - Estimate of changes in numbers of COMAH establishments as a result of the Seveso III alignment for acute toxic to humans

1. This Annex provides an explanation about the way in which HSE has estimated how many sites are affected by each category of the proposals. Figure 1 in Annex 1 shows the effects of the Seveso III alignment compared with that in Seveso II.

Estimate of sites changing scope as a result of the changes to Annex 1.

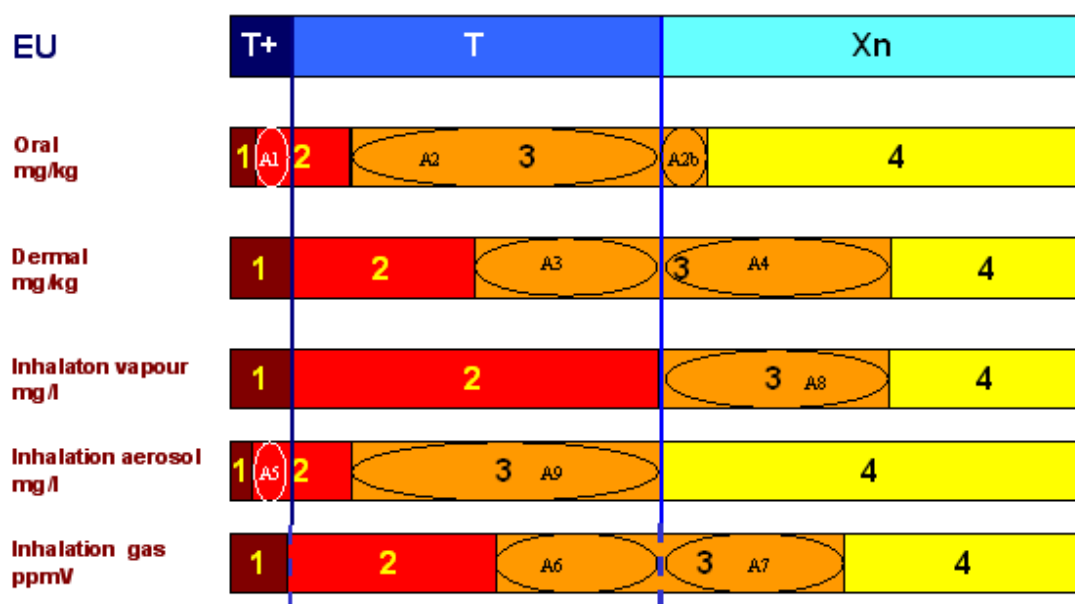
2. The EC carried out a study (COWI, 2010) to inform their IA of Seveso III alignment options, but this considered the impacts in terms of the number of substances that could change scope, which does not necessarily equate to the number of establishments changing scope. In order to determine the impact in terms of numbers of establishments which would change their Seveso status, considerable data was needed in terms of the substances and quantities held by each establishment. Moreover, there is a need to identify substances which could newly come into scope. An initial attempt was made by Trainor et al (2008) to do this by considering high tonnage substances in the IUCLID database (OECD, 2012) but it was considered unlikely that all such substances were successfully identified, and there were also issues with the quality of the data available.
3. In order to obtain such information, HSE commissioned ORC International to carry out a survey of all UK COMAH establishments. Two questions in the survey related to assessing the impact of different alignment options for acute toxicity. The first asked for on-site tonnages of substances which Trainor et al had already identified as being relevant. The second question asked for information and on-site tonnages of any other substances or mixtures which were classified as T+, T or Xn. In addition, to obtain the necessary toxicity data to allow the identified substances to be classified under GHS, Material Safety Datasheets (MSDSs, referred to as Safety Data Sheets in the REACH legislation (EC, 2006)) were requested for each substance identified. At that time, there was no information available on harmonised classifications under CLP or notifications under REACH. Use of data from MSDSs was a compromise to reduce the burden on industry in supplying toxicity data and to be able to obtain results early enough to usefully inform the negotiations of Seveso III. It was anticipated that the data in MSDSs would not be ideal but it was found to be worse than expected. N.B This data quality issue could have implications for how easy it is for companies to determine whether the changes to Seveso will affect them which is discussed in the IA above.
4. In addition to this survey evidence, data on around 6,000 substances has been made available via the European Chemicals Agency (ECHA) CLP inventory database²⁶, including substances with an EU harmonised classification under CLP and notifications under REACH. Account was also taken of the named substances in the final published text of the Seveso III Directive.
5. The number of valid responses received totalled 278, which equated to a 25% response rate. This was thought to be sufficient to provide robust data for this IA.

²⁶ CLP Inventory Database, <http://echa.europa.eu/information-on-chemicals/cl-inventory-database>

The current analysis of the Seveso III alignment involved the following steps:

- The data from the survey described above, carried out by ORC International, was analysed, based on toxicity data from the supplied MSDSs to determine the GHS categories for acute toxicity and hence which substances were in the 'areas of interest' (A1 to A8 in Figure 2). The areas of interest are those for which changes could occur i.e. whether the substance was in scope of Seveso/ COMAH. 100% of the data supplied was considered as far as possible given the quality of data in the MSDSs was poor (Wilday et al, 2012). Account was also taken of the named substances in Annex 1 of Seveso III. Some of the data was not useable for data quality reasons.

Figure 2: Definition of Areas of Interest (A1 – A9)



- All substances estimated to be within 'areas of interest', were checked against the ECHA CLP inventory database and/or specific peer reviews carried out by an HSE toxicologist. This removed the majority of the substances in this category.
- For each establishment, all the available data (including estimated GHS categories and tonnages; and any missing data) was considered and expert judgement was made about whether the COMAH/Seveso status of the establishment would change. This was based on a consideration of;
 - the number of substances which would aggregate under health effects,
 - their tonnages,
 - their estimated GHS categories or named substance status, and consequent qualifying quantities, and
 - the extent of missing data for the establishment.

For each establishment, the likelihood of the change in status was rated as definite (probability of 1), probable (probability of 0.6) or possible (probability of 0.1).

9. Numbers of establishments, which were calculated to change scope in different ways, were counted. The totals were divided by the number of establishments in the useable sample from the ORC survey to obtain the percentage of establishments which may change COMAH status. Results are given in Table 11.

Table 11 Proportion of COMAH establishments changing status for existing COMAH establishments – minimum estimate.

	% of existing COMAH establishments changing
<i>Decreasing status</i>	
UT to LT	1.2
LT to sub-COMAH	1.6
<i>Increasing status</i>	
LT to UT	0.053
sub-COMAH to LT*	0.16

* estimated using crude assumption that this equates to number of establishments that would have increased in scope if not already UT

10. It is noted that the process of peer review (see paragraph 7) removed the majority of the substances originally identified as being within the areas of interest. It was not possible to carry out a review against ECHA data on all the substances not tentatively identified as being within the areas of interest as this would have required disproportionate resource. However, it is possible that such an analysis would identify further substances and hence lead to the conclusion that more UK establishments would change their COMAH status. The estimates in Table 11 should therefore be considered as the minimum number that could change status.

11. A comparative maximum number of establishments has been estimated by HSL by not taking out of the analysis the substances that were based on the peer review and ECHA data. The results are presented in Table 12.

Table 12 Proportion of COMAH establishments changing status for existing COMAH establishments – maximum likely estimate

	% of existing COMAH establishments changing
<i>Decreasing status</i>	
UT to LT	2.1
LT to sub-COMAH	2.3
<i>Increasing status</i>	
LT to UT	0.79
sub-COMAH to LT*	2.7

* estimated using crude assumption that this equates to number of establishments that would have increased in scope if not already UT

Estimates of numbers of sites that could newly come into the Seveso/ COMAH regime

12. This is a difficult sample to estimate because these sites, by their very nature, are not known to HSE. Two methods have been used to obtain a tentative estimate of the number of sites that could newly come into the scope of Seveso III/ COMAH'15 Regulations in GB.
- (a) The number of sites which would have increased their COMAH status due to substances in areas A7 or A8 if the sites were not already UT establishments, was crudely equated with the number of sub-COMAH establishments which would newly come into the COMAH regime and are included in Tables 10 and 11 above.
 - (b) Substances in areas that could newly bring sites into Seveso/ COMAH (areas A7 and A8 in Figure 2) were studied to carry out a very approximate estimate (using expert judgment) of how many new sites might be brought in.
13. For method (b), substances were identified from the UK survey of COMAH establishments, from the COWI (2010) report, and from proposals made by member states during the Seveso III negotiations. Substances with the potential to bring in new sites are shown in Table 11. This suggests that an additional 4 or 5 new sites could be newly brought into the UK COMAH regime, probably all at LT. Again, this could be an underestimate because it is based only on substances which have currently been identified. However, this estimate is based on substances which have already been identified as changing scope. It therefore compares with the estimate of 0.16% of COMAH establishments from Table 10, which equates to 1 or 2 new sites. On average, this gives a minimum estimate of 3 new sites.
14. The upper estimate of 2.7% for COMAH establishments which would newly come into scope in Table 11 equates to 25 sites (based on the current number of COMAH establishments). It is assumed that 20% of these might come into scope at UT and the remaining 80% at LT. The rationale for this approximate estimate is as follows:
- The 25 sites relate to substances which were identified as being in areas of interest from a sample of less than 25% of sites (25% response to questionnaire but not all of these were usable).
 - Of these 25 sites, most were found not to actually increase in scope because:
 - Approximately 50% of the substances were found not actually in the areas of interest following a review of the toxicity.
 - Several remaining substances were made named substances.
 - The net effect of these two changes was to prevent any sites from being in the position that they would have increased in COMAH status had they not already been UT. It is these sites whose numbers were roughly equated to the number of new sites which might come into scope of COMAH.
 - We are concerned with the following possibilities:
 - Additional substances would have been identified by the sites which did not provide usable questionnaire responses. However, the usable responses were analysed in two rough halves. The second half of the sites identified very few substances which had not been identified in

the first half. This suggests that the sample of sites used may not have led to significant error.

- The questionnaires were from existing COMAH establishments. It is possible that a substance or substances could bring in new sector(s) but are not present at any COMAH establishments. However, this is relatively unlikely because all the substances identified by Trainor et al (2008) in a trawl of EU high volume substances were included in the analysis. However, not all the high volume substances had adequate toxicity data to allow analysis. Also, trade associations in the UK and other EU countries have had some opportunity to identify substances which could bring new sites into scope. Nevertheless, there remains some small possibility that important substances remain unidentified.
- Review of the toxicity data for a number of substances in the areas of interest which could potentially cause an increase in scope of COMAH led to revised classifications which were no longer in those areas of interest. It is possible that a review of data for some substances which were not in the areas of interest could conclude that actually they should be there. This might lead to increased numbers of new COMAH establishments. This is the main concern compared with the two possibilities above. It accounted for approximately 50% of the estimated 25 new COMAH establishments. Therefore the estimate has been reduced by 50% to 13 potential new COMAH establishments. Again it is assumed that 20% would become UT and 80% LT.

Table 12: Further analysis of substances in Areas A7 and A8 and their potential to bring new sites into COMAH

Name	CAS	Industrial use	Area	Potential to bring new sites in scope of COMAH	Tentative estimate of number of new sites
Ethane 1,2 diol	107-21-2	Chemical intermediate for pharmaceuticals and dyestuff etc.; cross-linking agent for textiles; manufacture of reactant resins in the textile industry; anti-lump treatment of cellulose ethers; component of adhesives and coatings; Hydrogen Sulphide (H ₂ S) scavenger in crude oil and gas industry (deodorising agent); cleaning agent and biocide for household and hospital disinfection; reducing agent in photographic industry	A8? ²⁷	Used in a variety of sectors, some of which will require several tonnes. Potential to bring in new sites via aggregation.	0.1 probability x approx 10 sites = 1
Hexa-fluoro 1,3 butadiene	685-63-2	Chemical intermediate	A7, A8? ²⁸	Potential to bring in new sites via aggregation	0.1 probability x approx 10 sites = 1
pent-2-enenitrile	25899-50-7	2-pentene nitrile is a by-product of the adiponitrile synthesis (precursor for the production of polyamides, used in the textile, plastic and coating industries).	A7, A8? ²⁹	Manufacturer(s) likely to be already Upper Tier. Likewise for users as pharmaceutical intermediate	Nil

²⁷ Question mark denotes that, based on the toxicity data available, it was possible but not certain that the substance would be in that 'area of interest'.

²⁸ Ditto reference 15

²⁹ Ditto reference 15

Name	CAS	Industrial use	Area	Potential to bring new sites in scope of COMAH	Tentative estimate of number of new sites
		The product is mainly re-used on-site as a combustible and is also used as an intermediate in the pharmaceutical industry. 2-pentene nitrile is only used for industrial purpose, there is no direct consumer exposure.			
trichloro(propyl)silane	141-57-1	Monomer/chemical intermediate	A8	Little information available. Most sites likely to be within COMAH already.	0.1 probability x approx 5 sites = 0.5
2,6-Dimethylcyclohexylamine	6850-63-1	Chemical intermediate	A8	Little information available. Most sites likely to be within COMAH already	0.1 probability x approx 5 sites = 0.5
3-Methyl-2-butenal	107-86-8	Intermediate. Manufacture of vitamin A. Flavour/aroma ingredient of foods.	A8	Only manufacturers/distributors likely to store large quantities. Manufacturers likely to be in COMAH already.	0.1 probability x approx 10 sites = 1
tert-Butylamine	75-64-9	Organic intermediate. Rubber accelerator. In the pharmaceutical industry used to make rifabutin. Used in the manufacturing of pesticide, fungicide. Dyestuff industry.	A8	Most sites likely to be in scope of COMAH already. Possible small number of smaller sites could be newly brought in.	0.1 probability x approx 5 sites = 0.5

Annex 3 - Estimated Cost of Compliance with COMAH'99

Data gathering

1. As explained in Annex 2, in 2010 HSE commissioned ORC International to survey all major hazard establishments in the UK, to find out information about substances used and stored. The survey also included questions on the costs of compliance with COMAH'99. In order to avoid the questionnaire becoming too onerous for industry to complete and thereby placing a disproportionate burden on them, instead of detailed questions on how long each different compliance duty might take, the cost questions were split into seven high level categories¹. The research agency reported total costs by these seven categories. Whilst the compliance duties within each category is clear it is not possible to report estimated compliance time for each duty separately.
2. The cost questions were also restricted to the time taken to comply in the current year, to increase the likelihood that the interviewee could answer the questions without having to look at past records. Again, this was to minimise the burden of the survey on business and to ensure they would be able to provide sufficient resource to answering the questions on substances used. However, it means that the costs captured are the on-going costs of compliance, but not necessarily the one-off cost when sites first come into scope of Seveso.
3. Due to the large scale nature of the survey, some qualitative work was undertaken to corroborate the findings. ORC research consultants used focus groups and depth interviews to discuss the cost estimates with industry, particularly whether these had changed over time, and to identify whether there are certain kinds of establishments or duty holders who incur different cost burdens for the same COMAH duty. This qualitative work did not identify any issues which would make us question the statistically significant cost estimates obtained from the quantitative survey work.
4. For each cost category, the research agency ORC reported the mean number of hours and the median number of hours from the survey results. For the purpose of this work, the mean number of hours was used. The total time for compliance was also reported by five occupation categories. For each occupation category, the average gross hourly wage rate per the Annual Survey of Hours and Earnings (ASHE) 2012 has been used². The gross hourly wage rates are grossed up by 30% as per BIS guidance³ to include the full costs of employing the staff (tax and NI contributions, pensions, overheads etc) to reflect the true economic cost associated with that employee's time being spent on non-chargeable work activities.
5. The estimated annual costs of compliance with the COMAH regulations for a UT establishment is £27thousand. Average annual costs for a low tier establishment are estimated to be £10thousand.
6. As the research survey did not capture the one off costs of becoming a COMAH establishment, the costs were discussed with industry trade associations and within HSE. For the purposes of this IA,

¹ The categories used by the research agency were as follows: familiarisation with the Directive and requirements; gathering data and relevant information (which specifically includes: prepare figures, hold internal meetings); planning activity and policy development (which specifically includes: prepare and implement a major accident prevention policy and review / revise where necessary); undertaking reporting activities (which specifically includes: prepare and supply information to people liable to be affected by a major accident and review information every three years); inspection activity (which specifically includes: preparation, attending inspections correction activity); other system changes; and any other tasks.

² ASHE available on line at: <http://www.statistics.gov.uk/statbase/Product.asp?vlnk=1951> Table 14. The occupation split is as follows: 1) Site manager / health and safety manager (ASHE occupation: Science, research, engineering and technology professional; 2) Health and safety officer / other officer (ASHE occupation Science, research, engineering and technology professionals); 3) Administrative staff (ASHE occupation Administrative occupations); 4) Site workers (ASHE occupation Science, Engineering and production technicians); 5) Any other (ASHE occupation: Administrative occupations).

³ See Measuring Administrative costs. UK Standard Cost Model Manual., Better Regulation Executive <http://www.berr.gov.uk/files/file44503.pdf> , Paragraph 5.9.2 which recommends that an overhead of 30% should be used.

the cost estimates have been informed by the main requirement for each tier when they come into scope: the safety report for UT establishments and the MAPP for LT establishments. The best estimate is that to draft a safety report from scratch could cost industry between £0.1m and £0.135m. The best estimate for a MAPP is between £0.015m and £0.023m with a best estimate of £0.02m.

7. Due to the large scale nature of the survey, some qualitative work was undertaken to corroborate the findings from the survey. ORC research consultants used focus groups and in-depth interviews to discuss the cost estimates with industry, particularly whether these had changed over time, and to identify whether there were certain kinds of establishments or duty holders who incur different cost burdens for the same COMAH duty. This qualitative work did not identify any issues which would make us question the statistically significant cost estimates obtained from the quantitative survey work.

Annex 4 - Description of establishment Estimates used for Different Cost Estimates other than Scope

Table 13 Summary of establishments affected for different cost estimates other than scope

	Reviewing inventories	Notifications	Updating safety reports	Costs of producing and reviewing NTS
Number of establishments used in calculations	942 – 954	937	323 – 332	333
Reason	<p>The assumption is that this will affect all establishments we know about, possibly plus some we do not know about.</p> <p>937 current COMAH establishments plus between 5 and 17 sites predicted to come into scope.</p>	<p>All existing establishments will have to re-notify. The costs of notification for any new sites will be captured in the section on scope.</p>	<p>Existing number of UT establishments, less those predicted to move out of UT. Not counting any moving into UT as costs of a safety report for new sites are captured in the scope section.</p> <p>344 current UT establishments less predicted movement out of UT of 12 and 21 establishments.</p>	<p>Applies to all establishments at UT, both new and existing as this is a new requirement in the Directive and not a consequence of the change in scope. Total number of establishments is that expected at UT after implementation of the Directive</p> <p>344 current UT establishments, plus the net movement in UT establishments of between -11.</p>
Source of estimate	HSL estimates, see Table 1 and Table 2	HSL estimates, see Table 1	HSL estimates, see Table 2	HSL estimates, see Table 2

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