EUROPEAN COMMISSION

Brussels, 21.12.2010
SEC(2010) 1590 final

COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT
Accompanying document to the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the control of major-accident hazards involving dangerous substances

COM(2010) 781 final
SEC(2010) 1591 final

COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT
Accompanying document to the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the control of major-accident hazards involving dangerous substances

Lead DG:	DG ENV
Other involved services:	DGs CLIMA, EMPL, ENER, ENTR, JRC, MOVE, SANCO, SJ, SG.
Agenda planning:	2010/ENV/006

The report commits only the Commission's services involved in the preparation and the text is prepared as a basis for comment and does not prejudice the final form of any decision to be taken by the Commission

TABLE OF CONTENTS

ANNEXES

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Overview

A review of the so-called Seveso II Directive 96/82/EC (1) on the control of major-accident hazards involving dangerous substances has been ongoing for the last two years. The main driver for this is the need to amend the Directive due to changes in the EU system of classification of chemicals. However the opportunity has been taken to examine whether any other amendments to the Directive would also be appropriate.

A revision of the Directive is a catalogue item in the 2010 Commission Legislative and Work Programme (CLWP) with an accompanying roadmap as set out at http://ec.europa.eu/governance/impact/planned_ia/roadmaps_2010_en.htm.

It is also included in the Commission strategy for simplifying the regulatory environment (3) and identified as a candidate in the list of simplification initiatives listed in Annex III to the CLWP 2010.

A number of stakeholders, experts and competent authorities of the Member States have been consulted. An Inter-Service Steering Group to support the overall review process, including work on the related Impact Assessment, was established.

1.2. Inter-Service Steering Group

Within the Commission, internal consultation has been pursued through an Inter-Service Steering Group (ISSG) for the GHS alignment set up in 2008, which met on 23 October 2008, 16 September 2009 and 22 March 2010 and had a several informal contacts during the same period; and an Inter-service Co-ordination Group, established in February 2010, which has also served as the ISSG for the overall review, and met on 9 March 2010, 1 June 2010, 1 July 2010, and 26 July 2010. The ISSG reviewed the two impact assessment studies on which this report is based. The final draft of this report was sent on 16 July to the members of the ISSG for written comment and their comments taken into account. The ISSG was led by the Directorate-General Environment with the participation of DGs Climate Action, Employment, Energy, Enterprise and Industry, Health and Consumer Protection, Home Affairs, Joint Research Centre, Mobility and Transport, the Legal Service and the Secretariat General.

1.3. Expertise and information

As part of the preparatory work of the review process, and to support this impact assessment, several studies were carried out by external contractors. The studies are listed in Annex I (4)-(8). The review has also taken into account experience gained on implementation of the Directive since its adoption, and in particular the findings from the three-yearly reports from Member States on implementation of the Directive, the latest of which, for the period 2006-2008, has recently been published on DG ENV's website, at:
http://ec.europa.eu/environment/seveso/implementation.htm.

This report is mainly based on the information gathered in the context of this process. Wherever possible a quantitative assessment has been made of the economic, social and environmental impacts of the various policy options based on the studies and other inputs. Where such data, could not be obtained or is uncertain, the analysis of the policy options is more qualitative in line with the principle of a proportionate level of analysis. All cost and other data are based on those contained in the two impact assessment studies referred to in Annex I ((7) and (8)), conducted by COWI A/S.

1.4. Stakeholder consultation

During the review process, stakeholders (individual companies, industry associations, NGOs, Member State competent authorities) were consulted in a number of ways:

- Web-based questionnaires available for all stakeholders and selected follow-up interviews with a representative sample as part of the two studies assessing the effectiveness of the Directive referred to in Annex I ((4) and (5);
- Consultation of competent authorities in the Member States through the committee of competent authorities (CCA) at its regular six-monthly meetings, and related seminars;
- On the GHS alignment, via 6 meetings of a technical working group, comprising experts from Member States, industry and environmental NGOs; and
- A stakeholder consultation meeting held on 9 November 2009 in Brussels, attended by around 60 representatives from national and European industry and environmental NGOs as well as individual companies, following which around fifty written submissions were received.

(Further details can be found in Annex III and on DG ENV's website at http://ec.europa.eu/environment/seveso/review.htm).

In the light of the above, the stakeholder consultation in the review process has been carried out according to the Commission's general principles and minimum standards for consultation (9).

1.5. The Impact Assessment Board

This Impact Assessment was submitted to the Board on 23 August 2010 and discussed at the Board meeting of 22 September 2010. The Board submitted its opinion on 24 September 2010 proposing the following main changes to the assessment:

- strengthening the problem definition and providing a clearer explanation of current deficiencies in implementation

- providing a more transparent presentation of the practical implications of the options related to land-use planning and information to the public

- providing a more detailed analysis of costs and benefits of the proposed policy options, especially with regard to compliance costs and possible simplification benefits

- improving the overall readability of the document.

All these recommendations have been taken into account and relevant sections of the report revised accordingly.

2. PROBLEM DEFINITION

Policy Context/Background

Accidents often have serious, even devastating, consequences: workers are killed; the public is exposed to chemicals resulting in immediate injury or long-term health impacts; rivers and underground water sources are polluted, impacting drinking water; facilities and nearby developments suffer significant damage, sometimes resulting in closure of companies. Some well-known major accidents like Seveso, Bhopal, Schweizerhalle, Enschede, Toulouse and Buncefield have taken many lives and cost up to billions of euro. In the wake of these accidents, political awareness has sharpened towards recognising the risks and taking appropriate precautionary action to protect citizens and communities.

The Seveso legislation addresses accident prevention and preparedness and lessons learned from such accidents. The current Seveso II Directive was adopted in 1996 and amended by Directive 2003/105/EC (10). Its main objective is to prevent major accidents involving large quantities of dangerous substances (or mixtures thereof) as listed in its Annex I and to limit the consequences of such accidents for man and the environment. There is a tiered approach to the level of controls, with the larger the quantities of substances, the stricter the rules. The main requirements are that all operators falling under the Directive must notify their activities and establish a major accident prevention policy. In addition, operators of 'upper tier' establishments have to establish a safety report, and put in place a safety management system and an internal emergency plan. There are also obligations on public authorities relating to, inter alia, external emergency plans and public information on safety measures for upper-tier establishments, domino effects, land-use planning, accident reporting and inspections. Further background information is provided in Annex IV of this document. The frequency of major accidents has fallen by some 20% between 2000 and 2008[1]. This downward trend suggests that the Directive is meeting its objectives. Furthermore, the fact that the goal-setting Seveso approach has been copied worldwide attests to its success[2].

The Directive has to be amended due to changes in the EU system of classification of dangerous substances to which the Directive refers. In the light of this, and taking into account implementation reports from Member States that identified some deficiencies, it was decided to undertake a wider review since the basic structure of

[1] Trend of reported Seveso accidents in the last three reporting periods per 1000 establishments: 2000-02: >10, 03-05: ~9,: 06-08: ~ 8 (Seveso Implementation report 2006-2008).
[2] Examples: UNECE Convention on the Transboundary Effects of Industrial Accidents, UNEP Flexible Framework for addressing Chemical Accident Prevention and Preparedness

the Directive and its main requirements have remained essentially unchanged since its adoption. This review has focussed on the effective implementation of the Directive and on whether any improvements should be made in this regard. The review has shown that the Directive has been instrumental in reducing the likelihood and consequences of chemical accidents thereby leading to better protection of human health, the environment, and economic resources. It has also confirmed that overall the existing provisions are fit for purpose and that no major changes are required.

However, the review also confirmed that in a number of areas amendments would be appropriate in order to clarify and update certain provisions and to improve implementation and enforceability while maintaining or slightly increasing the level of protection for health and environment. This impact assessment focuses only on those elements of the existing Directive identified as warranting consideration for possible amendment and, in view of the above, mainly on the cost implications of such additional action.

In all the areas considered, action at Community level is needed to ensure that existing high levels of protection of human heath and the environment are maintained, to promote greater harmonisation in implementation and thereby avoid significantly different levels of protection in the Member States and possible distortions to competition that could result. The subsidiarity principle is respected since the aim is to continue the existing approach of laying down harmonised goals and objectives, but leave detailed practical implementation to be determined by Member States since this can be done more effectively at national level.

Industry, competent authorities and the public will potentially be affected. Seveso plants are evenly spread among Member States. Dangerous substances are widely used in many industries with the main sectors being chemicals manufacture, energy storage, and wholesale and retail storage (see Annex IV).

As regards SMEs, the Directive is targeted at establishments with a high major-accident hazard potential due to the large quantities of dangerous substances present. There is not necessarily a correlation between the quantities of dangerous substances present at an establishment and the size of the operator. However, storage sites are often SMEs as they are not labour-intensive. Any SMEs falling within the scope of the Directive have to adhere to the basic rules. However where possible due account has been taken of the need for implementation and control measures to be proportionate to risk, size and management structure, and this approach will be maintained in the new Directive.

The issues/problems that require actions

As noted above, the key issue that requires action is the alignment of Annex I to the new chemicals legislation and the impact on the scope of the Directive (policy issue 1). Related to that issue are possible other technical amendments to Annex I (policy issue 2) and the procedures for adapting Annex I in the future (policy issue 3). The remaining issues are less major. The most significant of these relate to information to the public and information management systems (policy issue 4) and land-use

planning (policy issue 5), where experience of implementation to date indicates that some opportunities for improvements or new requirements may exist. The other issue relates to relatively minor technical adaptations to a number of detailed provisions which could usefully be clarified or updated (policy issue 6). This is reflected in the level of analysis provided, with the assessment focussing mainly on the most important issues in terms of possible impacts.

2.1. Policy issue 1: Alignment of Annex I to CLP

The Directive has to be amended due to changes in the EU system of classification of dangerous substances.

The Directive has links and interactions with Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)(10) and Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) (11)[3].

In brief, REACH is the system at EU level for registering, evaluating and authorising dangerous substances and it provides, amongst other things, information about the properties of dangerous substances. CLP uses information from REACH to classify substances under various categories of hazard, implementing within the EU the internationally- accepted GHS (Globally Harmonized System for Classification and Labelling of Chemicals), developed at UN level. EU

The scope of the Seveso II Directive is defined by its Annex I listing substances (and mixtures thereof) and the relevant threshold quantities above which an establishment falls under the Directive. Part 1 of Annex I lists 'named substances'. Part 2 of Annex I lists 10 selected categories of hazard under the previous EU classification system as set out in Directives 67/548/EEC (Dangerous Substances Directive - DSD) and 1999/45/EC (Dangerous Preparations Directive - DPD), including the categories Very Toxic, Toxic, Oxidising, Explosive, Extremely Flammable, Highly Flammable, Flammable, Dangerous to the Environment, and further hazards. All substances falling within these hazard classification categories automatically fall within the SevesoII Directive's scope. This previous classification system will be repealed. The references will be repealed by the CLP Regulation, which entered into force 20 January 2009, and applies to all substances and mixtures on the EU market. Substances can already be classified under the new system as from 1 December 2010, but this does not become mandatory until 1 June 2015, when the CLP rules become definitive. In amendments to downstream legislation like the Seveso II Directive, references to the old system have to be replaced by that date. To guarantee a robust, consistent and sustainable approach, all relevant EU legislation will be converted to the new rules. Specific adjustments to other downstream legislation are also taking place, for example, by Directive 2008/112/EC (an omnibus directive on cosmetics, toys, VOC, solvents, some waste streams) and Regulation (EC) No 1336/2008 relating to detergents.

3 Many provisions of CLP are closely linked to provisions under Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). However, as CLP is the new classification system for all chemicals and all downstream legislation like Seveso and REACH, Seveso will only refer to CLP and not to REACH.

In the future, as REACH will keep generating new information about substances, additional substances may be classified under CLP, which would in turn automatically affect the scope of the Directive.

The issue is therefore to replace the old hazard classification categories by 1 June 2015 by the new CLP categories. As explained above, it would be unworkable and make no sense to continue to refer to the old system once it no longer exists.

A change to the new system can not simply be done by an automatic change of reference to the new system. A downstream legislation study (12), accompanying the impact assessment for the CLP Regulation confirmed this. As a result, the Commission concluded already in its proposal (13) for the CLP Regulation that for the Seveso II Directive no simple one-to one "translation" from the old to the new categories is possible and that the CLP Regulation will have a substantial impact. Therefore, necessary measures would have to be tailor-made and introduced in a separate amendment to the Directive. Against this background, "do-nothing" is not a valid option and will not be pursued further.

2.2. Policy issue 2: Other technical amendments to Annex I

The Annex I review presents an opportunity to consider whether other amendments to its scope are necessary. The first driver for such amendments is lessons learned from past accidents. The review process has not identified the need to modify Annex I due to accidents with specific substances. The second driver is to adapt the scope due to technical progress, especially concerning new technologies, new energy carriers, emerging risks, - and also whether specific categories or substances are appropriately covered by the scope of Seveso. The following issues have been identified: Carbon dioxide ($CO_{2,}$), on which there were concerns from some competent authorities about possible emerging risks in the filed of carbon capture and storage; hydrogen (H_2), on which industry expressed concern about the impact of the Directive on possible developments in the use of the substance as a major energy carrier, and three substances/products concerned by CLP re-classification, namely heavy fuel oil, aerosols and sodium hypochlorite.

2.3. Policy issue 3: Procedures for adapting Annex I in the future

This issue is linked to policy issue 1. It is difficult to judge with certainty at this stage what will be the impacts of the initial alignment of Annex I, and in particular its automatic adaptation to future changes in classifications of substances and mixtures over time in the future as the CLP is gradually applied. This could lead to substances and possibly mixtures, due to their complex classification under CLP, being inappropriately included or excluded from the Directive irrespective of whether or not they present a major-accident hazard.

The only correction mechanism under the present Directive is very limited. Member States may grant a lowering of the safety report information requirements for upper-tier establishments when it can be demonstrated, on the basis of harmonised EU criteria (as laid down in Commission Decision 98/433/EC(14)), that the substance does not present a major-accident hazard. This derogation provision, which is little used, is inadequate as a means to deal with the situation at EU level when it can be shown that a substance does not have any major-accident hazard potential and

therefore should not be included within the scope of the Directive. There is no counterpart provision such as a safeguard clause to deal with substances that, notwithstanding their hazard classification, should be included in Annex I because they have a major accident hazard potential.

Furthermore the current procedure for amendments to Annex I, which have to be adopted via the normal legislative procedure (co-decision), does not facilitate the necessary adaptations to deal with these kinds of situation.

2.4. Policy issue 4: Information to the public and information management systems, including reporting

The Directive's current requirements in this area are summarised in Annex V of this report. It is important that the public is informed about major accident issues. The public has a right to such information (subject to appropriate confidentiality safeguards); and information about specific sites is very important for increasing awareness and ability to respond appropriately should an accident take place. The Directive requires that that information is both actively made available to affected members of the public without their having to request it and also kept permanently available for the public. It is silent on what form of communication is used and whether it is the operator or the competent authority responsible.

The latest three-yearly implementation reports from Member States indicate that there are uneven implementation and practices across Member States relating to the provision and use of information to potentially affected groups as well as the public more generally. Overall, during the period 2004 to 2008 the public received information for about only around 80% of establishments and it is unclear how frequently this was done. The two studies assessing the effectiveness of the Directive confirmed the shortcomings in performance and noted that there are information gaps (for example as regards external emergency plans) and a lack of monitoring that the information is being supplied. Furthermore the provisions pre-date and are not in line with Directives 2003/4/EC and 2003/35/EC implementing the Aarhus Convention. Member State reporting about Seveso plants and major accidents are also relevant in this context as these also contain information of interest to the public. At the same time there is a need to take into account the Directive's provisions as regards the confidentiality of such information, including intellectual property rights, and ensuring that this information will not facilitate possible terrorist attacks. Furthermore there is also the issue of whether more non-technical information would be helpful. For example, there is broad agreement that the safety report is not a very suitable way of informing the public; a non-technical summary in layperson's terms might be more appropriate.

In the light of the continued advances in information management systems and procedures such as the Internet, which enable frequent updating of information, there is also a need to consider how management of the information can be improved to ensure that the necessary information is made /kept available to the public.

Overall, most Member States operate databases for internal use in the relevant competent authorities. These databases might include site-specific information from the operator, but generally there is limited or no public access. Moreover these databases generally do not contain the safety information that has to be made

available to the public pursuant to Annex V of the Directive, since in most Member States responsibility for informing the public lies with the operator. There is thus a potential gap in collecting such information and ensuring that it is made available to the public.

All this suggests that there is a need to improve both the level and quality of the information provided to the public, but also the way information is managed so that it can be made available in an efficient and streamlined way.

2.5. Policy issue 5: Land-use planning

Article 12 of the Directive provides that Member States shall control the siting of new establishments, modifications to existing establishments and new developments in the vicinity of existing Seveso sites where this could increase the risk or consequences of a major accident.

Experience to date indicates that the current provisions are working satisfactorily, although the number of cases where the provisions take effect are limited. However although the existing provisions appear to be effective and are being properly implemented, they do not make it clear that they apply to both upper- and lower-tier establishments and lack any clear reference to the need to protect the environment, which could potentially give rise to some inconsistencies in implementation. In addition, there is a risk that in some cases the land use planning procedures under Article 12 may overlap with those under the EIA and SEA Directives.

Furthermore, although there have been no calls for major changes to the Directive in this regard, since the current provisions (controls on inappropriate land use, in particular controlling the siting of new establishments and ensuring in the long-term appropriate safety distances) have remained unchanged for a long time, it seems appropriate to consider whether the time is ripe to extend the requirements. For example,, the issue of existing establishments that are already situated in the immediate vicinity of residential areas and other areas frequented by the public, which is being addressed at national level by some Member States, is not covered at present.

2.6. Policy issue 6: Other areas where implementation could be improved

The various issues can be grouped under two broad headings: the need for closer integration of information and procedural requirements; and the need to update or clarify certain provisions to facilitate implementation and enforceability.

A) Closer coordination, Integration of information and procedures, etc

The review process identified some concerns about shortcomings in coordination between authorities, both within and between Member States that can lead to inconsistent implementation, conflicting or overlapping requirements and unnecessary administrative burdens for operators. Specific areas identified include inspections under the Directive and under other legislation; and possibly overlapping information and procedural requirements with other legislation applicable to Seveso establishments. There was widespread recognition of the value of existing activities undertaken to promote more consistent implementation of the Directive. There was

strong support for these to be maintained and further developed, such as support for inspections through exchanges of information and best practices, and cooperation between the Commission and Member States on implementation issues, including where appropriate, the development of further guidance. Further details on these issues are set out in Annex VI.

B) Other areas where improvements are needed

The review also identified a number of areas where the existing provisions lack the necessary clarity or precision to ensure greater consistency in implementation and its effectiveness. The issues include: the lack of any reference to the use of safety performance indicators; the need to take into account non-Seveso establishments in the context of domino effects; the need to clarify that underground gas storage sites fall within the Directive's scope; the need for clearer references to environmental aspects in the detailed provisions given that the aims of the Directive include protection of the environment; possible delays in the completion of external emergency plans due to the lack of any clear deadline; and, as regards the reporting of accidents, the threshold for reporting results in potentially important accidents going unreported and possible delays in reporting due to the lack of any specific deadline. The provisions in relation to safety management requirements for lower-tier establishments (and in particular the relationship between an operator's major-accident prevention policy and safety management systems) are also unclear, leading to widely differing approaches in the Member States. Further details on these issues can also be found in Annex VI.

3. OBJECTIVES

The overall aim remains the prevention of major accidents and mitigation of their consequences by maintaining and further improving existing levels of protection for human health and the environment. In line with the Commission's strategic objectives and better regulation principles, this should be achieved by improving the regulatory provisions to make them more effective and efficient, and where possible reducing unnecessary administrative burdens for Member States and industry. At the same time the Directive should be clear, coherent and easy to understand to help increase consistency of implementation.

In order to achieve the general objectives and address the different issues and problems described above, the following **specific objectives** have been identified:

- The main aim is to align Annex I to the CLP while maintaining existing levels of protection.
- The other aims are to clarify certain provisions to improve implementation and enforceability, while maintaining the existing hazards-based two-tier approach of the Directive and its goal-setting nature. Other provisions should be updated to take account of technological and regulatory developments since the current Directive's adoption.
- Where possible requirements should be streamlined or simplified to reduce the administrative burden for operators and competent authorities without compromising safety.

4. POLICY OPTIONS

A detailed description of the options examined is included in Annex II. With the exception of policy issue 1, the baseline scenario is business as usual, i.e. no changes to the Directive's existing provisions.

4.1. Policy issue 1: Alignment of Annex I to the CLP

The alignment to the CLP is straightforward for all categories of hazard (see Annex VII) except for toxicity. The options considered therefore only differ in the way they address toxicity.

CLP aligned legislation must refer to the new categories **Acute Toxic 1', 'Acute Toxic 2'** and **'Acute Toxic 3' ,** but these do not completely correspond to the old categories '**toxic '(T)** and '**very toxic' (T+)** which have different cut-off values for lethal doses. This implies changes in classification that could significantly increase or decrease the Directive's scope. Moreover the effects are further complicated because the new toxicity categories are divided into the three exposure routes: oral, dermal and inhalation, and the classification of individual substances in accordance with this differentiation is often not known.

In line with the objective of this alignment exercise, options with high impact on the scope or complexity of the directive were discarded at an early stage (See Annex II). In particular the individual screening of each substance, option A, would be complicated to implement, both for business and for authorities, and option B would strongly reduce the scope.

As the new category **'Acute Toxic 1'** is included in '**very toxic' (T+)** and **'Acute Toxic 2'** is mainly included in the old category '**toxic '(T),** the difference between the options considered is for which exposure routes the old category '**toxic '(T)** is aligned to **'Acute Toxic 3'**:

Option	Where marked by "X" old category 'Toxic '(T) is aligned to new category 'Acute Toxic 3'				
	Oral	Dermal	Inhalation		
			Vapour	Aerosol	Gas
C	**X**			**X**	**X**
D	**X**	**X**	**X**	**X**	**X**
E			**X**	**X**	**X**
E*		**X**	**X**	**X**	**X**

Whichever alignment option is chosen, there is a degree of uncertainty of the impact over time. The baseline will move in the future because as REACH generates new

information in a dynamic way, additional substances may be classified under CLP and thus automatically fall within the scope of the Directive. Potential correction measures are therefore necessary and are addressed in Policy issue 3.

4.2. Policy issue 2: Other technical amendments to Annex I

The policy options presented below deal with different issues where adaptation of the scope to technical progress may be appropriate, with alternative options as indicated. The first issue arose in the context of CCS (Carbon Capture and Storage) technologies, the second about energy carriers and the last three relate to the first examples of specific substances/products directly affected by the new classification system.

- Possible inclusion of CO_2: This option has been discarded given the early stage of development of Carbon Capture and Storage technologies and that further experience is needed to better understand any potential risks. At the same time, Directive 2009/31/EC on the geological storage of CO_2 establishes a legal framework for the environmentally safe geological storage of CO_2.
- Hydrogen: a) do nothing (retain in the list of named substances requiring individual treatment with thresholds of 5/50 tonnes for lower/upper-tier establishments); or b) grant an alleviation by doubling the lower-tier threshold and classifying the substance according to its flammability)
- Heavy fuel oil: a) do nothing (accept effect of possible re-classification as toxic to the aquatic environment with thresholds of 200/500 tonnes (); or b) avoid the possible effect by giving an exemption as for other petroleum products by including it in the list of named substances with thresholds of 2500/25000 tonnes.
- Flammable Aerosols: a) CLP approximation proposal of 150/500 tons thresholds to cover approximately existing sites; or b) higher thresholds of 1300/5200 tonnes
- Sodium hypochlorite: a) do nothing (CLP for mixtures will apply, with thresholds of 100/200 tonnes); or b) exemptions (named substance with increased thresholds 200/500 tonnes or a derogation for packaged products in limited quantities (inner pack up to 5 litres and combination pack up to 30kg).

4.3. Policy issue 3: Procedures for adapting Annex I in the future

The uncertainties caused by the new classification system suggest a need for flexible tools to be able to adapt Annex I as necessary via delegated acts. A precondition for using such tools would be to have clear criteria. The basic act would include the general criteria with detailed harmonised criteria to be adopted by the Commission through delegated acts. The latter would be developed in parallel to the legislative procedure in order to be ready for adoption immediately after the entry into force of the new directive. This would thus allow ample time for adopting derogation decisions before 1 June 2015, when CLP rules become definitive.

Options:

(a) Do nothing. Any amendments to Annex I would continue to be via an amendment to the Directive adopted by ordinary legislative procedure. The existing derogation rule, allowing Member States to grant establishment-specific exemptions to upper-tier establishments based on the existing harmonised criteria limited to information

requirements related to safety reports for upper-tier establishments, would be left unchanged.

(b) Extend the scope of the existing derogation rule based on the current harmonised criteria laid down in Commission Decision 98/433/EC to allow Member States to grant establishment-specific exemptions to upper-tier establishments covering requirements such as those relating to safety reports, emergency plans and information to the public.

(c) Allow EU-wide substance derogations from some or all Seveso requirements using harmonised criteria by further developing the existing harmonised criteria such as points 1 (criterion: physical form, properties) and 4 (criterion: classification) . The derogations, by delegated acts, could take the form of reduced requirements or complete exemption.

(d): General establishment-specific derogations at Member State level using harmonised criteria based on points 2 (criterion: containment and quantities) and 3 (criterion: location and quantities) of the existing harmonised criteria. The derogation would apply to all qualifying establishments and could take the form of reduced requirements or complete exemption.

(e) Introduce a 'Safeguard clause' as counterpart to options c) and d), to deal with situations such as those where, notwithstanding their falling outside the Directive's scope due classification under CLP rules, a substance presents a major accident hazard potential and should be covered.

4.4. Policy issue 4: Information to the public and information management systems including reporting

These policy options address possible improvements as to how information of better quality can be made available more efficiently and effectively to the public.

A) Options for type of information provided

(a) Unchanged policy. The information would be as currently required by Annex V of the Directive. The means by which the information is made available, and whether it is the operator or the competent authority responsible, would remain a matter for the Member States.

(b) Annex V information made available on-line.(c) Annex V information plus additional information for all establishments made available online as follows:

- for all establishments: basic information about each establishment (name, address and information about its activities);

- for upper-tier establishments, a summary of the main major accident scenarios and key information from the external emergency plan in case of an accident.

(d) Option (c) plus non-technical summaries of the safety report and external emergency plan made available online.

B) Options for information management

(a) Unchanged policy. Existing arrangements would continue with Member States deciding whether they operate databases and whether they allow public access.

(b) Member States databases. Member States would be required to operate databases with public access to Annex V information. Most Member States already operate something similar though there might not be public access to information about individual sites.

(c) Central EU-wide database with links to Member States websites. A simple website with links to documents either directly uploaded onto an adapted version of the database managed by the Commission for the purposes of Article 19.1a of the Directive (SPIRS) or links to Member States' websites with the information/documents.

(d) Central EU database, fully integrated.

4.5. Policy issue 5: Land-use planning

The policy options are as follows:

(a) Unchanged policy. The current system would be retained with no changes.

(b) Minor modifications to Article 12 to clarify that the requirements apply to both upper- and lower-tier establishments and are aimed at the protection of both man and environment (which currently is not expressly mentioned), including taking into account areas of particular natural sensitivity; and to make reference to procedures under the Environmental Impact Assessment Directive and similar legislation.

(c) Extension of provisions in full to all upper-tier plants, including existing plants.

4.6. Policy issue 6: clarifications to facilitate effective implementation

The overall aim is to facilitate effective implementation and enforceability and at the same time where possible to introduce streamlining and simplification to reduce administrative burdens. The option components, which are explained in Annex VI, fall under the following headings:

A) Closer Coordination/integration (inspections, etc.) and
B) Other areas where improvements are needed (clarifications, use of safety performance indicators, Safety Management System required or not for Lower Tier Sites)

5. ANALYSIS OF IMPACTS

Most affected by all impacts assessed will be the operators of Seveso plants, but also competent authorities. SMEs represent a significant percentage of operators and are

much more sensitive to cost impacts. Especially for micro-enterprises, for example for storage or surface treatment sites, or for sites with variable inventories, costs represent a much higher impact than for large companies (see also section 6.8 and Annex VIII).

Policy issues 1 to 3 have an impact on the scope, meaning that companies would have to comply newly with the provisions of the Directive, or that Seveso establishments would not any more be subject to the Directive. The key indicator to assess this impact on scope is the change in the number of establishments.

This and other impacts are predominantly presented as yearly costs for industry and authorities. The basic cost assumptions and limitations on which this analysis is based are set out in Annex VIII. It should be noted that, unless indicated otherwise, the estimated costs relate to net additional administrative costs for industry and authorities. It is not possible to quantify costs related to physical compliance measures for establishments that will be directly affected by changes to the scope of the Directive (this is discussed in further detail in section 5.1.4, relating to policy issue 1, which is main issue where the question is relevant). The impact estimates are limited to impacts arising from the Directive only. It would be disproportionate to extend the analysis to any stricter requirements in Member States.

Social impacts in terms of human health and employment are also assessed, but in a qualitative way (in the absence of data, it is not possible to quantify the impact on employment levels (see also section 6.9)). Where possible, the expected benefits of the options in terms of simplification and reduction in administrative costs are also assessed in a qualitative way (see also section 6.10).

5.1. Policy issue 1: Alignment of Annex I to the CLP

5.1.1. CLP adjustment

Whatever option is chosen, all Seveso operators have to review their inventories in the light of the new Annex I and provide information about the CLP adjusted substances, mixtures or categories to the authorities. For all Seveso establishments and for all hazards, the total one-off Seveso-related CLP adjustment costs for reviewing inventories have been estimated for operators at around 1.7 Million EUR (7.6 Million annualised over 5 years at 4%), which represents an average of around 200 EUR per establishment, per year. In addition to the costs for industry, the adjustment costs for authorities would be around 400.000 EUR per year (1.8 Million over 5 years).

To put these costs in context, the administrative costs of the Seveso II Directive for industry have been estimated by the administrative burdens study to be about EUR 52 million per year. The second COWI impact assessment study has estimated the total administrative costs to both industry and authorities to be at least of the order of 100 million EUR.

5.1.2. Mixtures

The CLP Regulation changes rules for the classification of mixtures in comparison to the current rules for preparations under the Dangerous Preparations Directive (DPD)

199/45/EC to which Seveso refers. In 2006, the CLP Impact Assessment on downstream legislation (12) mentioned concerns that combining the CLP mixture approach with the Seveso volume-based approach might lead to a significant increase in the scope of the Seveso Directive.

A study conducted by the UK HSE, and discussed by the multi-stakeholder Technical Working Group, gave examples of both increases and decreases in scope and concluded that the CLP mixture classification procedure would in practice not result in an increase in scope of Seveso, but rather may potentially reduce the scope of Seveso for some establishments. However, as for the whole issue of alignment to the CLP Regulation, there remains some uncertainty concerning mixtures so unwanted effects cannot be excluded. This confirms the need for flexibility tools as considered under issue 3.

5.1.3. Costs and benefits of Option (C) to (E):*

For the reasons already stated, an unchanged policy "0" is not a valid option.

The necessary switch to the new system with different Acute Toxicity Categories makes it inevitable that additional substances would be included within the Directive's scope or excluded. Depending on the choice of option this could lead to more or fewer establishments covered.

The data sources, the methodology and assumptions for estimating the number of possibly affected establishments, based on the classification of toxic substances, are explained in Annex VII. A more detailed assessment, including a list of substances potentially affected and figures for lower tier and upper tier sites, is included in the final report of the impact assessment study.

The main question under the options (C) to (E*) is how many establishments will no longer fall under the Directive, and how many will be newly included within the scope. Firstly, for all options the old 'Very Toxic' category has been aligned to 'Acute Toxic 1'. This leads for all options to a reduction estimated at 314 sites as (1) some substances currently captured by 'Very Toxic' will not be captured by 'Acute Toxic 1' and therefore the inventory of these sites falls under the Seveso Threshold for 'Acute Toxic 1' (5 tonnes), and (2) the inventory of these sites for 'Acute Toxic 1' and 'Acute Toxic 2' does not increase sufficiently to reach the applicable Seveso Threshold (50 tonnes). Secondly, the options differ concerning the alignment from 'Toxic' to 'Acute Toxic 2 and 3 ' between -91 and +342 sites. In detail, the impact of the options C to E* on the number of Seveso establishments, is as follows:

Option	Change of number of establishments				
	a) T+ alignment	b) T alignment excluded sites	b) T alignment newly included sites	Net-effect	% Change of establishments
C	*-314*	-10	+131	-193	-2%
D	*-314*	-	+342	+28	+0.3%
E	*-314*	-101	+10	-405	-4.2%
E*	*-314*	-91	+221	-184	-1.9%

Overall, the impact is quite limited. Although all options are intended to be close to the current scope, the number of establishments affected by the change in classification system replacement ranges from a minimum of around 400 to a maximum of 650 firms. A maximum of 350 new sites could be covered, and around 400 could fall out of scope.

The cost analysis has identified two different types of costs building upon information presented in Annex VIII, as follows:

(1) For establishments affected by the alignment options, the annual administrative adaptation costs range between around 1.7 Million EUR to 2.9 Million EUR (for more differentiated exposure routes, as in option C).

(2) Costs (or savings) related directly to the change in number of establishments falling within the scope range from savings varying between 2.5 and 3.3 Million EUR, to costs for new sites varying between 0.2 and 5.7 Million EUR.

These alignment option-related administrative costs for industry are summarised below (for more information and explanation on costs see Annex VIII):

Option	General adaptation (1)	Change in scope costs (2)		
		a) T+ alignment	b) T alignment excluded sites	b) T alignment newly included sites
C	2.9	-2.5	-0.1	+2.2
D	1.7	-2.5	-	+5.7
E	2	-2.5	-0.8	+0.2
E*	2	-2.5	-0.8	+3.7

The above figures take into account that the cost savings for an establishment falling outside the scope of the Directive will be lower and not offset the additional costs for a new establishment since the former will have already incurred costs.

The change of scope will also have related cost impacts for authorities and are assumed to be around 10% of the costs to industry.

5.1.4. Non-administrative compliance costs

It is very difficult to estimate non-administrative compliance costs for establishments that would fall under the Directive. The Directive is goal-setting in nature establishing a process for operators to demonstrate safety, mainly through various information obligations. These entail administrative costs. There are no specific requirements in relation to physical measures to be taken. These are a matter for Member States to determine in order to ensure that all necessary measures have been taken to prevent accidents.

Such physical compliance costs are site- or substance- specific and are expected to be significantly impacted by other legislation such as that on worker protection, product safety, industrial emissions, etc. They will also depend on the policy approach in each Member State.

The types of investment needed in physical measures could include equipment to monitor processes and facilities; storage capacity and containment infrastructure. A responsible operator would normally be making such investments anyway as part of their normal business activity. In doing so, they will also consider the risk of accidents and the costs of these (production losses, clean-up costs, compensation costs, etc). Whether they alter their behaviour, for example by switching to safer chemicals, reducing stocks to fall out of scope, relocation outside EU, etc, will depend on the costs of such changes of behaviour compared with the costs of compliance and how these impact on the overall costs of doing business.

See Annex VIII for further details.

5.1.5. Other impacts

Options C, E and E* all lead to a decrease in scope which could lead to a small decrease in protection levels for human health and the environment. Option D could lead to a slight increase. This could include a positive impact on worker protection. There could also be an effect on employment levels in line with the low economic effects of the option arising from the slight increase in the Directive's scope. However it is difficult to quantify these. Option E* would maintain a high level of protection taking into account the most likely and relevant exposure routes in the event of a major accident.

As regards simplification, the decrease in scope arising from options C, E and E* would lead to a reduction in administrative costs, but they would be complicated to apply in practice. D would be clear and simple to apply, which could offset some of the additional administrative costs arising from the increase in scope (see also comparison of the options in section 6.1).

5.2. Policy issue 2: Other technical amendments to Annex I

An impact assessment on options addressing the following issues has been carried out: hydrogen, heavy fuel oil, aerosols, and sodium hypochlorite. Only the costs and benefits of options that represent possible changes are included.

Hydrogen

The options for this component are either to keep the existing situation with hydrogen as a named substance with 5/50 tonnes as thresholds or to delete it and leave it covered by the generic classification for extremely flammable gas with 10/50 tonnes as thresholds.

It appears that currently there are only seven installations in the EU that employ hydrogen as an energy carrier and have inventories that exceed the existing Seveso threshold quantities. There are also a number of small-scale demonstration projects with modest capacities. The largest of hydrogen compressed gas customers have maximum inventories of about 800 kg.

An increase of the lower-tier threshold from five to ten tonnes would have little or no impact on existing industrial establishments.

If hydrogen were to become a major energy carrier for transport systems and a network of filling stations established, it is essential that safety is dealt with in a standardised way similar to the existing situation with petrol stations, considering the specific hazards of this gas and the rich accident history of hydrogen. It is a question whether the option of deleting hydrogen as a named substance, so that the lower threshold is increased from 5 to 10 tonnes, would be sufficient to cover future quantities at filling stations.

Choosing either option will have limited short term impact; increasing the threshold to 10 tonnes would at least postpone the need for further adjustments as the H_2 economy develops.

Heavy fuel oil

The impact of the no-change option (assuming heavy fuel oil were to be classified as Chronic Aquatic Toxicity 2 under CLP (classified as 'toxic to the aquatic environment according to DSD), would bring heavy fuel oil into Annex I Part 2 of Seveso with thresholds of 200/500 tonnes. The exact impact in terms of extension of scope could not be estimated, but it is likely that this may lead to the inclusion of some large energy - intensive establishments such as power plants and cement producers currently not yet covered. If heavy fuel oil were to be included within the named substances listed in Annex I under the category 'petroleum products', with thresholds of 2500/25000 tonnes, there would very likely be no or nearly no impact as these thresholds are above the amounts present in most storage sites.

Aerosols

Flammable aerosols are a new CLP category. Currently aerosols are classified for Seveso purposes based on their properties and quantities of their flammable components and subject to those thresholds. The estimated number of aerosol sites covered by Seveso is around 200 warehouses.

The option assessed is the setting of appropriate thresholds for the new aerosols categories capturing the sites currently covered by the Seveso Directive, i.e. 150/500 tonnes for aerosols containing flammable gases and 5,000/50,000 tonnes for aerosols not containing flammable gases. The impact on the scope of the thresholds proposed by the multi-stakeholder Technical Working Group is unclear. A check of the thresholds by France confirmed their proportionality indicating a slight reduction of establishments in this Member State The analysis of this proposal for the EU suggests that potentially 20-40 new sites could come under the Directive, which could amount to annual costs of around EUR 0.5 million for those sites.

The industry has raised the question whether aerosols, due to their specific characteristics and packaging, need to be covered or whether establishments with aerosols present should be excluded, for example by setting higher thresholds to 1300/5200 (and 5000/50000). This would imply that the +/- 200 establishments would be excluded from the Seveso Directive resulting in cost savings of the order of EUR 3-4 million annually for the affected industries.

In this context it is noted that aerosols have to comply with the Aerosol Dispenser Directive (Council Directive 75/324/EEC) and the Pressure Equipment Directive (Directive 97/23/EC) as amended. This is especially important given the treatment of stored and packaged consignments of aerosols in large lots of dispensers and pressure equipment in wholesale and retail storage and distribution.

Sodium hypochlorite

Sodium hypochlorite, frequently used in several Member States as a mixture (bleach), has been reclassified by the CLP as toxic to the environment without the past concentration exemption of 25%. An industry survey has estimated that up to about 200 or more sites, including warehouses, could consequently be caught by the current Seveso Directive, of which a significant number could be SMEs. It is estimated that the economic impact would be around 3.8 Million EUR (3.5 Million EUR for industry, 0.35 Million EUR for authorities see details in Annex VIII). The alternative to avoid the inclusion of such sites by this immediate CLP re-classification effect would be to grant exemptions by including sodium hypochlorite in the list of named substances, with higher thresholds, or to grant derogations for packaged products. The trade-off is therefore whether the inclusion of the additional sites results in improvement to the protection level that justifies the costs.

Strictly speaking, the inclusion of sodium hypochlorite already under the current Directive is not an issue arising from the CLP alignment of Annex I itself. It is one example where a reclassification under CLP has a significant impact in a Seveso context. However this case raises the question whether the Directive should have a mechanism to mitigate undesired reclassification effects, especially for mixtures. As note above, one option (also for future similar cases in the future) could be to exempt the substance/mixture by including it as a named substance with high thresholds or to give an exemption for packages in small quantities.

Other impacts

The impact of the different options on protection levels for human health (both for workers and the public) and the environment will vary according to whether or not these lead to an increase or decrease in scope. Likewise, the impact on employment levels will also vary. Options leading to a decrease in scope would contribute towards simplification to the extent that there would be reductions in administrative costs.

5.3. Policy issue 3: Procedures for adapting Annex I in the future

The main costs and benefits of the options are as follows (Annex IX provides further details).

Option (a) (Unchanged policy; the baseline) could lead to new substances being included in scope which present no major accident hazard. Given the limited scope of the existing derogation rule (see below), this could result in significant additional costs, although it is difficult to quantify these. Assuming the number of new establishments falling into scope represented a 5% increase in the total number of establishments, the total annual costs would be around 8 million EUR for industry (plus 800,000 EUR for competent authorities).

Amendments to Annex I would continue to be via co-decision, which could entail significant administrative costs for Member States, the Commission and the co-legislators. In cases where a substance should be added to Annex I, the protection level (environmental, health and social) could be adversely affected due to the length of time needed for possible amendments to the Annex I to be adopted.

Option (b) (Extending the scope of the existing derogation rule) would lead to increased costs for industry and competent authorities in dealing with derogation requests, but it is difficult to quantify these. The benefits in terms of savings for operators would depend on how far the scope of the derogation was extended beyond information requirements in relation to the safety report, but would be less than options (c) and (d). There would be no change in protection levels.

There would need to be strict adherence to the harmonised criteria in order to ensure that operators are treated equitably so that there is no risk of possible distortions to competition.

As regards option (c) (general derogation rule at EU level), the costs would be the administrative costs for industry, the competent authorities and the Commission in dealing with derogation requests. It is estimated that that these would be about 300,000 EUR per annum. However such costs could be more than offset by the benefits in terms of savings from any derogations that resulted in establishments being exempted. There would be no change in protection levels.

For option (d) (establishment-specific derogations at Member State level) the potential costs and benefits would be potentially greater than for option (b), but are difficult to estimate. It would allow greater flexibility in the application of the Directive at Member State level but the risks of possible distortion to competition would also be greater so there would need to be close monitoring to ensure that the criteria were being respected.

As regards option (e) (safeguard clause), the impacts would depend on how often such a clause is used. If and when used, the benefit will be an increased protection level for human health and the environment. The costs will be the compliance and administrative costs for industry and the competent authority.

The benefits of using delegated acts to effect changes to Annex I from application of options (c) and (e) would be increased speed, flexibility and efficiency in amending Annex I. The administrative cost would be relatively limited since the task would be taken up by the Commission using existing consultation procedures. The protection level would remain the same or slightly increase.

Other impacts

This package of correction mechanisms will mitigate the effects of the Annex I alignment (policy issue 1, also to some extent policy issue 2) without jeopardising protection levels for human health (both for workers and the public) and the environment. The derogation possibilities in particular will also mitigate any effects on employment.

The package will also lead to savings in administrative costs and simplification in terms of speedier and efficient decision-making through the use of delegated acts to amend Annex I.

5.4. Policy issue 4: Information to the public and information management systems including reporting

The costs and benefits of the various options are as follows (see Annex X for more details).

A) Options for type of information provided

The baseline or unchanged policy option (a) would impose no additional costs on operators or public authorities and bring no improvements in information provision. Indeed current deficiencies in implementation would remain, resulting in different levels of protection across Member States, which could result in the public's 'right to know' being ignored, and in particular those that could be affected by accidents failing to be aware of what action to take in the event of a disaster.

As regards option (b) (Annex V information made available on line) since all Member States can be assumed to have governmental websites where this information could be placed, and the information should be produced already, there should be no significant additional costs to competent authorities or operators. For authorities, it is estimated that the total one-off costs would be about 1 million EUR. Maintenance costs would be limited.

The benefit of this option would be that it would be easier for the public to access the information and easier for each competent authority to monitor that it is actually available and up to date.

Option (c) would extend the Annex V requirement in two ways. Firstly, basic data for all establishments would be included. Secondly, for all upper-tier establishments, information would be included about the main type of major accident scenarios as well as appropriate information from the external emergency plan.

The former would not entail any significant additional costs since this information is produced already and submitted to the Commission. For the latter, operators of upper-tier establishments already have to provide details of major accident scenarios in their safety reports that they are required to submit to the competent authorities; and competent authorities are already required to draw up an external emergency plan. It is estimated that the new requirements would result in total one-off costs of 2-4 million EUR. The annual costs of updating the information would be about 0.5 million EUR.

In addition to the benefits of option (b), this option would ensure that some clear basic information about the nature of the accidents hazards and information on how to behave in case of an accident is provided. This is likely to facilitate a more adequate response in case of a major accident taking place and thereby reduce the impacts of such accidents. It could also help operators and competent authorities draw lessons from the best practices of others.

Option (d) would add to option (c) by requiring also addition non-technical summaries of the key documents, the safety report and the external emergency plans, to be made publicly available. As noted in (c) above the full documents already have to be produced by the operator and competent authority respectively so the only new requirement would be to summarise these for public use.

It is estimated that the total one-off costs for all upper-tier establishments could of the order of EUR 20 million (of which EUR 3 to 4 million would be costs for competent authorities) assuming that no such documents are currently produced. On the assumption that the information would need to be updated every three years, the average total annual costs of updating the material would be around EUR 2-5 million.

The additional benefit of this option is that more detailed information from the non-technical summaries will further increase the population's awareness of the possible risk scenarios and the need to understand and follow the advice included in the emergency plans. Furthermore, it will generally inform the interested public about major accident potential issues.

Other impacts

Options (b) to (d) would not preclude other methods of making the information available or impact on the operator's role and responsibilities.

There would be positive impacts on protection levels for human health (both for workers and the public) and the environment. The impact on employment levels will also vary in line with the economic impact but should not be significant. Over time the use of the internet will lead to streamlining and simplification in making information available and keeping it updated.

There could also be costs arising from security and other confidentiality concerns. Article 20 of the Directive (which will need to be brought into line with Directive 2003/4/EC on public access to environmental information) provides a safeguard mechanism. Defining in each case where the balance lies between transparency and confidentiality could potentially increase costs, particularly for competent authorities. It is very difficult to estimate these costs as it depends on how many establishments there are where confidentially and/or security issues are significant. Moreover these costs are not necessarily additional costs as Member Status should already be making such assessments.

B) Options for information management

Option (a), the baseline, would maintain the status quo, with the generally fairly limited on-line systems. It thus imposes no additional costs on operators or public authorities and brings no improvements.

Option (b) (Member State databases) would require all Member State to have a system that allows public access to relevant information for each establishment. Since this would require only a simple website structure and uploading relevant documents and information for each establishment, this should not entail significant

resources. It is estimated that the total one-off costs would be about 1 million EUR. Maintenance costs would be limited.

The benefit of this option would be that it would facilitate the online availability of options (b) to (d) in part A) above in relation to the type of information to be made publicly available. Having to upload information for each establishment will make it easier for Member States to monitor that this information (which is required to be publicly available) actually exists and is available. In principle it should therefore help to reduce enforcement costs once the system is in place, though this benefit can not be quantified.

Option (c) would establish a central EU website that can be used to access information in all Member States either through links to documents directly uploaded on to it or links to Member State websites/databases.

Such a central database would not be very costly as it would use existing IT infrastructure and existing databases. If links or documents need to be made/uploaded for all establishments the total set-up costs would be around 0.5 to one million EUR. The operation and maintenance costs would be about 50,000 to 100,000 EUR per year.

In addition to the benefits of option (b), this option has the added benefit that it will make sharing of relevant information more efficient. Not only will it provide easier public access to the information, it will also support the competent authorities in their activities.

As regards option (d), this would be a centralised EU database with all information integrated within it. This would be a more resource intensive solution and would necessitate Member States adapting their existing systems.

The specific costs of such an approach cannot be estimated without a detailed analysis of the system requirements, but are likely to be very substantial.

The benefits of this option would be the same as option (c).

Other impacts

Modalities for putting the information online on Member States' databases (integrated database at national level, or links to operators' websites, etc) would be a matter for Member States.

For options (b) to (d) there would be positive impacts on protection levels for human health (both for workers and the public) and the environment. Since there would be no costs for operators, there would be no impacts on employment levels. Over time the use of databases will streamline and simplify the management of information. They would also provide a structure that could help to facilitate Member States' implementation reporting pursuant to Article 19.4 of the Directive.

5.5. Policy issue 5: Land-use planning

The no-change baseline option (a) would have no impact on costs. There are only a limited number of new establishments and not many cases where the full

requirements of Article 12 have been applied. The existing provisions are being properly implemented so the level of protection they provide would remain unchanged.

Option (b) suggests minor clarifications. The additional administrative costs would be limited and indeed there could be savings if the references to the EIA/SEA Directives led to more coordinated consultation procedures. It is difficult to assess whether more specific references to environmental aspects will have any significant impact since this depends on current practices in the Member States. In principle such aspects should have been addressed already by competent authorities and in practical terms there are unlikely to be major changes in the way they are already working. There could be some positive impacts in terms of improving protection levels, but these are unlikely to be significant.

Option (c) would extend the requirements to all existing upper-tier establishments, This would require competent authorities to make an in-depth site-by-site analysis of the situation to assess whether or not there are appropriate safety distances and to identify what remedial land-use measures such as relocation of establishments or neighbouring population might be needed after existing risk reduction measures have been taken into account. It is estimated that such work alone would result in total costs of more than EUR 130 million. The form these remedial measures could take would be a matter for the competent authorities. Physical modifications or relocation of plants could lead to very substantial additional one-off costs, but it is very difficult to quantify these. Data from one Member State indicate that if all its 420 upper-tier establishments were forced to relocate, the costs would be about 2.3 billion EUR. However it is difficult to extrapolate this since to the whole of the EU since it is not known how many existing sites would be affected, which would depend on their specific characteristics, the surrounding environment, and the policy approach followed by the authorities. More details are included section 5.10.1 of the Impact Assessment Study (7). The potential benefits in terms of protection levels could also be very significant, although again it is difficult to quantify these.

Other impacts

Options (a) and (b) would have no significant impacts on protection levels for human health (both for workers and the public) and the environment or on employment levels. Option (c) could have significant impacts given the potentially significant costs and benefits.

Option (b) would contribute towards better regulation by making the existing provisions clearer and minimising possible divergences in implementation. In addition the envisaged integration of procedures with those under other environmental legislation like the EIA and SEA Directives should help to reduce administrative costs.

5.6. Policy issue 6: Clarifications to facilitate effective implementation

A) Closer coordination, integration of information and procedures, etc

This option takes together several option components to facilitate effective implementation and enforceability. The no-change option would have no impacts,

positive or negative. Overall only a qualitative assessment of the impacts of the components is possible. The impact is likely to be positive in terms of simplification and reduction of administrative burdens with possibly some improvements in existing levels of protection.

Coordination of inspection requirements of different pieces of legislation may result in a more consistent assessment and reduce administrative burdens for the operator (estimated by the study on administrative burdens to amount to savings of around 0.5 million EUR), but may have disadvantages and could be burdensome for competent authorities, make inspections much more general and thereby less effective and thus reduce protection levels.

Integration of information requirements with those under other applicable legislation may result in some simplification and reduction of administrative burdens, although it is difficult to quantify these benefits. Likewise, integration of the procedures for land-use planning under Article 12 with those under the EIA and SEA Directives could lead to similar benefits without any impact on existing protection levels.

As regards the possible options to further facilitate more consistent implementation, measures like codifying the Mutual Joint Visits programme for inspections and formalising cooperation between the Commission and Member States in support of implementation would build on existing information-sharing and exchange of best practices and would entail no additional costs. Guidance already exists for certain aspects such as for the preparation of safety reports and guidelines for land-use planning. However the development of additional guidance material would lead to greater consistency in implementation and enforcement, with positive effects on protection levels. There would be no direct economic impact as the direct administrative costs would remain the same as at present. Overall, these types of action could indirectly reduce costs to both operators and competent authorities since guidelines could help to deal with implementation issues more effectively and efficiently. However, it is difficult to quantify these indirect effects.

B) Other issues where improvements are needed

The no-change option has no impacts. The costs and benefits of the different elements are described in Annex XI. In summary, overall these would have no significant impact on costs but would provide some increase in protection levels. The two areas where various sub-options exist which could lead to additional costs are summarised in the table below.

Impacts of options under this heading

Option component	Economic impacts	Protection level	Other impacts
Safety performance indicators (SPI) [4]			
a) Mandatory requirements to use SPI	Potential significant costs	Potential increase	SPIs still under development; some Member States lack knowledge and experience in their use:
b) Include reference to the use of SPI	No significant additional costs	Potential increase	
c) Develop guidance	No additional costs	Potential increase	
Safety management requirements for lower-tier sites			
a) Clarify existing provisions	Potential small savings	Unchanged	
b) Increase safety management requirements for lower tier to include SMS	Potential high costs for those establishments that do not have an SMS	Some increase	Removes variation across MS due to difference in national requirement, but undermines two-tier approach
c) Require mini-safety report and internal emergency plan for LT sites	25 million EUR (one-off costs)	Increase	As above. Further undermines two-tier approach
d) Require SMS, mini-safety report and IEP	> 25 million EUR (one-off costs) App. 1 million EUR per year	Significant increase	As above. Effectively nullifies two-tier approach.

6. COMPARING THE OPTIONS

Before comparing the options, it should be underlined that these options do not represent new policies as such, rather technical adaptations to existing provisions.

6.1. Policy issue 1: Alignment of Annex I to GHS

In summary, a comparison with the current situation shows that the impact of all options, as well as the difference of impacts between the various options, is limited. An increase in scope would result in increased compliance costs and an increase in the level of protection. Whilst SMEs are particularly sensitive to cost impacts, no

[4] SPIs: Indicators used to mean observable measures that provide insights into a concept – safety – that is difficult to measure directly (OECD SPI Guidance: http://www.oecd.org/dataoecd/7/15/41269639.pdf)

evidence was found that SMEs would be more concerned by the potential change of scope than large businesses.

The Directive currently covers about 10 000 establishments. Whatever the option chosen, the scope variation would be limited to a maximum of 415 establishments currently covered falling out of the scope of the Directive (-4.1%) and 342 establishments newly falling under the scope of the Directive (+3.4%). It is common to all options that the particularities of the alignment of 'Very Toxic' to 'Acute Toxic 1' leads to an exclusion of 314 establishments.

Option C, contrary to options E and E*, would include oral toxicity which would bring under the scope of the directive 131 additional establishments. The overall scope change would be 131 new sites, 324 out. This option suggests treating the three inhalation routes differently, which would be difficult to apply in practice as all three inhalation exposure routes use the same hazard labelling statement H331. Furthermore, the exclusion of dermal toxicity and vapour inhalation which are possible exposure routes in case of accident could weaken the protection level. However covering substances that display oral toxicity and for which complete information on dermal and inhalation may not be available has a favourable effect on the protection level.

Option D would include Acute Toxic 3 for all exposure paths. Contrary to option C, it would keep all inhalation routes together. Contrary to option E and E*, it includes oral toxicity since for many substances complete information is limited mainly to this exposure route, and a correlation between oral and other types of toxicity cannot be excluded, as observed for many substances for which information is available for different exposure routes. This would bring under the scope of the Directive 121 additional facilities. Therefore the impact on the scope would be 342 new sites, 314 out. The main advantages of this option would be (1) covering all exposure paths that are relevant in case of accident, (2) covering some substances that display oral toxicity and for which complete information on dermal and inhalation may not be available, and (3) the substances covered are all labelled with "danger" and the symbol "skull and crossbones" (all toxic substances of Acute Toxic 1, 2 and 3 carry this label) which makes implementation by businesses and public administration simple.

Option E is limited to inhalation toxicity. The scope impact would be 10 new sites, 415 out. Inhalation exposure is an important exposure route in case of accident. However, the level of protection would be lower because the dermal exposure route which could also be relevant in case of accident is excluded. Furthermore, as oral toxicity is not retained in option E, and inhalation toxicity data is not available for all toxic substances, other methods would need to be applied to extrapolate inhalation toxicity, which could be administratively complicated. Furthermore, although an identification of substances covered by options E would be possible by using the individual hazard labelling statements, an easy distinction is not possible just by the categories and the labelling.

Option E* is similar to E, but would also include Acute Toxic 3 dermal, which would bring under the scope of the directive some 220 additional establishments. The impact on the scope would be 221 new sites, 405 out. As oral toxicity is not retained, and complete inhalation and dermal toxicity data are not available for all toxic

substances, other methods would need to be applied to extrapolate dermal and inhalation toxicity.. Identification of substances covered by option E* would be possible by using the individual hazard labelling statements.

The analysis of costs has further shown that the administrative CLP adaptation costs are in the range of several million EUR. Therefore, practical implementation and administrative burden issues, which will run over a long period beyond the initial alignment to Annex I, should also be taken into account bearing in mind the general objective of simplification.

In the light of this assessment, option E* is the preferred option as, in addition to having a relatively limited impact on scope, shared with other options, option E* maintains a high level of protection taking into account the most likely exposure routes (dermal and inhalation) in the event of a major accident.

6.2. Policy issue 2: Other technical amendments to Annex I

Hydrogen

The option to increase the lower-tier threshold quantity for hydrogen from five to ten tonnes would have little or no impact on existing industrial establishments. Choosing either option will have limited short term impact; increasing the thresholds to 10 tonnes would postpone the need for further adjustments as the H_2 economy develops to a later date. At this stage the preferred option is to leave the threshold unchanged, although it should be recognised that appropriate risk management may be required should the H_2 economy develop in the longer-term.

Heavy fuel oil

If heavy fuel oil were to come under the scope of the Directive due to its changed classification, this may bring some energy-intensive establishments using heavy fuel oils under the scope of the Directive. If heavy fuel oil were to be included within the named substances listed in Annex I under the category 'petroleum products' with thresholds of 2500/25000 tonnes, an exemption as for other petroleum products would effectively be granted and there would be very likely no or nearly no impact as the thresholds for petroleum products are so high. That is therefore the preferred option.

Aerosols

An approximate one-to-one translation from the CLP would keep the scope nearly unchanged. However, the option to effectively exclude aerosols sites by setting higher thresholds would imply that about 200 establishments (mostly wholesale and retail storage and distribution establishments, storing packaged consignments of aerosols in large lots of dispensers and pressure equipment) would be excluded from the scope. The economic impact would be of the order of up to EUR 3-4 million annually in cost savings for the affected industries.

At this stage the preferred option is the one-to-one translation from the CLP since this would be consistent with the Directive's current approach. However aerosols could be a candidate for the derogation correction mechanism under the envisaged

approach for policy issue 3 if it can be demonstrated that there is no major-accident hazard.

Sodium hypochlorite

The options to exempt this substance/mixture by including it as a named substance with high thresholds or to give an exemption for packages in small quantities could lead to cost savings of around 3 Million EUR. Following the CLP for this substance would be in line with the Directive's current approach and is the preferred option, although this is another case where the derogation correction mechanism could come into play..

6.3. Policy issue 3: Procedures for amending Annex I in the future

The assessment in section 5.3 shows that business as usual is not really an option and that mechanisms are needed to adapt Annex I to the Directive should its alignment to the CLP Regulation lead to substances being included/excluded that do not/do present a major-accident hazard. This situation could arise either as part of the initial alignment to the CLP (policy issue 1) or subsequently when future changes to classification of substances via delegated acts under CLP will automatically impact on the scope of the Directive.

The envisaged derogation and safeguard clauses, together with the use of delegated acts to amend Annex I, would provide the necessary flexibility to deal with this situation. These are not separate options, but necessary elements of an overall package, which should have a positive effect on protection levels and a net positive effect on costs.

For the derogation clause, the two basic sub-options for a changed approach are: 1) to allow Member States to grant establishment-specific derogations (sub-options (b) and (d); and 2) to provide for EU-wide derogations for substances (sub-option (c)). In both cases, the derogations could apply to some or all of the Directive's requirements and would be based on harmonised criteria to be established.

Derogations at establishment level granted by Member States could lead to net potential cost savings for the establishments concerned. There should be no reduction in protection levels provided that the agreed criteria are applied correctly. Derogations at substance level throughout the EU would have a potentially greater impact in terms of net cost savings and avoid any possible distortion that could arise from derogations at Member State level. Again, there would be no impact on existing protection levels. The wider the scope of the derogation, the greater would be the cost savings.

A combination of both sub-options would be the preferred approach. In both cases harmonised criteria would need to be clearly specified.

The safeguard clause (option (e)) would be the corollary of the derogation clause. The costs would be limited and protection levels would be increased. This could be a means to deal with any unwanted effects from substances falling out of scope due to the alignment of T+ to Acute Toxic 1. It would also allow for the coverage of materials such as nanomaterials that form a potential risk.

The use of delegated acts to amend Annex I in the future would offer a relatively quick and efficient way of making the necessary changes to Annex I flowing from the application of the EU-level derogation and safeguard clauses.

6.4. Policy issue 4: Information to the public and information management systems including reporting

A) Type of information provided

The aim is to improve the level and quality of the information provided to the public. This would be in the interest of transparency and furthermore ensure that the public has the necessary information so to be aware of the dangers and appropriate action to take in the event of an accident. Making use of IT tools to ensure that the information is readily available and kept up to date, without precluding other forms of communication, is an important part of this. The different options for improvements that are assessed in section 5.4 and Annex X represent a scaled approach, starting from business as usual and then ranging from making the information currently required available on line (option (b)) to including much more detailed information (option (d). The more information has to be made available, the greater the costs. Cost estimates mainly relate to the competent authorities since they are responsible for setting up the required IT tools and collecting the information (while in most cases the operator will have the information). At the same time, the more the level of the information is improved, the greater the potential benefits in terms of protection levels.

Option (b) would have additional costs of €~1Million to make the information online available plus maintenance costs of the order of 50,000 to 100,000 € and would lead to better access to the information currently required.

Option (c) would require additional information such as 1) basic data about all sites; and 2) for upper-tier establishments the main accident scenarios and appropriate information from the external emergency plan; to be made available online. 1) would not entail any additional costs since the information exists and is already compiled in one way or another. 2) would entail one-off costs of 2-4 million EUR. Annual costs of updating the information would be 0.5 million EUR.

Option (d) would go further and require in addition non-technical summaries of the safety report and emergency plans to be made available. It is estimated that this option would entail one-off costs of around 20 million EUR, with annual costs of around 2-5 million EUR for updating.

Weighing up the costs and benefits, and taking into account the need for proportionality, option (c) is the preferred option.

B) Information management

The options under this heading represent a gradual increase in the stringency of the options aimed at ensuring that the information is collected, managed and shared in an efficient and streamlined way, thereby also facilitating reporting. Here again, the greater the scale of the improvements, the greater the costs and benefits. The various options are assessed in section 5.4 and Annex X.

As far as improvements are concerned, option (b) would require the establishment of databases at Member State level. These databases/costs are one and the same as under option A) b).

Option (c) would be a central EU-wide database using the existing SPIRS database run by the Commission. This database accesses information in the Member States through links to documents directly uploaded on the system or with links to Member State websites/databases. It would have the added benefit of facilitating the sharing of information between the Member States (and with the Commission). The estimated additional one-off cost for setting up such a system is 1 million EUR with annual maintenance costs of 50,000-100,000 EUR.

Option (d) would be a centralised EU-wide database with all information fully integrated within it. This ambitious option would involve substantial costs to adapt all existing systems to one database format. While this may be worth exploring in the longer term, it does not seem a very realistic approach at this time.

Accordingly, option (c) is the preferred option.

6.5. Policy issue 5: Land-use planning

Apart from the no-change option, there are two options for amendments as follows.

Option (b) the current rules would be retained with minor changes to clarify that the requirements are aimed at the protection of the environment as well as of human health and to make reference to the possible integration of procedures with those under the EIA and SEA Directives (which is also relevant in the context of part A) of policy issue 6). This is not expected to have any major impacts on costs, but may improve protection levels.

Option (c) would extend the requirements to all existing upper-tier establishments. As noted in section 5.5, this could have major cost implications, but would also lead to significant increases in protection levels. In view of this, and given the limited experience with the practical implementation of such an approach to date, it would not be appropriate to make this policy change at this stage.

Option (b) is therefore the preferred option.

6.6. Policy issue 6: Clarifications to facilitate effective implementation

A) Closer coordination and integration of information and procedures, etc

It is difficult to quantify the impacts of the options set out in section 4.6 and 5.6. Across all these options the impact is likely to be positive in terms of simplification and reduction of administrative burdens, with possibly some improvements in existing levels of protection.

Coordination of inspections would reduce administrative burdens for operators (estimated savings of around 500,000 EUR), facilitating sharing of information and harmonisation of inspection practices, although it is not clear if such coordination would be more effective and what the effects on the protection level would be in practice.

Measures such as codifying the MJV programme, Commission/Member State cooperation in support for implementation and the development of guidance would facilitate a more harmonised approach towards implementation and enforcement, and could lead to greater efficiency and effectiveness, with positive effects on protection levels. There would be no direct economic impact as the administrative costs would remain the same as at present. Indirectly, support to implementation in the above-mentioned forms could reduce costs to both operators and competent authorities. More harmonised implementation could also reduce - if they exist - negative effects on competition and the internal market. The elements could therefore overall lead to cost reductions both regarding existing obligations and new obligations as part of other possible amendments discussed in this report. This likely cost reduction effect can however not be quantified.

B) Other improvements

In general, the options identified, presented and discussed in sections 4.6 and 5.6.4 are elements that could be included in a package aimed at clarifying and improving certain provisions, which taken together will lead to clearer and better regulation, and improve protection levels without imposing significant additional costs.

There are two options with alternative sub-options, these relate to 1) safety performance indicators; and 2) safety management requirements for lower-tier sites. These are discussed in Annex XI.

On 1), given the current state of development and use of such indicators and the potentially significant costs involved, making their use mandatory (sub-option (a)) would not be appropriate. A combination of sub-options (b) and (c) – including a reference to their possible use and developing guidance would be the preferred option. This would entail no additional costs and still potentially increase protection levels.

On 2), the sub-options are to: clarify the existing text without any substantive change (sub-option (a)) or a range of graduated sub-options ((b) to (d) that would increase the requirements for lower-tier sites. Sub-option (a) could lead to potential small savings, with no impact on existing protection levels. As can be seen from the table in section 5.6.4, for sub-options (b) to (d), the more stringent the requirements, the higher would be the protection levels. However there would be greater costs, which would increase commensurately according to which sub-option were to be followed, and the existing two-tier approach would be eroded. Sub-option (a) is therefore the preferred option.

6.7. Summary Table

The table below presents a summary of the comparison of the main options within the six policy issues. A detailed table including a summary of costs/impacts, benefits and, where appropriate, the contribution to better regulation and simplification, is included in Annex XII.

Explanation of the (+++, ++, +, 0, -, --, ---) summary table:

- "+" means increase, "0" means no effect, "-" means decrease;
- +, - low; ++, -- medium,; +++, --- strong impact;

- Preferred options are shaded in dark grey;

Option component[5]	**Economic impacts**[6] in Mio EUR per year	**Protection level**[7]	**Administrative effort/complexity**
Policy Issue 1: Alignment of Annex I (change of scope)[8]			
C	**+2.5**	**-**	**++**
D	**+4.9**	**+**	**0**
E	**-1.1**	**--**	**+**
E*	**+2.4**	**-**	**+**
Policy Issue 2: other technical amendments to Annex I			
Hydrogen: a) do nothing	**0**	**0**	
Hydrogen: b) to grant an alleviation by doubling the threshold	**0-**	**0-**	
Heavy fuel oil:: a) accept possible re-classification effect	**0+**	**0+**	
Heavy fuel oil:: b) avoid the possible effect by listing as named substance with other petroleum products	**0**	**0**	
Aerosols: a) CLP proposal of 150/500	**+ 0.5**	**0**	
Aerosols: b) higher threshold	**- 3 to 4**	**-**	
Sodium hypochlorite: a) accept re-classification effect for mixtures	**+ 3.8**	**+**	**0**
Sodium hypochlorite: exemption	**-**	**-**	**+**
Policy Issue 3:Procedure for changing Annex 1			
3 b)/d: Allow MS to grant derogations from some or all Seveso requirements based on harmonised criteria	**-**	**0**	**+**
3 c): Allow EU wide substance derogations from some or all Seveso requirements based on harmonised criteria	**-**	**0**	**-**
3 e) Introduce Safeguard clause	**+**	**+**	**-**

[5] In this summary table, the "do nothing" options for policy issues 3,4,5,6 are not included to keep the table short and because they are no preferred options in line with the review objective in this regard to clarify and improve the text of the directive

[6] Economic impacts are administrative costs. Non-administrative compliance costs, for example related to such physical modifications have not been considered as they are very site specific, are influenced by other legislation, and it has not been possible to quantify these.

[7] The protection level aspect covers protection against environmental damage, damage to human health and damage to public and private property. Therefore the environmental and part of the social impacts correlate directly the results regarding the protection level.

[8] In the summary tables in 6.7 and Annex XII, net figures for the Annex I alignment costs have been used. Chapter 5.1.3 and Annex VIII describe the alignment costs and change of scope costs and savings in more detail.

Option component[5]	**Economic impacts**[6] in Mio EUR per year	**Protection level**[7]	**Administrative effort/complexity**
Policy Issue 4A – Type of information to the public[9]			
b) Annex V information on-line	**+ 0.1**	+	-
c) Additional information on basic data for all sites plus accident scenarios and key information from external emergency plan for upper tier (revised Annex V) on line	**+ 0.5**	++	-
d) Additional information plus non-technical summaries of SR and EEP on line	**+ 2**	+++	-
Policy Issue 4B: management of information			
b) MS databases	**+ 0.1**	+	-
c) Information management: Simple website with links to documents either directed uploaded on the EU site or links to MS websites with the information/documents	**+ 0.1**	+	--
d) fully integrated central EU database	++	+	---
Policy issue 5: land-use planning			
b) minor clarifications	**0**	**0**	**0**
c) extend requirements	**billions**	++	+
Policy issue 6: clarifications			
A) Closer coordination, integration of information and procedures, etc	**- 0.5**	+	-
B) Other improvements			
Safety performance indicators			
a) mandatory requirement to use SPI	++	+	
b)Include reference to the use of SPI for internal safety	**0**	+	
c) Guidance	**0**	+	
Safety management requirements for LT sites			

[9] Confidentiality issues will be considered (see discussion in section 2.4)

Option component[5]	Economic impacts[6] in Mio EUR per year	Protection level[7]	Administrative effort/complexity
a) Clarify existing provisions	-	0	-
b) Increase safety management requirements for lower tier to include SMS	++	+	+
c) Require mini-safety report and internal emergency plan for LT sites	+ 25 one-off	+	++
d) Require SMS, mini- safety report and IEP	+>25 one-off + 1	++	++
Other clarifications (such as underground gas storage, domino effects, environmental aspects, deadlines for emergency plans, and deadlines and thresholds for accident reporting	+ 1.5	+	-

It should be noted that the policy options in the six policy areas are compatible from the perspective of an overall policy package. There are few cross impacts where one option component would increase the costs of another option component.

Taken as a whole, the potential changes considered represent a moderate adaptation of the Directive and would not strongly affect the level of protection or the costs of the Directive. Overall the costs are low compared with the total costs of the Directive.

6.8. Effect on SMEs

The Seveso approach addressing major hazards of large quantities of chemicals, which are predominantly present in larger companies, limits the possible impacts on SMEs. This is reflected in the tiered approach in the Directive's provisions, with only basic requirements for operators of lower-tier establishments, which take into account SMEs' capacities. As this approach will be maintained, the impact should continue to be relatively limited.

There are limited data to support a specific assessment of the impacts on SMEs. Nevertheless some indications were obtained (for example from industry in relation to sodium hypochlorite and from the metal finishing industry) and these are included in Annex VIII. Although there is not necessarily a correlation between the quantities of chemicals present in an establishment and the size of the operator, it can be assumed that lower-tier sites are more likely to be an SME. In the following, a rough assessment is made of whether the options could result in a relatively higher cost burden for lower tier sites.

In the context of the alignment of Annex I of the Directive to the CLP, it should be noted that SMEs and in particular smaller firms may have a lower capacity to incur the one-off implementation costs of the new CLP system. These costs will have to be incurred by these firms regardless of the alignment of Annex I to the CLP (since they will occur in any case under the CLP). Therefore it is not only important that the Seveso hazard classification categories are switched to those in the CLP (as closely as possible to a one-to-one translation), but also that the necessary changes to the

Seveso provisions are effected in time to link with the definitive entry into force of the CLP rules so as to ensure a smooth CLP/Seveso adaption.

For SMEs the net benefits of the alignment of Annex I will coincide with the CLP benefits: a single classification system will reduce costs and administrative burdens as the future system will use the same classification and labelling for transport, storage, and Seveso purposes. The new system will reduce the burden for hazard identification, facilitate international trade and lead to cost savings in the long term.

Most of the other proposed amendments to the Directive will lead to only moderate costs and would present only a limited proportion of existing costs. This would apply to investment as well as to administrative costs as well as to big companies and SMEs alike. If some of the more ambitious options in relation to imposing further requirements on lower-tier sites were to be included, these could lead to more significant costs to SMEs.

For upper-tier SMEs, the cost burden however could be higher and some of the options have impacts on their business activity. However, apart from the example of the metal finishing industry, where upper tier establishments can be found in some MS, there is limited data available to this study on such SMEs within the EU. Therefore, no specific conclusions could be drawn.

In addition, differences in Member State implementation make it difficult to draw general conclusions. There are Member States that have imposed additional requirements on lower-tier establishments, which have increased the administrative costs and hence the burden for lower-tier SMEs. In general, the approach in Member State implementation (e.g. "gold-plating") is an important factor in the costs facing any operator.

The envisaged amendment in relation to derogations could lead to more flexibility in exempting SMEs if it can be demonstrated that there is no major accident hazard potential related to their activity. Since this is likely to lead to reductions in costs to industry overall the positive effects of such flexibility provisions could be particularly important for SMEs.

6.9. The social impacts, effects on human health, environment, employment, and other effects

Concerning the environment, human health and social impacts, including the effects on employment, as explained in the relevant sections the impact assessment shows that the impact of the different policy options will vary. However overall the preferred options, which are really modifications to existing provisions, will not significantly affect the current high level of environmental and human health protection (see section 5), while they may have limited impacts on employment in individual SMEs (see section 6.8 and Annex VIII).

6.10. Simplification

There are a number of elements in the preferred options that are identified in section 5 that will contribute towards simplification and better regulation. It is difficult to quantify these benefits in terms of savings in administrative costs; in some areas it

will be for Member States to decide whether and to what extent they use the possibilities for simplification that are set out. These are mainly to be found under policy issues 4 (information to the public and management of that information) and 6 (closer coordination of inspections, integration of information and procedural requirements with those under other EU legislation. Option D for policy issue 1 (alignment of Annex I) and the various clarifications to existing provisions elsewhere in the Directive will also contribute towards simplification.

6.11. Subsidiarity and proportionality

With respect to the **subsidiarity** principle, the options provide for action at EU level since only this will ensure that there are not significantly different levels of protection in the Member States or possible distortions to competition. Member States will however retain their central role in the practical application and management of the Directive and its implementation. They will continue to determine at which level- national, regional or local, action should be taken as appropriate. As regards, **proportionality**, the preferred options do not go beyond what is necessary what is necessary to achieve the objectives. Overall there would be no impact on the existing Directive's proportionate approach, with the level of controls based on the quantities of dangerous substances present in establishments.

7. MONITORING AND EVALUATION

The Seveso II Directive has several monitoring tools to check its level of implementation and to check whether the overall policy objective to prevent major accidents and to mitigate their consequences in case they occur is being achieved. The main indicators used are:

a) the number of major accidents reported;

b) the number of Seveso establishments; and

c) the provision of plans, reports and other information required from operators and authorities.

These indicators will also be valid in the future and are being derived from data that has to be reported by Member States to:

a) an Accident database (MARS);

b) a (restricted) database on establishments (SPIRS); and

c) the three-yearly reporting exercise to the Commission with the Member States and Commissions reports published on the Commissions website.

However, the existing monitoring tools will be simplified and streamlined as outlined under policy issue 4 e.g. information will only be collected once and then be made available to the different stakeholders such as Member States' authorities, the Commission and the public through appropriate formats. This will increase not only their effectiveness but also help reduce unnecessary administrative costs.

With regard to the specific objectives, set out in section 3, the main issue in the future will be to monitor the impact of the CLP alignment of Annex I in practice and the effectiveness of envisaged correction mechanisms. Indicators in this regard are:

- The number of lower-tier and upper-tier establishments, including information about their activities and the main dangerous substances concerned; and

- The number of derogations granted at EU and Member State level, and reasons for derogations including information about the activities, dangerous substances and hazards in the establishments concerned.

On the basis of the data collected and the three yearly implementation reports, the Commission will publish overall reports, which will include an assessment of the progress made in implementing the changes made to the Directive and their impacts.

ANNEX I

REFERENCES

(1) OJ L10, 14.1.1997, p.13, as amended

(2) COM(2010) 135 final, 31.3.2010

(3) Commission working document- Third progress report on the strategy for simplifying the regulatory environment COM(2009)17 final, 28.1.2009

(4) F-SEVESO – Study of the effectiveness of the Seveso II Directive, August 2008, conducted by EU-VRi, available at http://ec.europa.eu/environment/seveso/pdf/seveso_report.pdf

(5) Seveso II Directive – Study of the effectiveness of the requirements imposed on public authorities, conducted by ERM, available at http://ec.europa.eu/environment/seveso/review.htm

(6) Impact assessment study into possible options for adapting Annex I of the SEVESO II Directive into the GHS (final report submitted April 2010), conducted by COWI A/S, available at http://ec.europa.eu/environment/seveso/pdf/ghs_impact%20assessment.pdf

(7) Impact assessment study into possible options for amending the Seveso Directive (final report submitted July 2010, conducted by COWI A/S; when approved, will be available at http://ec.europa.eu/environment/seveso/review.htm

(8) Final report (2009) Measurement data and analysis as specified in the specific contract 5&6 on Modules 3&4 under framework contract No. ENTR/06/61 Report on the Environment Priority Area, EU PROJECT ON BASELINE MEASUREMENT AND REDUCTION OF ADMINISTRATIVE COSTS

(9) ' Towards a reinforced culture of consultation and dialogue – general principles and minimum standards for consultation of interested parties by the Commission' (COM(2002)704 final)

(10) OJ L 345, 31.12.2003, p.97

(11) OJ L 353, 31.12.2008, p.1

(12) Analysis of the potential Effects of the proposed GHS Regulation on Its Downstream legislation (Commission services, August 2006).

(13) COM(2007)355 final

(14) OJ L 192, 8.7.1998, p.19

(15) Stakeholder meeting and follow-up feedback from various participants, see: http://ec.europa.eu/environment/seveso/review.htm

ANNEX II

Detailed Description of Options as referred to in Chapter 4:

Policy issue 1: Alignment of Annex I to the CLP

As noted in section 2.1, the scope of the Directive is partly defined by hazard classification categories which have to change to the new CLP categories. For most of the hazard categories listed in Part 2 of Annex I, for example those relating to physical and environmental hazards, a one-to-one translation is more or less possible with negligible impacts. This translation work is explained in more detail in Annex VII.

However, no such one-to-one translation is possible with regard to health hazards. Substances with the health hazards '**toxic '(T)** and '**very toxic' (T+)** are covered by the Directive above the related quantity thresholds in Annex I. This hazard-based approach ensures that all toxic and very toxic substances are treated equally according to their properties. To give an example, a substances is "very toxic" if its lethal dose is lower than 25 mg/kg. All substances with a classification value lower than 25 mg/kg are covered by the Directive.

The CLP legislation includes new categories Acute Toxicity Category 1 to Category 3 (hereinafter called '**Acute Toxic 1', 'Acute Toxic 2'** and **'Acute Toxic 3'**). These categories do not completely correspond to the old categories 'toxic' and 'very toxic'. They have other cut-off values for the lethal doses. To illustrate the differences, a substance will now be classified Acute Toxic 1 if the lethal dose is lower than 5 mg/kg, and Acute Toxic 2 if lower than 50 mg/kg. This means that both very toxic substances (with a lethal dose between 5 and 25 mg/kg) and also substances classified as toxic (lethal dose between 25 and 50 mg/kg) are now allocated to one new category Acute Toxic 2.

This downward (from T+ to Acute Toxic 2) or upward (from T to Acute Toxic 2) change in classification could impact significantly on the Directive's scope. Moreover unfortunately, the effects are further complicated because:

- The allocation from T to category Acute Toxic 2 or 3 is more complicated than from T+ to Acute Toxic 1 or 2 (as used in the example);
- Acute Toxic 3 covers many non-toxic substances, which are outside scope of the current Directive and for which very limited reliable information is available;
- The new categories are divided into the three exposure routes: oral, dermal and inhalation, with the latter split into three sub-routes for vapours, aerosols, and gases. For all these exposure routes, the classification cut-off values have changed. Where hazard classes are differentiated on the basis of the route of exposure, the substance must be classified in accordance with such differentiation. This means that data for all exposure routes must be available to classify according to the respective (strictest) class.

The following options have been developed to align from T+/T to Acute Toxic 1/2/3:

Option ("0"): Unchanged policy

This is not a valid option as set out in section 2.1.

Option (A): Screening tool

In general, it would be possible to maintain the existing scope by introducing a screening tool approach. This option would introduce a screening procedure, to be applied to groups of substances or individual substances that would enable the current scope to be maintained. The procedure would apply criteria that would have to be developed to establish firstly whether a candidate substance poses a hazard based on its physical form and toxicity, and secondly whether the substance has a major accident hazard potential, based on its dispersive energy and toxicity. A technical committee would then determine whether the substance should be included in Annex I as a named substance, using expert judgment to take into account any additional relevant factors such as the extent of industrial use.

Options (B) – (E):*

All options use the alignment from T+ to Acute Toxic 1 and from T to Acute Toxic 2, but as Acute Toxic 2 catches only a part of T, the options differ as regards which exposure routes of Acute Toxic 3 they include.

Therefore the following options have been developed:

Overview Table

Option	*T+ aligned to* ***Acute Toxic 1***	T aligned to **Acute Toxic 2**	T aligned to the following Exposure Routes of **Acute Toxic 3**				
	All exposure routes		Oral	Dermal	Inhalation		
					vapour	aerosol	Gas
B	*X*	X				**X**	
C	*X*	X	**X**			**X**	**X**
D	*X*	X	**X**	**X**	**X**	**X**	**X**
E	*X*	X			**X**	**X**	**X**
E*	*X*	X		**X**	**X**	**X**	**X**

Option B: This option is a narrow option that only includes Acute Toxic 3 for inhalation aerosols.

Option C: This option is more inclusive than Option B as it covers Acute Toxic 3 for the oral, inhalation aerosol and inhalation gas exposure routes. It considers that T coincides for Inhalation vapour with Acute Toxic 2 and for Inhalation aerosol with Acute Toxic 3, representing an exact translation for these two sub-routes. This option was preferred by the majority in the TWG 2009 where competent authorities and stakeholders were represented.

Option D: This option covers Acute Toxic 3 entirety.

Option E: This option covers the three inhalation routes Acute Toxic 3.

Option E*: This option covers the inhalation and dermal exposure routes for Acute Toxic 3, but excludes the oral route.

A few additional remarks should be made. Options B-D were identified at an early stage and discussed extensively with experts and stakeholders. Options E/E* are possible additional options that were subsequently identified. It was already clear from the beginning that all alignment options represent for the T+ alignment a reduction in scope as the cut-off values for two of the five exposure routes (oral and inhalation aerosols) are lower for Acute Toxic 1 than for T+, whereas for the T alignment is was unclear whether the options would lead to an extension or reduction in scope. A detailed analysis is in section 5.1.

Apart from these options, many further combinations would be possible, as well as other correction measures, possibilities to adapt the thresholds for the three Acute Toxic categories, etc. For this analysis, it is assumed that the current thresholds would be transferred to the new categories. For reasons that are explained further in section 5.1, whichever alignment option is chosen, there is a degree of uncertainty over the impact over time.

Policy issue 2: Other technical amendments to Annex I

The policy options presented below deal with different issues where adaptation of the scope to technical progress may be appropriate, with alternative options as indicated. The first issue arose in the context of CCS (Carbon Capture and Storage) technologies, the second and third about energy carriers, and the last two relate to the first examples of specific substances/products directly affected by the new classification system.

CO_2

Under option (a) - Unchanged policy, CO_2 would remain outside the scope of the Directive. Under Option (b) - Include with appropriate thresholds, CO_2 would be included in Annex I as a named substance with 5000/10000 tonnes as lower/upper-tier thresholds; or with lower quantities of 500/1000 tonnes as the respective thresholds.

Heavy fuel oil

Under option (a) - Unchanged policy, Heavy fuel oil would fall within the scope of the Directive due its likely classification as toxic to the aquatic environment, with thresholds of 200/500 tonnes (lower/upper-tier). Under option (b) - Include as named

substance with appropriate thresholds, heavy fuel oil would be included within the named substances listed in annex I under the category 'petroleum products' with thresholds of 2500/25000 tonnes (lower/upper-tier).

Hydrogen

Under option (a) - Unchanged policy, Hydrogen would remain as a named substance in annex I with thresholds of 5/50 tonnes. Under option (b) - Delete as named substance and increase threshold, Hydrogen would be deleted as a named substance, but would still be caught by its generic classification as an extremely flammable gas, for which the thresholds are 10/50 tonnes (lower/upper-tier).

Aerosols

Under option (a) - Unchanged policy, in line with the CLP alignment process, the lower/upper-tier thresholds for flammable aerosols containing flammable gases or liquids and such aerosols not containing such gases and liquids would be 150/500 tonnes and 5000/50000 tonnes respectively. Under option (b) - Increase thresholds, the thresholds would be increased to 1300/5200 tonnes (lower/upper-tier).

Sodium hypochlorite

Under option (a) - Unchanged policy, Sodium hypochlorite and mixtures thereof would fall within the scope of the Directive based on the CLP classification with thresholds of 100/200 tonnes (lower/upper-tier). Under option (b) - Include as a named substance with appropriate thresholds or a derogation for packaged products, Sodium hypochlorite would either be listed in annex I as a named substance with thresholds of 200/500 tonnes in line with those applicable to substances classified as very toxic to the aquatic environment up until the 2003 amendment (when these thresholds were lowered to 100/200 tonnes); or alternatively there would be an exemption for mixtures when they are packaged in limited quantities (inner pack up to 5 litres and combination pack up to 30kg).

Policy issue 3: Procedures for adapting Annex I in the future

The uncertainties caused by the new classification system for policy issue 1 (and 2) suggest a need for flexible tools to be able to adapt Annex I as necessary. There are three inter-related aspects: a derogation clause, a safeguard clause and more generally the procedure to be used to make amendments to Annex I in the future. These should be seen as one overall package. Such correction mechanisms could help solve the problems outlined above, including in particular subsequent changes to the classification of substances and mixtures under frequent updating of the CLP regulation via comitology (equivalent to delegated acts) that will automatically impact on the scope of Annex I in a timely way by appropriate changes to Annex I. A pre-condition for to be effective would therefore be for adaptations of Annex I to be also made via delegated acts (namely options (c) and (e)).

Derogation Rule

Under option (a) - Unchanged policy, any amendment to Annex I would continue to be via an amendment to the Directive adopted by ordinary legislative procedure. Moreover the existing derogation rule, allowing Member States to grant

establishment-specific exemptions to upper-tier establishments based on the existing harmonised criteria limited to information requirements related to safety reports for upper-tier establishments, would be left unchanged.

Under option (b) - Extend scope of existing derogation rule, the rule, based on the existing harmonised criteria laid down in Commission Decision 98/433/EC, would be extended to allow Member States to grant establishment-specific exemptions to upper-tier establishments covering requirements such as those relating to safety reports, emergency plans and information to the public.

Under option (c) - Introduce general derogation rule at EU level, there would be EU-wide substance-specific derogations based on points 1 (criterion: physical form) and 4 (criterion: classification) of the existing harmonised criteria which could be further developed, for example to covercriteria like physical form, properties, classification, concentration or generic packaging. The derogations, by delegated acts, could take the form of reduced requirements or complete exemption (which could be appropriate in cases where a substance falls into scope due to its generic classification under the CLP legislation but does not present any major accident hazard). The means could also vary, for example by separate listings, increased thresholds, etc.

Under option (d): General establishment-specific derogations at Member State level, Member States would get the possibility to grant establishment-specific derogations based on points 2 (criterion: containment and quantities) and 3 (criterion: location and quantities) of the existing harmonised criteria. The derogation would apply to all qualifying establishments and could take the form of reduced requirements or complete exemption.

The policy options (b) to (d) are alternatives but certain elements of options (c) and (d) could be combined in various permutations.

The basic act would include the general criteria with detailed harmonised criteria to be adopted by the Commission though delegated acts. The latter would be developed in parallel to the legislative procedure in order to be ready for adoption immediately after the entry into force of the amended directive. This would thus allow for ample time for adopting derogation decisions before 1 June 2015, when CLP rules enter into effect.

Safeguard clause

This option (e) – Safeguard clause, would complement and be the corollary to options (c) and (d). It would deal with situations such as those where, notwithstanding their falling outside the Directive's scope due classification under CLP rules, a substance presents a major accident hazard potential and should be covered.

Policy issue 4: Information to the public and information management systems including reporting

The policy options presented below address possible improvements as to how information of better quality can be made available more efficiently and effectively to the public.

The options presented are mutually exclusive. They all address the same problem and offer different solutions to it (in some cases by including components from other options). They relate to the requirements for information to be made permanently available. Active dissemination of information (and the media used for disseminating that information and responsibility for this) would remain unaffected.

A) Options for type of information provided

Under option (a) - Unchanged policy, the information would be as currently required by Annex V of the Directive.

Under option (b) – Annex V online, the information required by Annex V would be made available on-line.

Under option (c) - Additional information, , the following information in addition to the current Annex V information would be made publicly available, including on-line:

- for all establishments: basic information about each establishment similar to what is currently contained in the Seveso Plants information Retrieval System (SPIRS) database managed by the Commission (based on information provided by Member States under Article 19.1a of the Directive); and

- for upper-tier establishments, a summary of main major accident scenarios, key recommendations for the public in case of an accident.

Under option (d) - non-technical summaries of key documents, the additional information as in option (c) would be supplemented by non-technical summaries of the safety report and external emergency plan.

B) Options for information management

Under option (a) - Unchanged policy, existing arrangements would continue with Member States deciding whether they operate databases and whether they allow public access.

Under Option (b) - Member State databases, Member States would be required to operate databases with public access to Annex V information. Most Member States already operate something similar though there might not be public access to information about individual sites.

Under option (c) - central EU wide database version1, a simple website would be required with links to documents either directly uploaded on an adapted EU SPIRS site managed by the Commission or links to Member States' websites with the information/documents.

Such an option would be in line with the ongoing efforts to improve the efficiency of information management - the Shared Environmental Information System (SEIS) initiative and the INSPIRE Directive 2007/2/EC Directive and its common Implementing Rules (Regulations on Metadata, Data Specifications, Network Services, Data and Service Sharing and Monitoring and Reporting). One of key principles in that initiative is to collect information only once and then share it

among all relevant parties including the public. It is also about setting up IT systems that allow easy reporting of the necessary information. Doing this at EU level would bring increased benefits in terms of increased openness and transparency as well as greater efficiency and effectiveness.

A central website does not require a complicated database to be programmed. It could be organised in various ways:

• By Member State: Link to Member State website with relevant information - one link per Member State

• By Member State and list of establishments - each with a link to relevant documents (link can be to documents uploaded on the central database or link to Member States website where documents are uploaded).

• SPIRS kind of database with basic data on each establishment and link to documents with further information (will allow search by defined parameters - Member State, type of activity etc).

Finally, Option (d) - central EU wide database version2, would be a fully integrated database.

Policy issue 5: Land-use planning

The policy options set out below are alternatives but within (b) and (c) certain elements could be combined (see section 6.5 for more details).

Under option (a) - Unchanged policy, the current system would be retained with no changes.

Under option (b) - Minor clarifications, the current system would be retained with minor changes such as to clarify that the requirements are aimed at the protection of both man and environment (including taking into account areas of particular natural sensitivity; and to make reference to procedures under EIA and similar legislation. Under option (c) - Extension of provisions, the obligations would be extended in full to all upper-tier plants, including existing plants, and it would be clarified that these also extend to new lower-tier plants.

Policy issue 6: clarifications to facilitate effective implementation

As noted in section 2.2.6, the overall aim is to clarify certain provisions to facilitate effective implementation and enforceability and at the same time where possible to introduce streamlining and simplification to reduce administrative burdens.

A) Closer coordination, integration of information and procedures, etc

The options would be to make no changes or to introduce measures that could reduce overlapping requirements and unnecessary administrative burdens for operators. These could include, for example, closer coordination of inspections, allowing the use of reporting formats and information provided under other legislation in a Seveso context, and where possible integrating procedures such as those under land-use planning with those under other legislation such as the EIA and SEA Directives.

To further facilitate more consistent implementation, options could include codifying the existing arrangements for cooperation between the Member States in support of implementation, including the Mutual Joint Visits Programme for inspections, and the continued development of tools and mechanisms to encourage information exchange and sharing of best practices such as further guidance where needed. Annex VI provides further details.

B) Other areas where improvements are needed

There is a raft of possible options, which could be pursued separately or combined in a single package, to address the kind of issues outlined in section 2.2.6 where clarifications or greater precision would improve implementation and enforceability. For most those issues there is a choice of no action or minor clarifications to the text. However for some issues, there is graduated range of possible sub-options. For example, for safety performance indicators the sub-options range from introducing mandatory requirements to softer measures such as guidance; for requirements for lower-tier establishments around safety management, etc these range from clarifying the existing requirements to significantly increasing them. Annex VI provides further details of the kind of possible options that could be included.

Options discarded at an early stage

Policy issue 1: Alignment of Annex I to the GHS

Before options differentiating between different exposure routes were developed, and bearing in mind that in addition to the main aim of maintaining existing levels of protection, there was a wish to keep the new GHS categories as far as possible intact, two framing options were considered:

- a very simple alignment transferring T+ to Acute Toxic 1 and T to Acute Toxic 2, and

- a very precautionary alignment, transferring T+ to Acute Toxic 1 and 2 and T to Acute Toxic 3.

However, as it was clear from the cut-off values that both options were far away from the current scope, they were discarded at an early stage from a detailed assessment.

Furthermore, it should be noted that also options A and B, which were identified early in the process and assessed in detail in the Impact assessment study, have not been further considered. Option A has not been pursued as the procedures to apply the screening tool would be complicated and it is doubtful whether a backwards-oriented approach referring to the current Seveso II cut-off values would be sustainable over time when the whole chemicals classification world will refer to the new CLP categories. Option B has been discarded because it would be a fourth option reducing the scope and reducing it more than other options by around 475 sites.

Another option that could be used independently and also applied in combination with other options would be an approach based on named substances. There is already a list of named substances in Annex 1 Part 1. These are mainly substances whose specific characteristics warrant thresholds different from those applicable to the relevant hazard classification category under which they would fall. Using named substances

could be useful way of avoiding a reduction in scope. In particular, in cases where there are only few substances in a boundary area, they could easily be identified. However such an approach has drawbacks. It is difficult to identify a shortlist of substances that should be included. Furthermore, using named substances would mean inequality of treatment between existing, known substances, which can be identified, and new substances that are identified subsequently. It has not therefore been considered further. This drop of the named substances approach which had been incorporated in the options B to D within the COWI study had the consequence that the compensation effect had to be abstracted in the options considered in this report.

Policy issue 2: Other technical amendments to Annex I

CO_2

The option to possibly include CO_2 has been discarded due to the following reasons. CO_2 is not classified as a dangerous substance. However, the review of the available data suggests that there could be a major accident hazard potential if CO_2 is used in high quantities (for more details, see reference (7)). A preliminary analysis with two different upper-tier threshold limits of 1,000/10,000 tonnes found that this inclusion would cover about 10/100 existing sites, and could lead to administrative costs in order of EUR 0.5/2 million EUR annually, but this would not make any difference to the protection level for capture and transport in the context of CCS. For storage, Directive 2009/31/EC on the geological storage of CO_2 ('CCS-Directive') establishes a legal framework for the environmentally safe geological storage of CO_2., and it was unclear whether Seveso requirements would add significantly to those under the CCS-Directive. As CCS schemes are only at an early stage, it is premature to judge whether a major accident hazard would emerge should the technology be widely used in the future. Therefore, it has been decided not to include CO_2 in the revised Seveso Directive. Further development of the technology will help to better understand any potential risks. The situation will be kept under review in the context of the CCSDirective. As part of the review of the CCS-Directive the Commission will assess and report by 31 March 2015 whether permanent containment of CO2 in such a way as to prevent and reduce as far as possible negative effects on the environment and any resulting risk to human health and the environmental and human safety of CCS has been sufficiently demonstrated.

ANNEX III

Stakeholder consultation

During the review process, stakeholders (individual companies, industry associations, NGOs, Member State competent authorities) were consulted in a number of ways, as follows.

The two studies undertaken to evaluate the effectiveness of the current Directive were both based on web-based questionnaires and selected follow-up interviews, allowing operators, competent authorities and NGOs to give their views. The questionnaires were widely publicised. For the first study these were available to interested stakeholders for completion from February to April 2008; and for the second study from May to July 2009. Both studies concluded that overall the directive is fit for purpose. Most of the recommendations related to guidance and tools to support implementation. No fundamental changes to the directive in the short-term were recommended (for further details see the study reports available at

http://ec.europa.eu/environment/seveso/review.htm

The competent authorities have been further consulted through the committee of competent authorities (CCA) at its regular six-monthly meetings. On the GHS alignment, a technical working group, comprising experts from Member States, industry and environmental NGOs), was established to examine the issue and met on six occasions during the period October 2008 to November 2009. (The group's discussions focussed mainly on option C. Options E and E* were identified subsequently by the Commission services). The results of this work, and the accompanying impact assessment on the alignment options, were regularly discussed at the CCA meetings. On other subjects covered by this report, the results of the two evaluation studies referred to, as well an outline of the other possible amendments to the Directive that are envisaged, have also been presented and discussed at those meetings. The study findings were broadly accepted as a good basis for taking the review process forward. Several seminars held in conjunction with the CCA meetings, such as those held on enforceability, on lower-tier sites and on emergency plans, have also provided useful inputs to the review process.

From these consultations it can be concluded that there is general agreement that overall the Directive is achieving its objectives, leading to a recognisably higher level of safety, and that the approach is appropriate and proportionate. No fundamental changes to the Directive are required. In particular the flexibility of the Directive's existing approach, including the two-tier approach and the goal-setting nature of the requirements, should be retained. However there was support for some modifications to clarify and update several provisions to improve implementation and enforceability, while at the same time not unduly adding to the administrative burdens on operators. Comments subsequently received were generally supportive, although views differed on some of the details. On policy issue 3, views varied on whether there was a need for extended derogations and whether Annex I should be amended in future via delegated acts. On policy issue 4, Member States generally recognised the case of greater accessibility of information and that the public's right to the safety report was important (but that a non-technical summary would be more useful). However some expressed concerns about any extension of level of detail of

information that should be provided and security aspects, as well as possible impact on existing databases at national level. The wish to retain the right to use other forms of communicating the information was also underlined. On policy issue 5, there was broad agreement that no major changes required, but that the provisions could usefully be clarified to better reflect the aims of the provision and existing practice. On policy issue 6 there was general support.

So far as other stakeholders are concerned, to garner further input a stakeholder consultation meeting was also held on 9 November 2009 in Brussels. The meeting, which was publicised, amongst other means, through 'Your Voice in Europe', was attended by around 60 representatives from national and European industry and environmental NGOs as well as individual companies. At that meeting the Commission invited views on the findings of the two evaluation studies and a series of questions on a range of subjects covered by this report, including : industry obligations (major accident prevention policy; safety management systems; safety reports and internal emergency plans); the public (consultation with and information to the public; emergency planning and testing; land-use planning; risk assessment; reporting, information sources and data bases) and application of the Directive (scope, definitions, exclusions, readability, etc; and review of Annex I, GHS). There was also an opportunity for participants to give their general views. Subsequently around fifty written comments were received.

The comments confirmed that no major changes to the directive are needed. Industry would welcome any measures that would improve coordination between authorities, reduce administrative burdens and lead to more consistent implementation. Many of the industry comments focussed on the possible extension of the Directive to other installations such as railway marshalling yards and harbours and the integration of security issues (which were suggestions made by EU-VRi in the first evaluation study referred to above) and the possible inclusion of CO2 in the context of carbon capture and storage (which is addressed further in this impact assessment). Some industry representatives also expressed concern about any changes to the two-tier approach. A number of specific sector concerns were also expressed about the impact on the scope of the Directive of the GHS alignment (also covered in this impact assessment). Views of environmental NGOs went in the opposite direction, arguing for extending the scope of the Directive and its requirements. In particular they called for the provisions on information to the public, etc to be brought into line with the Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters. A report of the stakeholder consultation meeting, together with copies of the presentations made during the discussions and further comments, can be accessed on the Seveso review webpage.

ANNEX IV

Background information

The Seveso II Directive, which is based on Article 192 TFEU, was adopted in 1996.

It is one of the key instruments in the field of 'industrial risk management' and applies to fixed industrial sites where around 30 named dangerous substances or groups of substances and other substances falling under certain EU hazard classifications (very toxic, toxic, oxidising, explosive, flammable, highly flammable, extremely flammable, and dangerous for the environment) listed in its Annex I are present in large quantities. There is a tiered approach to the level of controls, with the larger the quantities of substances, the stricter the rules. The main requirements are that all operators caught by the Directive must notify their activities and establish a major accident prevention policy. In addition, operators of 'upper tier' establishments have to establish a safety report, a safety management system and an internal emergency plan. There are also obligations on public authorities relating to, inter alia, external emergency plans and public information on safety measures for upper-tier establishments, domino effects, land-use planning, accident reporting and inspections.

The Directive was amended by Directive 2003/105/EC, which extended its scope, mainly to cover risks arising from storage and processing activities in mining, from pyrotechnic and explosive substances and from the storage of ammonium nitrate and ammonium nitrate based fertilizers following several major accidents involving these substances. However the basic structure of the Directive and its main requirements have remained essentially unchanged since its adoption.

Currently, the Directive covers around 10,000 establishments storing or using dangerous substances, mainly in the chemicals, petrochemicals, storage, and metal refining sectors. It does not apply to military establishments; nuclear safety; transport of dangerous substances; intermediate temporary storage outside establishments, ports, railway yards; offshore exploration and exploitation of minerals, including hydrocarbons; the transport of dangerous substances by pipelines; or (with certain exceptions) mining activities and waste land-fill sites.

The breakdown of establishments by Member State is as follows:

Country	Total number of plants	Upper Tier	Lower Tier	Not known/ not applicable
Germany	**2119**	1071	1048	
UK	**1147**	411	736	
Italy	**1117**	519	598	
France	**1106**	553	553	
Spain	**673**	267	406	
Netherlands	**384**	221	163	
Sweden	**379**	199	180	
Poland	**366**	158	208	
Belgium	**365**	174	191	
Romania	**277**	115	162	
Finland	**264**	128	136	
Czech Republic	**190**	115	75	
Greece	**189**	83	106	
Portugal	**164**	57	107	
Austria	**146**	80	64	2
Hungary	**144**	64	80	
Bulgaria	**135**	54	81	
Denmark	**121**	31	90	
Ireland	**88**	34	54	
Slovakia	**78**	41	37	
Latvia	**63**	30	33	
Slovenia	**60**	23	37	
Lithuania	**53**	19	34	

Estonia	**50**	25	25	
Luxembourg	**21**	8	13	
Cyprus	**16**	10	6	
Malta	**10**	6	4	
TOTAL	**9725**	**4496**	**5227**	**2**

- Source: SPIRS (November 2009)

Breakdown of Activities:

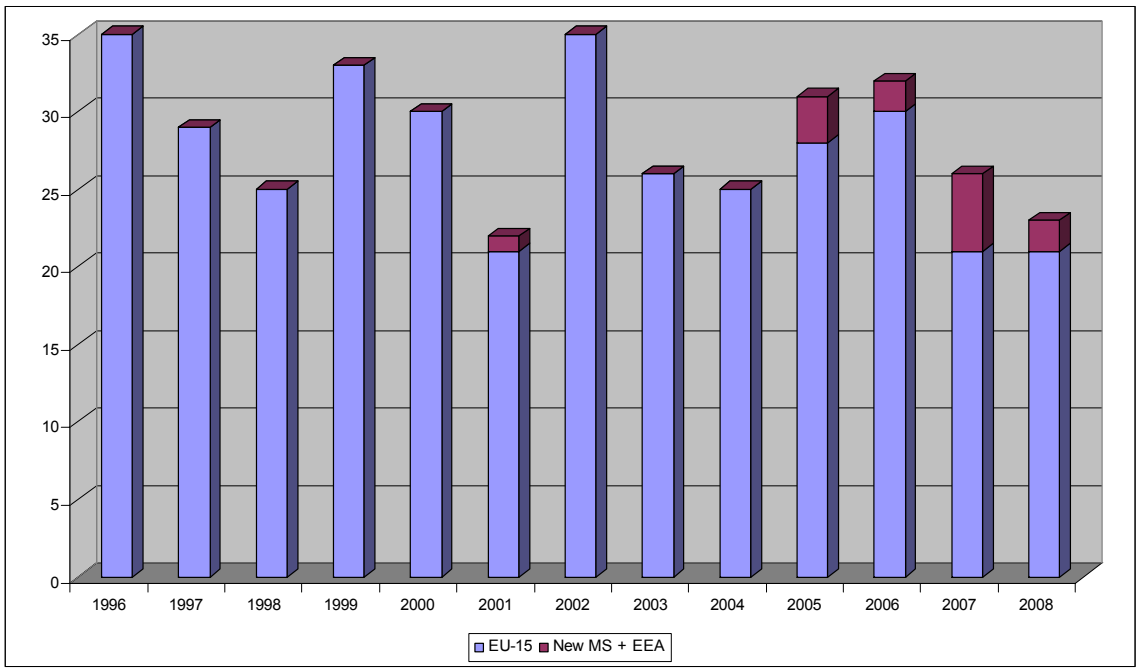
IndustryType	**Percentage**
Fuel storage (including heating, retail sale, etc.)	10.92%
Wholesale and retail storage and distribution (excluding LPG)	10.36%
General chemicals manufacture (not included above)	7.41%
Power generation, supply and distribution	7.12%
LPG storage	5.53%
Production of basic organic chemicals	5.01%
Production, destruction and storage of explosives	4.36%
Processing of metals using electrolytic or chemical processes	4.30%
Chemical installations - other fine chemicals	3.82%
Chemical installations – Industrial gases	3.52%
Other activity (not included above)	3.39%
LPG production, bottling and bulk distribution	3.30%
Plastic and rubber manufacture	3.10%
Production and storage of pesticides, biocides, fungicides	2.95%
Petrochemical / Oil Refineries	2.55%
Production and storage of fertilizers	2.50%
Manufacture of food products and beverages	2.38%
Waste storage, treatment and disposal	1.90%
Handling and transportation centres	1.80%
Production of pharmaceuticals	1.53%
General engineering, manufacturing and assembly	1.29%
Production and storage of fireworks	1.15%
Processing of ferrous metals (foundries, smelting, etc.)	1.08%
LNG storage and distribution	1.02%
Production and manufacturing of pulp and paper	0.97%
Processing of non-ferrous metals (foundries, smelting, etc.)	0.91%
Agriculture	0.73%
Electronics & electrical engineering	0.72%
Water and sewage (collection, supply, treatment)	0.61%
Ceramics (bricks, pottery, glass, cement, etc.)	0.54%
Manufacture of glass	0.54%
Processing of metals	0.45%
Chemical installations - chlorine	0.36%
Medical, research, education (including hospitals, universities, etc.)	0.33%
Mining activities (tailings & physicochemical processes)	0.24%
Wood treatment and furniture	0.24%
Chemical installations - ammonia	0.21%

Shipbuilding, shipbreaking, ship repair	0.18%
Chemical installations - inorganic acids	0.15%
Manufacture of cement, lime and plaster	0.13%
Chemical installations - fluorine or hydrogen fluoride	0.09%
Chemical installations - hydrogen	0.06%
Building & works of engineering construction	0.04%
Textiles manufacturing and treatment	0.04%
Leisure and sport activities (e.g. ice rink)	0.03%
Chemical installations – carbon oxides	0.01%
Chemical installations - nitrogen oxides	0.01%
Chemical installations - sulphur oxides, oleum	0.01%
Total	100.00%

- Source: SPIRS (May 2010)

Every three years, the Member States submit reports to the Commission on the implementation of the directive. In general, the Directive is being correctly transposed and implemented by Member States, although there are shortcomings in performance in some Member States; and the level of compliance by industry is good.

Over the last 10 years or so there have on average been about 30 major accidents per year as can be seen in the table below. It is very difficult to derive overall conclusions about the accident rate trend. The reason for this difficulty is that accidents are sometimes reported late (so that numbers in more recent years could increase) and the fact that the population of industrial sites is not constant. Apart for normal variation over time – industrial plants closing, changing or starting operation – and the effect of 2 EU enlargements during this period (in 2004 and 2007), there is also the effect of changes in the legislation defining the scope of the Seveso II Directive. Following the 2003 amendment and adaptations to EU rules on the classification of dangerous substances many substances and establishments have entered the Seveso regime. Since there is a relatively constant number of accidents per year over an increasing population of establishments, this suggests that the accident rate (accidents per year per 1000 establishments) is declining over time.



- Source: MARS

The costs, both economically and environmentally, of just one major accident can be significant, not just for the industrial establishment concerned, but also for local, regional or national authorities in the Member State concerned, but also, in the case of accidents with transboundary effects, other countries. It is often difficult to estimate the costs of such accidents, since these need to take into account, inter alia, the loss of lives, both short and long term damage to human health and the environment, damage to property, loss of production, loss of amenity, and the costs of response and remedial action. Nevertheless costs estimates have been made for some of the more high profile accidents, which can run into EUR billions. By way of example, the cost of one major accident, the explosion and fire at the Buncefield oil depot in 2005, reached £1 billion, according to a final report by the UK Major Incident Investigation Board. This means that the overall impact of all Seveso safety requirements in Europe in terms of administrative costs is lower than the costs of one severe accident, and the costs of aligning Annex I is several orders of magnitude lower.

.

ANNEX V

Existing information obligations under the Directive

The information obligations are closely linked to the various reporting obligations. Currently, there are the following information obligations and systems and reporting arrangements:

Operators:

To CAs: Notification (Art 5), Safety reports (Art 9), Information necessary for external emergency plans (Art 11(b)

Information to the public:

Directly to those around the site that could be affected (Art 13 and Annex V); and/or

Via the CA for the use of public information (Art 13 and Annex V): adequate information on safety measures and requisite behaviour in "simple terms".

The responsibility is sometimes with operators sometimes with CAs - the Directive is not prescriptive. The Directive requires the information to the concerned population to be given regularly and without the population having to request the information (active information). It also provides that the information should also be kept permanently available (passive information).

Member State CAs:

To the Commission: Information about establishments (Art19) (information held in SPIRS database) and three-yearly implementation report (Art 19 (4))

To the public: Information on safety measures (Art 13*),* Safety reports (13)

Specifically in relation to Accidents:

Operators to CA: Inform about accidents (Art 14)

Member States to COM: Info about accident (Art 15)

COM: Maintain database with accident info (MARS database)

Public consultation:

Member States to undertake public consultation in case of new upper tier establishment, modification of existing (Art 10) and development around existing establishments.

Member States have to consult the public in relation to the external emergency plans both when they are first drawn up and at any later update.

ANNEX VI

Policy Issue 6: clarifications to facilitate effective implementation

The various issues can be grouped under two broad headings: the need for closer integration of information and procedural requirements; and the need to update or clarify certain provisions to facilitate implementation and enforceability.

A) Closer coordination, Integration of information and procedures, etc

The review process identified some concerns about shortcomings in coordination between authorities, both within and between Member States that can lead to inconsistent implementation, conflicting or overlapping requirements and unnecessary administrative burdens for operators. The specific areas concerned are discussed below.

Coordination of inspections

The Directive requires that there shall be a programme of inspections of all establishments. Unless a programme is in place, based on a systematic appraisal of major accidents hazards of the particular establishment concerned, each upper-tier establishment shall be subject to at least one on-site inspection every 12 months. It is estimated that around half of the installations that fall under the Directive also fall under the IPPC Directive. Although some Member States coordinate inspections performed by the various authorities involved, it has been widely suggested that such initiatives should be extended to all Member States. This could reduce the administrative burdens for operators and facilitate the sharing of information between IPPC and Seveso inspectors to minimise duplication.

Mutual Joint Visits Programme

The Commission's support for inspection activities via the Technical Working Group on Inspections and the Mutual Joint Visit (MJV) Programme (established in 1999 to promote technical exchange among Seveso inspectors in the Member States) is widely appreciated. The Programme is currently a voluntary means to encourage the sharing and adoption of best practices for inspections through a system of regular information exchange with the aim of increasing the effectiveness of inspections practices and to ensuring a consistent approach in interpreting and applying the Directive's requirements through inspections across the Member States. Codifying this in some way in the Directive would help to that this important activity continues and develops further.

Commission and Member State cooperation in implementation

The Commission plays an active role in facilitating close coordination and sharing of experience among Member States and supporting effective implementation of the Directive. This involves various activities, undertaken together with experts from the Member States and other stakeholders, such as the development of guidance and guidelines, preparing answers to questions on interpretation of certain provisions, etc; as well as the development, updating and management of the Major Accident Reporting System (MARS) and the Seveso Plants Information Retrieval System

(SPIRS), required under Articles 15 and 19 respectively. Currently there is reference in the Directive to these activities. Including such a provision would put such co-operation on a firmer footing.

Integration of information and procedural requirements with other legislation

Although there is no clear evidence of significant overlaps between the Directive and other legislation such as the IPPC Directive in terms of information requirements, some savings may be possible in administrative costs if these could be more closely integrated. For example, information used to meet the requirements in another piece of legislation could be re-used to (partly) address Seveso requirements if these are similar. Such a possibility already exists in the context of safety reports (Article 9) and could be extended to other provisions.

Likewise integration of procedures under land-use planning and those under the EIA and SEA Directives could also help.

Guidance

There is general support for tools such as guidance, together with other mechanisms such as information sharing and exchange of best practices, to facilitate more consistent implementation. Much has already been done in this area. However further guidance could be considered where there is an identified need. Specific areas identified in the review process have included safety report assessment and emergency planning,

B) Other issues where clarifications needed

The issues are as follows.

Safety performance Indicators (SPIs)

SPIs can be an effective tool to focus on safety issues and thus promote a safety culture and help to improve safety performance levels. Annex III of the Directive includes requirements where SPIs may be relevant in the context of safety management systems. However there is no explicit reference to them.

Some Member States would like to require the use of such indicators to assist monitoring, assessment and enforcement. However although there has been substantial progress in developing such indicators, this is a complex area and experience in using and analysing them is relatively limited. Given the uncertainty whether SPIs are sufficiently mature and well-developed to form the basis for a mandatory tool, other options should also be considered.

Domino effects

A domino effect occurs when a Seveso installation is impacted by an external accident in another installation. In accordance with Article 8, Member States must identify relevant establishments and ensure "a suitable" information exchange between the two parties.

The existing provisions are rather generally worded. As regards exchange of information, a particular area of concern is the issue of non-Seveso establishments in the vicinity of Seveso establishments such as in industrial parks. It is clear that the Directive cannot impose obligations on operators of establishments falling outside its scope. However it is generally recognised that it is important that Seveso establishments take into account the risks of such sites in their notifications and safety reports and that information about requisite behaviour in the vent of an accident is exchanged with them.

Underground gas storage sites

The Directive applies to natural gas if the quantity is above the thresholds laid down in Annex I (50/200t). However the language used in Article 4(e) about the exception to the exclusion of mining activities from the Directive has created some legal uncertainty about the status of underground gas storage sites under the Directive, which has led to a non-harmonised approach among Member States. Following consultation with the Member States, it has been agreed that Article 4(e) needs to be amended to make it clear that such sites would only be excluded from the scope of the Directive if they fall under the exploitation (exploration, extraction and processing) of minerals in mines, quarries or by means of boreholes. Since "exploitation" must be seen in a strict sense, this means that storing natural gas in natural strata and disused mines should thus fall within the scope of the Directive.

Environmental aspects

Although the Directive refers to the protection of both human heath and the environment, there are a few, if any specific references to the latter in the detailed provisions. There is general support for rectifying this omission. Such an approach should apply in particular to the following provisions.

In Annex II relating to safety reports, it would be advisable that external accident causes such as natural disasters are taken into account and that major accident scenarios include an assessment of the consequences for the environment and how these should be addressed.

For Annex IV, on emergency planning, it could similarly be specified that environmental impacts should be considered and that appropriate measures to mitigate such impacts - typically on the aquatic environment - should be part of the plan.

Including specific reference to environmental aspects in Article 12 on land use planning, would also be appropriate.

Deadlines for external emergency plans

Emergency plans are a key tool of the directive I terms of preparedness and response to major accidents. In accordance with Article 11.1(c,) the competent authorities are obliged to draw up an external emergency plan for each upper-tier establishment based on information provided by the operator. In the past in several Member States there have been significant delays in completing such plans, which has given rise to a

number of infringement proceedings. Setting a clear deadline could help to improve implementation.

Reporting of major accidents

Article 15 of the Directive requires that Member states shall inform the Commission 'as soon as practicable' of major accidents meeting the criteria laid down in Annex VI.

There are two issues in this area that should be addressed. First, there is currently no specific deadline for when a Member State have to report an accident. This means that in some cases reports are only sent after a long delay. Secondly, section 1.1 of Annex VI requires the reporting of any fire or explosion or accidental discharge of a dangerous substance involving a quantity of at least 5% of the upper-tier threshold laid down in Annex I. This means that an accident with for example release of 1 tonne of chlorine (< 5 % of the upper tier threshold) would not require reporting. A reduction of the threshold to 5% of the lower tier threshold or some other threshold could possibly bring more accidents with significant high quantities of dangerous substances within the reporting system and improve its benefits.

Safety management requirements for lower-tier establishments

The safety management requirements for especially lower-tier establishments are not very accurately defined. In particular, the relationship between the major-accident prevention policy (MAPP) and the safety management system (SMS) is not very clear, Article 7 stipulating only that they adhere to the principles laid down in Annex III.

This has resulted in widely different practices among the Member States. As a result many Member States require lower-tier establishments to require an SMS in one form or another. Moreover about half the Member States go further and impose additional requirements on lower-tier establishments such as a safety report (or mini-safety report) and internal emergency plans. The issue is therefore not only whether the existing provisions should be clarified (which would still allow those Member States that wish to do so to impose stricter requirements) but also whether there is a case for the Directive's requirements in relation to lower-tier establishments should be extended further bearing in mind the current two-tiered hazards-based approach.

By way of illustration, the main options that could be pursued to address the issues outlined above include the following:

Issues/possible amendments	Options
A) Closer coordination/integration	1) Unchanged policy in each area 2) Separate options below, which could be combined in one package
Coordination/ Integration of inspections	1) Encourage coordination/integration
Codify Mutual Joint Visits programme	1)Underline importance of MJV as means to encourage information exchange and sharing of best practices
Member State/Commission cooperation in implementation	1) Provide a legal basis for the Commission to cooperate with and to support Member States in developing tools and mechanisms to facilitate more consistent implementation
Integration of information and procedural requirements	1) Allow use of reporting formats and information provided under other legislation in Seveso context (e.g. information contained in an IPPC report); and 2) Integrate procedures for land-us e planning cases under art.12 with those under the EIA and SEA Directives
Guidance	1) Develop guidance and exchange of best practices as regards assessment of safety reports, emergency planning and in other areas if needs identified
B) other issues where clarifications are needed	1) Unchanged policy in each area 2) Separate options below, which could be combined in one package since they address different aspects (sub-options for each aspect are alternatives unless indicated otherwise)
Safety Performance Indicators (SPIs)	a) Mandatory requirements; or b) Non-binding requirements (make reference only; MS to decide whether to use); or c) Provide guidance on their use (can be combined with 1) or 2)
Domino effects	1) Include requirement for exchange of information with and need to take account of risks from non-Seveso sites
Underground gas storage sites	1) Include within scope of Directive
Environmental aspects	1) Include more details in relation to the environmental aspects in Annex II, IV and LUP
External emergency plans	1) Set deadline for MS to complete plans (say 12 months)

Issues/possible amendments	Options
Accident reporting	1) Set deadline for MS to report accidents (say 12 months); and 2) Reduce reporting threshold in Annex VI 1.1 (say to 5% of LT quantity threshold in Annex I)
Requirements for lower-tier (LT) establishments around safety management, etc	a) clarify existing requirements in annex III as regards MAPP (full SMS not required);or b) Extend full SMS to LT;or c) 'Mini' safety report(SR) including internal emergency plan(IEP) for LT; or d) Combination of 2) and 3) : require SMS, IEP and mini SR

The costs and benefits of these are assessed in Annex XI

ANNEX VII

Annex I issues

Annex I Part 2 of the Directive contains health, physical, environmental and other hazards. The impacts on health hazards are explained first; further information on the other hazards and the translation work follows at the end of this Annex.

Health Hazards Classification

The CLP legislation includes new categories Acute Toxicity Category 1 to Category 3 (hereinafter called '**Acute Toxic 1', 'Acute Toxic 2'** and **'Acute Toxic 3'**). These categories do not completely correspond to the old categories '**T toxic'** and '**T+ very** toxic'. They have other cut-off values for the lethal doses for all exposure routes.

The following approach has been followed to calculate the number of affected establishments:

- To assess the differences and different cut-off values between the old very toxic T+ and toxic T category and the new CLP categories, especially in between a narrowing alignment with Acute Toxic 2 and the widening alignment with Acute Toxic 3,
- To define the "boundary" areas for the five exposure routes around the old toxic category T, one part of these areas reduces the current scope, one part widens it;
- To identify substances that have their determinating classification within these areas.

As the **first step**, the following boundary areas and 108 substances have been identified:

Table:Impact of substances in areas A1 to A7

Area	Number of substances		Net effect	
	T+	T	T+	T
A1	2		-10%	
A2		9		-10%
A2b		12		14%
A3		1		-1%
A4		21		24%
A5	4		-19%	
A6		6		-7%
A7		1		1%
Total number of substances	21	87		

There are many uncertainties about the substances included in these areas. Key uncertainties which limit the assessment include:

- Toxic substances shall be classified in accordance with the differentiation into different exposure routes. Often only the oral exposure data is available, however an available extrapolation approach for, e.g. mixtures, under CLP can be used to obtain the needed information for the other exposure routes, i.e. dermal and inhalation. However, for Seveso purposes available information should be used as far as possible. The Seveso attribution of substances and mixtures should not depend on and delayed by the application of methods to evaluate hazard information.

- Many substances are classified and counted for Seveso due to their physical or environmental hazards, but the health hazards are not considered.

- The assessment does not include substances classified as Acute Toxic 3 Inhalation Vapour (Area A8, currently excluded), due to unavailability of data. Although the first impact assessment suggests that the number of substances in this area is low, this underestimates the number of potential new establishments that could be included.

Spreading of the identified 87 toxic substances, details broken down for T:

The results of the identified T substances 87 for the main areas:

Net effect %	Impact of substances in boundary areas				
	Oral	Dermal	Inhalation		
			vapour (currently totally excluded)	Aerosol (currently totally included)	Gas
T -> Acute 2	-10	-1	-	-	-7
T-> Acute 3	+14	+24	-	-	+1

The **second main step** is to extrapolate from these lists of substances to the number of sites possibly affected. For this extrapolation, the following assumptions have been made:

- As no information on the share of establishments that fall within the scope due to the use of toxic substances is known, it is assumed that

    - The share of substances falling into the scope due to health hazards, roughly deduced from substances/activities reported to the SPIRS database, is 30% (sensitivity analysis: 50 per cent)

    - Of these, T+ accounts for 70% (low thresholds), and T for 30%

- There are limited data on why companies have been covered by Seveso II (e.g. how many currently fall within the scope due to health hazards is not known);

- The effect of changes in substance covered depends on many factors (e.g. establishment already Seveso II site, the company response, replacement of substances, reduced quantities on site);

Below is a table with the number of affected establishments identified:[10]

	Absolute effect on no of establishments			Relative effect in %	
	Lower tier	Upper tier	Total	Lower tier	Upper tier
A1	-60	-45	*-105*	-1.1%	-1.0%
A2	-49	-42	-91	-0.9%	-0.9%
A2b	65	56	*121*	1.2%	1.2%
A3	-5	-5	-10	-0.1%	-0.1%
A4	114	98	211	2.2%	2.2%
A5	-119	-90	*-209*	-2.3%	-2.0%
A6	-32	-28	-60	-0.6%	-0.6%
A7	5	5	*10*	0.1%	0.1%

As a **third important step**, the number of potentially affected establishments (+ or -) have now to be allocated to the options.

COWI has calculated, based on the number of establishments affected within the different areas, the effects for options A-D in detail. However, COWI factored in an adjustment for including in Annex I named substances to compensate for any change of scope, which is not followed in this IA report. Therefore the options in this report follow the same approach and have the same names, but the results are slightly below the COWI figures as they do not take into account the named substance compensation factor.

Option	Number of establishments		% change in no of establishments	
	Lower tier	Upper tier	Lower tier	Upper tier
Option A	0	0	0.0%	0.0%
Option B	-206	-136	-3.3%	-3.0%
Option (C)	-54	-34	-1.1%	-0.9%
Option (D)	*65*	*68*	1.1%	1.4%

To illustrate the differences: COWI identified for options C and D (sum of lines 3 and 4): -88 / 133sites, whereas the unadjusted total number of establishments is -193/+28.

[10] For the hazard class Acute Toxic Inhalation Vapour Cat. 3, not assessed by the TWG (as beyond the current scope, in some pictures included as area 8) no substances have been identified. Substances in this hazard class would count for options D, E, E*

This report has calculated the following changes of number of establishments. All options C,D,E, E* align T+ to Acute Toxic 1. This reduces the scope by Areas A1 and A5 by 314 sites.

- Option C adds areas A2b (oral), subtracts A3 (dermal) and adds (A7 inhalation gas)
- Option D adds areas A2b (oral), addsA4 (dermal) and adds (A7 inhalation gas)
- Option E subtracts areas A2 (oral), subtracts A3 (dermal) and adds (A7 inhalation gas)
- Option E* subtracts areas A2 (oral), adds A4 (dermal) and adds (A7 inhalation gas)

This leads to the following figures of establishments affected by Options C-E* used in this IA report:

Option	Change of number of establishments				
	a) T+ alignment	b) T alignment excluded sites	b) T alignment newly included sites	Net-effect	% Change of establishments
C	*-314*	-10	+131	-193	-2%
D	*-314*	-	+342	+28	+0.3%
E	*-314*	-101	+10	-405	-4.2%
E*	*-314*	-91	+221	-184	-1.9%

All options maintain the current approach, transferring the current threshold levels with 5/20 and 50/200 tons to the new health hazard categories.

Two other important aspects:

1.) The following figure further illustrates which are the most important areas for the comparison of options:

Importance of Acute Toxic 3 Oral and Dermal:

Acute Toxic 3				Included in Option:			
Exposure route	% Establishments within Toxic	% Establishments not within Toxic	Sum/ total Number	C	D	E	E*
Oral[1)]	43%	57%	212	X	X		

Dermal	5%	95%	221		X		X

[1)] This exposure route is less important for major accidents where inhalation and dermal form the relevant exposure routes.

The analysis shows that both areas each have a similar relevance for the scope of around 2% of establishments. A possible extension or reduction of scope is roughly equal for oral (+/- 1%), whereas it is predominantly an extension (+2%) for dermal..

2) The T+ Alignment to Acute Toxic 1

The T+ alignment, which all options have in common, leads to a reduction in scope as the cut-off values for Acute Toxic 1 oral and inhalation aerosols are lower than before. An additional problem for this alignment is that there is a "gap" between the thresholds for upper-tier establishments and lower-tier establishments T+: 5/20t; T: 50/200t. Establishments with substances classified as T+ in quantities between 20 and 50t could not only switch from upper- to lower-tier, but even fall completely fall out of the scope. The assessment identified for the inhalation aerosol exposure route for T+ an effect on the number of establishments that could be a decrease of up to two to three percentage points or more within the EU). However, there are no real alternatives to this approach given the need to keep the categories as far as possible intact and to keep as close as possible to the existing scope.

A sensitivity analysis has been carried out for this approach. This sensitivity analysis, including doubling the number of substances by a factor of 2, show that the assumptions have to be radically changed to make a significant impact on the number of establishments.

GHS" translatable" categories, physical, environmental and other hazards, etc

For all Seveso Annex I categories preparatory work has been carried out by a Technical Working Group (TWG) "Seveso and GHS" chaired by the Commission, which reported to the Committee of Competent Authorities established under the Directive. The work was done in a transparent way, drafts and interim reports were publicly available. The TWG provided suggestions how to translate the old categories to the new ones. In cases where no direct technical translation was possible, these were left open, especially concerning the proposals for the health hazards 'toxic' and 'very toxic'. For these two important categories, separate impact assessment work is presented in the next section of this annex.

For physical hazards, environmental hazards and other hazards, the TWG not only provided a translation, but the group also always assessed whether the new categories cover the same substances as before. In some cases, due for example to new test methods, modified definitions, changed flashpoints, etc, the new categories do not match 100% the old scope. However the initial technical assessment by the technical experts ensured that the scope is as close as possible to the current one so that that for all suggested categories there is practically no impact. The results of the work will be summarised in a JRC Technical Report.

The table below gives an overview of all the existing and proposed categories:

Hazard Class	Existing Annex I Part 2Categories	Proposed categories
Health hazards	Very Toxic, Toxic	**Acute Toxic 1, 2, 3 (part of IA)** STOTs
Physical Hazards	Oxidising, Explosive, Extremely Flammable, Highly Flammable, Flammable	EXPLOSIVES, FLAMMABLE GASES, **FLAMMABLE AEROSOLS ,** OXIDISING GASES, FLAMMABLE LIQUIDS, SELF-REACTIVES AND ORGANIC PEROXIDES, PYROPHORIC LIQUIDS, OXIDIZING LIQUIDS AND SOLIDS
Environmental Hazards	Dangerous to the Environment	Hazardous to the Aquatic Environment
Other hazards	Further hazards in combination with the R-phrases R14 or R14/15 and R29.	Other hazards, Hazard statements EUH014,…,EUH029

Only a few categories or groups of substances require a short additional explanation.

- Pyrophoric solids

Pyrophoric solids are currently not included in the Directive. However, to have a systematic application of the CLP which assigns oxidizing solids and liquids together, and also because they are subject to the same packaging rules under the transport of dangerous substances legislation, they should be treated the same as pyrophoric liquids. The assessment has shown that only a few substances are expected to be affected, and that it is not possible to quantify this marginal impact.

- STOT

Several very toxic and toxic substances (with the labelling risk phrase R39) are aligned with a new category Specific target organ toxicity (single exposure) Category 1 STOT-SE (Hazard labelling Statement H360). A comparison of substances covered has shown that Category 1 is the most appropriate. The alignment covers STOT single exposure, but excludes STOT repeated exposure (Category 1, H370). Some substances that are currently covered as 'toxic' (R48), but only have chronic effects that are not relevant for major accident hazards, will fall out of the scope. The assessment has shown that only a few substances are expected to be affected, and that it is not possible to quantify this marginal impact.

- Other Hazards

The current entry number 10 in Part 2 of annex I refers to "ANY CLASSIFICATION not covered by those given above" in combination with certain specified risk phrases. Since these risk phrases can only occur in combination with another classification,

i.e. they are not ”stand alone” classifications (CLP-Regulation, Annex II, 1.), the wording ”in combination with” is superfluous. It is already inherent in the conditions for assigning these two risk phrases specified that they occur in combination with other risk phrases. Therefore, the words “in combination with” can be deleted. So far, this entry "other hazards" is exceptionally excluded from the summation rule for health, physical and environmental hazards. However it could be split and referred to health and physical hazards which could slightly increase the scope. Data available indicate no significant impact on establishments covered.

Overall Impacts, Costs and benefits for "translatable" physical, environmental and other hazards

The suggested translation by the TWG of the non-toxic hazards leads to a practically unchanged scope and therefore the costs relate mainly to the change in classification, labelling and the update of the Seveso notifications.

Regarding alternative alignment options for categories related to the physical hazards, the main issue is with aerosols. The analysis of has shown that the suggested approximate one-to-one translation would maintain the current situation. However, this issue is included in this Impact Assessment Report under policy issue 2.

For environmental and other hazards, due to the one-to-one translation, no economic or other impacts have been found.

ANNEX VIII

Cost assumptions

This Annex sets out the basic cost assumptions on which the analysis in this study is based. They are drawn from the impact assessment studies undertaken. Although there is a degree of uncertainty over the impacts, the models and data used in the analysis are the best estimates we have based on the available data. In some areas only a qualitative assessment can be made. Moreover due to lack of data it is not possible to include in the impact assessment information concerning impacts on various types of affected parties (large companies vs. SMEs, UT vs. LT) and to show how benefits/costs evolve over time, except in a limited way

Compliance Costs

Costs of compliance include:

- Costs to establishments (divided on initial cost and recurring cost);
  - Administrative costs
  - Investment and operational costs related to physical compliance measures
- Cost to competent authorities (administrative costs - measured in time usage (days).

Any establishment facing a situation where it is about to become within scope of the Seveso II Directive might have the option of either complying with the Seveso requirements or avoiding to become within scope by supply chain adjustments - reducing its maximum stocks of dangerous substances.

One would assume that the company would evaluate the two alternatives and use supply chain measures to reduce stocks of dangerous substances if that option is cheaper than complying with the Seveso requirements. Thus, using the costs of complying with the Seveso requirements when assessing the impacts of scope change would give an overestimation of the total costs, as some establishments might chose to apply the supply chain adjustments to avoid becoming within scope.

It is not so simple to estimate the costs of physical modifications (infrastructure costs) as it is to estimate the administrative costs. A company that looks to optimise their operations could consider the risk of accident that they face:

- Identification of the events
- Consequence (impacts of each event)
- Probability of the event occurring

For each event they might assess relevant mitigation measures where each measure will reduce the consequence and/or the probability but will imply additional costs. There will be an optimum level of risk reduction based on the losses that the company will suffer if an accident will happen and the costs of reducing or eliminating the risk. The cost of an accident could comprise production losses, clean up costs, compensation costs in case of injuries etc. In most cases some prevention measures such as monitoring equipment, leakage detection etc will be profitable to

invest in based on the direct financial cost-benefit assessment. Not directly financial elements such as safe working environment, reputation etc will provide further incentives to reduce risks. On top of this, legislation on worker protection, product/equipment safety, etc might require additional measures to be taken. It is not possible to generalise about whether this will be sufficient to comply with any requirements for investment in physical measures stemming from the Directive.ives requirement with respect to. In some cases it might be sufficient and the company will only face the administrative costs as the additional costs of compliance with the Directive. Even if physical measures are required, the costs of such measures will be very site specific.

Each of the cost components are discussed in this section.

Overall, the impact assessment should be based on the additional costs or savings compared to a baseline situation. It is therefore cost differences and marginal costs that are the focus.

The amendment issues being investigated can result in either scope changes (changes to number of establishments being subject to the Directive) or changes in the specific requirements for those already in scope.

This section describes the total costs per establishment - a figure used to estimate the marginal costs of changes to scope. It also includes unit costs for certain requirements of the Directive, and these unit costs support the assessment of changes to these requirements. A unit cost is for example the cost of a safety report that upper tier establishments are required to prepare. If an amendment option would imply that lower tier establishments had to do the same, this unit cost is applied to assess the marginal costs of such a possible change to the Directive.

Administrative Costs

The following studies include relevant information and data regarding the cost of becoming and being a Seveso II establishment. These include:

- EU-VRi (2008) Study of the effectiveness of the Seveso II Directive, August 2008;
- UK (2005) Regulatory Impact Assessment (final) of Seveso II;
- Nutek (2006) Näringslivets administrativa kostnader på miljöområdet; and
- The estimates presented by FEA at the 4th TWG meeting;
- Administrative burden study[11];
- Data from European Committee for Surface Treatment - Plating section (CETS) regarding costs for the plating industry and in particular data on SME issues.
- Data from the International Association for Soaps, Detergents and Maintenance Products (AISE) regarding costs for this industry branch related to SMEs, retailers 'warehouses' and Seveso II compliance cost issues.

[11] FINAL REPORT (2009) Measurement data and analysis as specified in the specific contracts 5&6 on Modules 3&4under the Framework Contract n° ENTR/06/61Report on the Environment Priority Area, EU PROJECT ON BASELINE MEASUREMENT AND REDUCTION OF ADMINISTRATIVE COSTS.

In particular, the study from EU-VRi (2008) presents estimates of the costs to industry based on a survey. Estimates here suggest that costs for the safety report are 'less than 10 person months' for the major part of the respondents (62%). On average, the financial costs of the safety report ranges from EUR 20-50 k [12]. Implementation of the safety management systems are for the major part of respondents (75%) estimated to 'less than 10 person months', the same goes for the costs of emergency plans (81% of respondents). The major part of Competent Authorities (77%) did not have estimates on costs of administration. A general observation was that approximately half of the respondents have not estimated the costs of the Seveso II implementation.

The estimate of "less than 10 person months" is not very precise. Assuming that the other elements mentioned, the SMS and the IEP imply expenditure similar to the safety report, total costs would be about 60,000- 150,000 EUR. Though the costs of the SMS could be high, the IEP is less than the SR so this combined estimate of the total administrative costs is on the high side. As these are not annual costs, they should be annualised over at least 5 years. In doing so the annualised costs would be between 13,000 and 33,000 EUR per year. The average value would be a bit more than 20,000 EUR and would be for an upper tier establishment.

A study of the English COMAH estimates 'costs to business …' of the existing Seveso II requirements at GBP 42,000 (excl. control costs (present value over appraisal period). An appraisal period of five years (after which the safety report must be renewed), makes yearly costs at GBP 11,070, which equals roughly EUR 13,179. These numbers are for the lower tier of the COMAH - upper tier estimates range at GBP 255-268,000. The average GBP 261 500 translated into Euro *per year* equals EUR 62,256. [13]

A Nutek study (2006) estimates the total costs of implementing Seveso II in Sweden at SEK 2,203,440[14]. The report divides the costs on population and total hours. Although, the study does not reveal the number of establishments in Sweden, each cost of documentation demand can be divided by the population, and subsequently summarised on the different types of documentation. The calculation estimates cost per establishment ranging from SEK 13,350 to SEK 239,972, this equals EUR 1,298 - 23,328.

In sum, these three brief examples present an administrative compliance costs ranging from EUR 1,298 - 13,179 for the lower tier and EUR 23,328 - 62,256 for the upper tier per year.

The FEA cost estimates are based on data from the survey conducted by Atkins on behalf of the FEA. The costs of an establishment (not manufacturing) included in the Seveso II are displayed in the following table.

[12] EU-VRi (2008) Study of the effectiveness of the SEVESO II Directive, August, pp.46-47
[13] UK (2005) Regulatory Impact Assessment (final) of SEVESO II

[14] Nutek (2006) Näringslivets administrativa kostnader på miljöområdet

Aerosol Industry estimate of Seveso II costs

	Lower tier	Upper tier
Duty holder initial costs	197,000	568,000
Competent authority costs (first five years)	10,000	61,000
Duty holder ongoing costs (first five years)	30,000	183,000
Total costs	*237,000*	*812,000*
Total annual costs	*50,000*	*180,000*

Source: Atkins 2009 on behalf of FEA

As the table shows, the costs of becoming a Seveso II establishment are EUR 227,000 including the initial costs and current expenses. In addition, the costs to the competent authority are EUR 10,000 over five years. For the upper tier establishments these are about three times higher, at EUR 751,000 for the establishments (including ongoing costs for five years), and EUR 61,000 for the Competent Authority over five years.

The table indicates that administrative costs to the CA are about 4-8% of the industry costs. It is generally assumed that costs to the CA for inspection etc are 10% of the administrative costs to the industry.

In July 2010, the International Association for Soaps, Detergents and Maintenance Products (AISE) has provided the Commission, in addition to an earlier information from March 2010, with data collected from countries where sodium hypochlorite mixtures are largely used:

"Table 1 – SEVESO impact on SMEs and retailers' warehouses –

Number of sites impacted:

Country	SMEs If classification N, R50 applies to mixtures ≥ 4.9 % hypochlorite (active chlorine)	SMEs If classification N, R50 applies to mixtures at ≥ 2.5 % hypochlorite (active chlorine)	Retailers' warehouses
France	4	5	No data available
Italy	3	7	No data available
UK	No data available	No data available	57*
Spain	5	18	No data available

*Pilot study from a multinational company for measuring impact on customers in UK:

The company collected and summarised dispatch volumes of all sodium hypochlorite-containing -mixtures over the last 3 months of 2008. Average stock holding per week was determined, which was then extrapolated (based on market share) to the total market stock level for 141 retailer warehouses across the UK.

Out of these 141 retailer distribution centres:

- 84 (60%) had less than 100 tonnes of sodium hypochlorite-containing-mixtures on site and will not be affected by Seveso directive,
- 57 (40%) had on average above 100 tonnes of sodium hypochlorite-containing mixtures on site and would require low or high tier Seveso compliance.

Table 2 – SEVESO compliance cost estimation -

Data were collected from France. It should be borne in mind that the costs of compliance with the Seveso Directive may differ significantly from one country to another due to differences in implementation of the Seveso Directive.

Company	preliminary study lower tier	investments lower tier	investments upper tier	annual costs lower tier	annual costs upper tier
A	25 000 €	50 000 €	?	> 12 000 €	> 25 000 €
B	30 000 €	?	?	?	> 100 000 €

Notes:

- Annual insurance fees will increase dramatically for companies falling under the scope of Seveso.

- Not included in the calculation: safety management study, safety report, emergency plan, land-use planning.

Table 3 – SEVESO tonnages in production sites–

These are examples showing the impact of either sodium hypochlorite as a substance or packaged products for Seveso classification.

Company	Sodium hypochlorite tonnage (raw material, N, R50)	Mixtures packaged in limited quantities if classification N, R50 applies ≥4.9 % hypochlorite	Mixtures packaged in limited quantities if classification N, R50 applies at ≥2.5 % hypochlorite
C	100 tons	110 tons	460 tons
D	490 tons	410 tons	1390 tons
E	100 tons		350 tons
F	190 tons	55 tons	850 tons
G	65 tons	115 tons	700 tons"

AISE concludes in this paper that the above information is provided as a means to refine the impact assessment. AISE points out that the above information is based on their current understanding of the classification threshold (2.5% being the concentration limit based on an M-factor of 10 and 4.9% being the concentration limit based on test data on representative mixtures from the sector).

Administrative burden study

In January 2007, the EC launched an Action Programme to reduce the administrative burdens in the EU with a focus on the administrative cost from EU legislation. The Programme had 13 priority areas of which one is the environment. Within environment the Seveso II Directive is one of the Directives selected for particular attention.[15] The study has estimated that the Seveso II Directive has a yearly administrative cost of EUR 52 million in total[16].

The study covered the following main activities:

Written update of safety report (one every five years)

Written update of internal emergency plan (updated every three years)

Cooperation with inspectors (frequency not indicated)

Notification of presence or changes in presence of dangerous substances (5-10% of establishments every year)

Based on estimates of the time spent for each activity, the hourly salary for the relevant staff, consultancy support, and the number of occurrences, the total costs for each activity were estimated. Update of safety reports is most expensive at 19.7 million per year. The cost per establishment is therefore around 22,000 EUR. Updating of internal emergency plans is estimated to cost 13.9 million EUR. With the occurrence of once every three years, the cost

[15] http://ec.europa.eu/enterprise/policies/better-regulation/administrative-burdens/action-programme/index_en.htm

[16] *Conclusions of a DG ENTR study* as part of the Commission's programme of reducing the administrative burdens of EU legislation (which included the Seveso II Directive) 2009

per establishment is around 9,300 EUR. The estimated notification cost is around 8.1 million EUR and that is approximately 11,000 EUR per establishment.

Updating of safety reports and emergency plans are required by upper-tier establishments only, while notification applies to all Seveso establishments. Using these data to estimate the costs of a new establishment entering the scope of Seveso II means that the costs for a lower-tier establishment will be around 11,000 EUR, while the costs for an upper-tier establishment will be around 42,000 EUR. Annualising these initial costs, the lower-tier establishment will have annual costs of 2,200 EUR while the cost for upper-tier establishments can be estimated to 10,400 EUR.

These costs are for update of plans, etc and therefore less than what a company will face when it first falls within the scope of the Directive.

Costs from CETS – the metal finishing industry

During the Commission's general stakeholder consultation on the Seveso II Directive review, the European Committee for Surface Treatment provided data on costs and other information related to the industry's coverage by the Seveso II Directive.

Based on reporting from several Member States the CETS have collected data on costs of complying with the Seveso. Many of the companies within the industry are SMEs.

The collected cost data are summarised in the table below.

Netherlands		
	44	Annual costs from specific company
	49	Annual costs from specific company
	24	Annual costs from specific company
	21	Annual costs from specific company
	200-250	One-off entry costs - general estimate
Italy		
	25	Annual costs from specific company
	157	One-off entry costs from specific company
	178	One-off entry costs from specific company
France		
	1 to 5 million	One-off entry costs for upper tier - no actual upper tier company currently
Germany		
	30	Annual - one company
UK		
	25	Lower tier one-off (general estimates from study on costs of COMAH (2003)
	180	Upper tier one-off (general as above)
Denmark		
	24 -50	One-off entry costs

Source: European Committee for Surface Treatment (CETS) in undated paper (costs are from 2008 or 2009)

It is indicated in the table whether the data refer to upper or lower-tier establishments, although this information is not known for some of the examples. It is assumed that the costs refer to upper tier.

If one takes the average of the annual costs provided, the result is a value of 32,000 EUR, while the simple average of the one-off costs is 163,000 EUR.[17] From the reporting, it is not possible to identify exactly what is included in the stated costs. It seems that the main element is the administrative costs, though in some examples also physical modifications are included.

[17] This assumes that the 1-5 million costs for upper tier for France are excluded. The figure is significantly higher than any other data.

In terms of the difference between the one-off entry costs and the annual costs, it could be assumed that annual costs do not include any "depreciation" of the one-off entry costs. If the entry costs that are one-off are annualised over 5 years and 4%, the average annualised cost is about 37,000 EUR. Adding the two elements give a value of about 70,000 EUR as total annual costs for the first 5 years; thereafter the annual costs will be less - around 30,000 EUR.

The data from CETS includes also other relevant observations.

- They present an example of an SME investing 40,000 EUR in reducing the vats used in their manufacturing process in order to go below the Seveso threshold. There is no information about possible loss of income caused by this behaviour, but the investment cost suggests that it is cheaper to reduce the qualifying quantities of the chemicals used rather the complying with Seveso.

- The CETS paper compares the estimated Seveso costs with the typical turnover values for SMEs in metal finishing industry. The comparison indicates that with turnover values from less than one million EUR to about 10 million EUR, the share of Seveso compliance costs range from 0.5% to about 3%.

Summary of costs

The table below presents an overview of the cost data by source and the resulting costs used in this impact assessment. The best estimate is the average of the identified sources (except the high industry estimate); the low estimate is 50 per cent of the best estimate, while the high estimate is three times higher.

The cost estimates includes only the administrative costs for industry. The extent to which companies will need to invest in protection measures and reorganising of storage facilities etc is not known. Therefore costs could be higher for new establishments entering the scope of the Directive. In general, the costs of both safety plans and physical measures depend on whether safety management systems already existing due to other types of legislation, for example protection of workers. However, the estimates presented here are the best available estimates of the Seveso costs.

Overview of cost estimates in '000 EUR - total annual administrative costs per establishment

Source	Lower tier	Upper tier
EU-VRi (2008)	-	<20
UK (200x)	13	60
Nutek (2006)	1.3	23
FEA (2009)	50	180
CETS (2008/9)	-	≈70
Administrative Burden study (2009)[1]	2	10
Average used in IA	2-15	15-100
Low	2	15
Best	5	30
High	15	100

- Note 1) This is for updates of reports and plans

Differences in cost estimates

The EU-VRI report observes that the majority of respondents recognise that Seveso II implementation differs greatly across borders, and even within a given country (EU-VRI, p. 9).

The EU-VRi (2008) and the Administrative Burden studies are based on surveys or assessments covering in principle several Member States and industries and they are therefore likely to be more representative.

The variations in costs can be caused by many factors:

- Differences in actual implementation where some Member States have more demanding requirements than others;
- Cost and price level differences; and
- Cost elements included - though the above data in principle cover the administrative costs there could be physical measures included.

Cost differences between Member States

There are some data on country-specific costs from the Administrative Burden study. They have based the cost estimation on data from six Member States (CZ, FR, IT, LV, SK and ES). The country specific data show that there are differences in the time estimate for the different requirements and the unit costs (salary level) vary across Member States. There is a factor of up to 10 in the unit costs while the time spends varies by a factor 2.

The majority of the costs of Seveso II compliance are man-hour costs. They will vary with the price level in each Member State. It means that the relative burden is likely to be of the same order of magnitude across Member State measures as costs per GDP.

Cost assumption for specific requirements

Based on the Administrative Burden study, where data on time consumption and other cost elements have been compiled for key administrative requirements, the following cost assumption has been applied for the impact assessment.

Unit cost assumptions for administrative requirements - EUR per event

	Low	Best	High
Notification		3,000	
Notification of change		2,500	
Safety report – new	20,000	35,000	50,000
Safety report – update	15,000	17,000	20,000
IEP- new	6,000	8,000	10,000
IEP – update	3,000	4,000	5,000

Source: Final Report on Modules 3&4 for Environment Priority Area July 2009 - part of an EU (DG ENT) project on baseline measurement and reduction of administrative costs (which included the Seveso II Directive).

It should be noted that the costs above are unit costs per event and therefore higher than the annual average unit costs displayed in the previous table.

Non-administrative compliance costs

Should an establishment become a Seveso II site they might need to undertake investments in changes to their manufacturing process or to the way they store chemical substances. As discussed earlier, such costs are difficult to estimate

Such costs are difficult to estimate due the following factors:

- They are very site-specific and they vary with an order of magnitude;
- There is other legislation, both at EU and Member State level, for example regulations addressing worker protection, product/equipment safety, industrial emissions, etc, that might lead an establishment to invest in physical changes to equipment and installations to reduce the risk of a major accident.
- The level of safety systems in each Member State

The kinds of modifications that a site might need to invest in could include:

- Equipment to monitor processes and storage facilities;
- Additional storage capacity; and
- Containment infrastructure to prevent liquids leaving the site.

The costs of such investments will depend on the size and complexity of the establishment, the nature of its operations, and the hazard potential.

There are a few studies that have looked at the non-administrative costs under the heading of control costs. These studies cover the costs for UK industries of adapting to the Seveso requirements as they are implemented in the UK's COMAH regulation.

In the Regulatory Impact Assessment(RIA)[18] - made when implementing the 2003 amendments to the Seveso Directive - it is argued that the status of these control costs are uncertain and they show cost results both with and without the control costs. The main argument was that some of these costs in reality would have been incurred due to other legislation.

The control costs were assessed in two studies[19] - the later also providing a review of the data used in the first study. The combined results suggest that the costs for upper tier establishments are in the same order as the administrative costs. For lower tier establishments there is a large variation in the results of the two surveys and they could vary within a range of 5% of the administrative costs to be at the same order as the administrative costs.

The above discussed control costs relate the UK industry adoption of the Seveso requirements around 10 years ago. If the level of health and safety management in the European industry has generally improved, the costs for a non-Seveso site to enter within scope of the Directive today might be less than it was 10 years ago.

In addition to these factors making the data on physical compliance costs uncertain, there is also the potential financial benefits to consider. Savings from reductions in the frequency of minor incidents that typically lead to loss of production would be such a benefit. This element has not been considered in detail in the studies on the control costs.

On the basis of these data it is not possible to provide a sufficiently solid estimate to be used in this analysis. However, they suggest that the non-administrative costs would be at the maximum the same as the administrative costs.

It is also important to note that for nearly all of the specific amendment issues covered in this impact assessment study, the proposed changes will not affect the number of establishments and the options will have no or very limited impacts on the physical conditions at the sites and therefore not lead to physical compliance costs.

Industry adaptation to threshold

It is sometimes reported that companies adjust their stocks of substances to quantities below the relevant thresholds and thereby avoid coming within scope of the Directive. Such behaviour implies costs, but it is assumed that such downsizing only happens if the costs are less that the compliance costs of being within scope of the Directive. For options that could imply a change in scope, no adjustment is made for this effect that could lead to fewer changes to the number of establishments within scope of the Directive. Therefore, by using

[18] UK (2005) *Regulatory Impact Assessment* (final) of the 2003 amendments to the SEVESO Directive

[19] HSE 2003 *Safety report regime - evaluating the impact on new entrants to COMAH*, study by Entec UK Ltd for HSE.

HSE 2006, "*Impact evaluation of the Control of Major Accident Hazards(COMAH) Regulations 1999"* by Risk Solutions for the Health and Safety Executive 2006

the costs per establishments as presented above, the overall cost assessment will in principle overestimate the costs as some companies might find it cheaper to adjust stocks or production volumes.

The effect on the protection level of such behaviour is difficult to assess. If it leads to overall fewer sites holding dangerous substance, then it is positive; otherwise it could lead to a decrease if sites are not taking the necessary measures to reduce the risk of major accidents. If such behaviour leads to more transport of substances, this is likely also to decrease the protection level though transport activity is also subject to specific legislation regarding transport of dangerous goods.

Adaption through supply chain management to the Seveso thresholds can have unwanted effects, but it is difficult to avoid such behaviour as it is necessary to define thresholds in the Directive.

SMEs

The impact of the amendment options could be significantly different for SMEs compared with other operators. The general situation with regard to impacts of Seveso in SMEs is as follows.

There are no exact data on the share of SMEs out of the about 10,000 establishments currently covered by the Seveso II Directive. About half of the establishments are lower-tier, but this does not necessarily mean that a lower-tier site typically is an SME.

An industry questionnaire as part of the EU-VRi study included respondents also from SMEs. Out of 102 respondents 16 were from SMEs[20]. As this was a web-survey, it is not a very precise indicator for the share of SMEs.

The industry survey also covered the question of specific implementation issues for SMEs. The results suggested that guidance and other forms of support to the implementation of the Directive are particularly important for SMEs. There were also references to the cost burden being high for SMEs, but there were no further data included in the study to assess or validate these statements.

The data from the metal finishing industry provides an example of SMEs being upper-tier establishments, at least in some Member States. The industry association argues that the Seveso requirements comprise a significant burden on the industry. They quote numbers where the annual Seveso costs amount up to several percentage points of the annual turnover.

Using the unit administrative costs as presented above, a rough assessment can be made. The estimated annual cost is the order of 5,000 EUR for lower-tier sites and this would be equivalent to 0.5 % of total turnover for a company with a turnover of 1 million EUR. If the profit rate of such a company is assumed to be 10% of turnover, the administrative costs would be 5% of the profit. On its own, this not a high burden, but combined with many other pieces of legislation it could an issue for certain SMEs.

[20] EU-VRi (2008) Study of the effectiveness of the SEVESO II Directive, August, pp.44-45

If the SME, as in the case of the metal finishing industry, is in many cases upper-tier, and using an average value of 30,000 EUR, the share of Seveso costs in turnover is around 3% as quoted by the industry and using the assumption of profit of 10% of turnover, the costs for an upper-tier SME could be of the order of 30% of the company profit.

Total costs of the Seveso II Directive

It is relevant to be able to compare the changes in costs that could results from the amendments being considered in this impact study to the total costs of the Directive.

The total costs have not been subject of any identified study. Various previous assessments have addressed certain aspects. The Administrative Burden study provides an estimate of the administrative costs to industry (operators). Compliance costs in physical modification are very difficult to assess as described above. The Admin Burden study estimates the total administrative costs of Seveso II to be in the order of 52 million EUR.

The costs to the competent authorities have not been directly assessed. The study on the effectiveness of implementation[21] includes replies a number of respondents on the average man-years used for Seveso in the organisation they represent. In most Member States there are several organisations that have a formal role in the implementation of the Seveso II Directive. By assuming an average number of organisations with responsibilities in the implementation, it is possible to make a rough estimate of the total costs for competent authorities in Member States.

Based on ERM (2009), the average man-year per organisation can estimated to roughly 5 and assuming that there are 3 organisations involved in each Member State the total number of man-years is about 400. Assuming an average day rate for experts of 500 EUR, the total annual costs would be the order of 40 to 50 million EUR.

The UK RIA referred to above also includes an assessment of the implication to the competent authorities authorities involved - for example the emergency services. The data indicate costs per establishment of in the order of 10k EUR per year and 40k EUR per year respectively for lower and upper tier establishments. This suggests total costs for competent authorities and other public authorities in the same order or even higher than the administrative costs for the operators. Applying these estimates to provide EU wide costs would most likely be an overestimation as the UK costs are higher than the EU average. It suggests though that the above estimate of 40-50 million EUR is at the lower end and that the costs to Member States competent authorities could be higher.

This leads to an overall estimate of the total administrative costs to both industry and CAs to be at least in order of 100 million EUR. Though it should be emphasised that this is only an order of magnitude estimate, it provides nevertheless a basis for assessing the cost of the various amendments.

<u>Administrative cost impacts estimates used for policy issue 1 (Seveso Annex I alignment)</u>

All estimates and assumptions are taken from the COWI Impact Assessment Studies.

[21] ERM (2009) Seveso II Directive - Study of the Effectiveness of the Requirements Imposed on Public Authorities

COWI used the following general assumptions to calculate the cost impacts for industry:

- Establishments that are already Seveso II sites might not experience much cost savings as a result of the changed status. They have already invested in safety reports, safety systems and emergency plans and in physical modifications, if those were necessary. They will only save on future updates of the plans.
- Review notification/safety report: The costs of such reviews are difficult to estimate. Only purely illustrative calculations can be used with the following assumptions:
- The reclassification process already started should be regarded independently from the Seveso adaptation to the CLP and is not included in these cost estimates,
- Technical protection measures are in place and no investment in technology, construction etc. is necessary,
- Overall costs are incurred reviewing existing inventories, reviewing and understanding the new Annex 1 and notifying changes
- There is likely to be asymmetric effects so the cost savings for one establishment falling out of scope will not offset the additional costs for a new establishment coming into scope. The total aggregated costs could therefore increase, even if there is no net increase in the number of establishments falling within scope.
- Each company spends one to three days on reviewing the substance and mixture inventories (average 1.5 days) in addition to the CLP motivated reviews;
- The number of non-Seveso II establishments that need to make reviews in order to determine if they might fall within scope is assumed to be 50% of the number of Seveso II establishments;
- The total number of Seveso II establishments is approximately 9725 and these will need to review their inventories;

An average annual day costs is assumed to be EUR 350.

For policy option 1, 3 types of costs have been considered:
1) CLP adjustment costs for all establishments;
2) General adaptation costs for such establishments using toxic/very toxic substances
3) Change of scope costs/savings.

1) All Seveso operators have to review their inventories in the light of the new Annex I and provide information about the CLP adjusted substances, mixtures or categories to the authorities. For all Seveso establishments and for all hazards, the total one-off Seveso-related CLP adjustment costs for reviewing inventories have been estimated for operators at around 1.7 Million EUR (7.6 Million annualised over 5 years at 4%), which represents an average of around 200 EUR per establishment, per year. In addition to the costs for industry, the adjustment costs for authorities would be around 400.000 EUR per year (1.8 Million over 5 years).

2) The costs for the general adaptation have been taken from COWI's Impact Assessment Study. COWI has estimated the general adaptation costs for option D as 1,700,000 Euro and for B and C (with differentiation of exposure routes) as 2,900,000 Euro. The figure for options C and D have been taken, and the figures for E and E* estimated as 2,000,000 Euro, in between C and D, but closer to D.

3) The change of scope costs/savings in this assessment are based on the COWI figures, but had to be modified due to the following two reasons: Firstly, COWI has not assessed in detail options E and E*, and second and more importantly s the COWI options C and D were

calculated with a compensation mechanism of named substances, leading to different numbers of establishments, and accordingly to different costs related to the change of scope.

The costs for a change in scope have been calculated by COWI as follows, for

- A reduction of 88 sites (-54 lower tier, -34 upper tier) to -1,300,000 Euro, and
- An extension of 133 sites (65 lower tier, 68 upper tier) to +2,400,000 Euro.
- A reduction of -342 sites (-206 lower tier, -136 upper tier) to -5,100,000 Euro.

The costs for upper establishments coming newly under Seveso are estimated with annual costs of around 30,000 EUR and for lower tier establishments of around 5,000 EUR. Establishments already Seveso II sites might not experience much cost savings as they have already invested in safety reports, safety systems and emergency plans. They will only save future updates of plans. Therefore the cost savings are only estimated of around 50 % of the change of scope costs (15,000 EUR and 2,500 EUR respectively). The distribution between lower and upper tier sites is roughly 50/50; the exact distribution for each area assessed is included in Annex VII.

Taking into account the similarities, this IA report comes to the following figures

Option	General adaptation (1)	Change in scope costs (2)		
		a) T+ alignment b) T alignment	b) T alignment excluded sites	b) T alignment newly included sites
C	2.9	-2.5	-0.1	+2.2
D	1.7	-2.5	-	+5.7
E	2	-2.5	-0.8	+0.2
E*	2	-2.5	-0.8	+3.7

Short explanation per option:

- Option C: Adaptation costs: same as COWI; Scope change -2%, Annual savings for 324 sites, costs for 131 new sites;
- Option D Adaptation costs: same as COWI, Scope change +0.3 %: ~ 1/3 COWI option D, Annual savings for 314 sites, costs for 342 new sites;
- Option E: Adaptation Costs slightly higher than D, but lower than C (differentiation exposure routes, but no differentiation within Inhalation); change in scope savings for 415 sites costs for 10 new sites;

- Option E*: Adaptation Costs same as for E, change in scope savings for 405 sites, costs for 221 new sites.

Competent Authorities

Authorities will have one-off costs of adapting to a revised Annex I (review notifications; update, control/translation of chemicals databases and IT). To estimate how much time each CA will use on such a one-off review of the implications of the changes to the Directive. Using the following assumptions, a rough estimate can be made:

• Each Member State would spend about 50 days to review the necessary changes to national implementation;

• The CAs would then use one day to review site-specific Seveso II permits for 40% of all Seveso II establishments (i.e. about 3900);

• An average annual day costs is assumed to be EUR 350.

The effort that the transition to the CLP legislation will imply could possibly be reduced if more tools were available. Harmonised translation tables or even electronic translation tools would reduce the administrative costs. They would not include all the self classified substances but still could be a useful measure to reduce the administrative burden.

ANNEX IX

Costs and benefits of options for Policy Issue 3: Procedures for adapting Annex I in the future

For more information about the basis for the cost calculations please refer to section 3.1 of the COWI impact assessment study (7).

Costs and benefits of Option (a): Unchanged policy

The no-change option could lead to new substances being included in scope which present no major accident hazard. Given the limited scope of the existing derogation rule (see below), this could lead to significant additional costs, although it is difficult to quantify these. If it is assumed that there are 20 such substances, and their inclusion under the scope of the Directive would increase the number of both lower and upper tier establishments by 5%, this would equate to about 250 lower and upper tier establishments. Based on the administrative cost assumptions in Annex VIII and applying a cost of 5,000 and 30,000 EUR per lower/upper tier establishment per year as average administrative costs, the total annual costs would be around 8 million EUR for industry (plus 800,000 EUR for competent authorities). However this assumes that the establishments concerned only fall into scope because of those new substances and are not already caught because of other substances in their inventory. There would be no impact on protection levels.

The no-change option would also mean that amendments to Annex I would continue to be via co-decision, which could entail significant administrative costs for Member States, the Commission and the co-legislators. In cases where a substance should be added to Annex I, the protection level (environmental, health and social) could be adversely affected due to the length of time needed for possible amendments to the Annex I to be adopted.

Costs and benefits of Option (b): Extend scope of existing derogation rule

This option would give rise to increased costs for industry and competent authorities in dealing with derogation requests, but it is difficult to quantify these. The benefits in terms of savings for operators would depend on how far the scope of the derogation was extended beyond information requirements in relation to the safety report, but would be less than options (c) and (d). There would be no change in protection levels.

There would need to be strict adherence to the harmonised criteria in order to ensure that operators are treated equitably so that there is no risk of possible distortions to competition.

Costs and benefits of Option (c): general derogation rule at EU level

The costs of this option would be the administrative costs for industry, the competent authorities and the Commission in dealing with derogation requests. It is estimated that that these would be about 300,000 EUR per annum. However such costs could be more than offset by the benefits in terms of savings from any derogations that resulted in establishments being exempted. The option would bring benefit in terms of bringing greater flexibility to the Directive's application. There would be no change in protection levels.

Costs and benefits of Option (d): general establishment specific derogations at Member State level

The potential costs and benefits of this option would be potentially greater than for option (b), but are difficult to estimate. It would allow greater flexibility in the application of the Directive at Member State level but the risks of possible distortion to competition would also be greater so there would need to be close monitoring to ensure that the criteria were being respected.

Costs and benefits of Option (e): safeguard clause

The impacts will depend on how often such a clause is used. In any specific use of such a clause, the benefit will be an increased protection level for human health and the environment. The costs will be the compliance and administrative costs for industry and the competent authority.

The benefits of using delegated acts to effct changes to annex I from application of options (c) and (e) would be increased speed, flexibility and efficiency in amending Annex I. The administrative cost would be relatively limited since the task would be taken up by the Commission using existing consultation procedures. The protection level would remain the same or slightly increase.

ANNEX X

Costs and benefits of options for Policy Issue 4: Information to the public and information management systems including reporting

For more information about the basis for the cost calculations please refer to section 3.1 of the COWI impact assessment study (7).

A) Options for type of information provided

Costs and benefits of Option (a): Unchanged policy

This no-change option would impose no additional costs on operators or public authorities and bring no improvements in information provision.

Costs and benefits Option (b): Annex V information made available on line

This option goes beyond the existing situation by requiring that information currently covered by Annex V should be available online.

As all Member States can be assumed to have governmental websites where this information could be placed, no further data management system would be needed. Moreover since this information should be produced already there should be no significant additional costs to competent authorities or operators. For operators it is estimated that the total one-off costs would be about 1 million EUR. Maintenance costs would be limited

The benefit of this option would be that it would be easier for the public to access the information and easier for each competent authority to monitor that it is actually available.

Costs and benefits Option (c): Additional information

This would extend the Annex V requirement in two ways. Firstly, basic data such as name, location and activity for all establishments would be included. Secondly, for all upper-tier establishments, information would be included about the main type of major accident scenarios and the events that could trigger each of these scenarios as well as appropriate information from the external emergency plan.

The former would not entail any significant additional costs since this information is produced already and submitted to the Commission's SPIRS database. For the latter, it is estimated that there would be total one-off costs of 2-4 million EUR to produce such information for all upper-tier establishments. The annual costs of updating the information would be about 0.5 million EUR.

In addition to the benefits of option b), this option would ensure that some clear basic information about the nature of the accidents hazards and information on how to behave in case of an accident is provided. This is likely to facilitate a more adequate response in case of a major accident taking place and thereby reduce the impacts of such accidents. It could also help operators and competent authorities draw lessons from the best practices of others.

Costs and benefits Option (d): Additional information plus non-technical summaries of key documents

This option would add to option c) by requiring in addition non-technical summaries of the key documents, the safety report, the internal and the external emergency plans, to be made publicly available.

It is estimated that, assuming that non-technical versions of all three documents would cost around 10% of the costs to produce the full technical documents, the total one-off costs for all upper-tier establishments could of the order of EUR 20 million (of which EUR 3 to 4 million would be costs for competent authorities) assuming that no such documents are currently produced. On the assumption that the information would need to be updated every three years, the average total annual costs of updating the material would be around EUR 2-5 million.

The additional benefit of this option compared with option c) is that this more detailed information from the non-technical summaries will further increase the population's awareness of the possible risk scenarios and the of the need to understand and follow the advice included in the emergency plans. Furthermore, it will generally inform the interested public about major accident potential issues.

Other impacts of options (b) to (d)

Underlying these options is the need to ensure that the provisions, including those in Article 20 of the Directive on confidentiality, are brought into line with the provisions of Directive 2003/4/EC on public access to environmental information. (Likewise the provisions on public consultation in the context of the development of external emergency plans and land-use planning procedures need to be brought into line with Directive 2003/35/EC on providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment). At the same time transparency and openness needs to be balanced against security and other confidentiality concerns.

The more information that the public should have access to, the more effort is required in defining in each case where the balance lies, which could potentially increase the costs, particularly for competent authorities. It is very difficult to estimate these costs as it depends on how many establishments there are where confidentially and/or security issues are significant. Moreover these costs are not necessarily additional costs as Member Status should already be making such assessments.

Another possible impact, which cannot be quantified, is that detailed information could reduce the prices or property neighbouring Seveso sites. It could also generate public pressure to reduce the risks or to re-locate certain establishments.

<u>B) Options for information management</u>

Costs and benefits of Option (a): Unchanged policy

This no-change option would maintain the status quo, with the generally fairly limited on-line systems. It thus imposes no additional costs on operators or public authorities and brings no improvements.

Costs and benefits of Option (b): Member State databases

This option would require all Member State to have a system that allows public access to relevant information for each establishment.

Given that establishing this would require only a simple website structure and uploading relevant documents and information for each establishment, this should not entail significant resources. It is estimated that do this the total one-off costs would be about 1 million EUR. Maintenance costs would be limited.

The benefit of this option would be that it would facilitate the online availability of options (b) to (d) in part A) above in relation to the type of information to be made publicly available. Having to upload information for each establishment will make it easier for Member States to monitor that this information (which is required to be publicly available) actually exists and is available. In principle it should therefore help to reduce enforcement costs once the system is in place, though this benefit can not be quantified.

If such a database also included information relevant for the purposes of Member States' implementation reports pursuant to Article 19.4, this could facilitate and streamline such reporting.

Costs and benefits of Option (c): central EU wide database version 1

This option would establish a central website that can be used to access information in all Member States either through links to documents directly uploaded on to it or links to Member State websites/databases.

Establishing a central database as described here would not be very costly as it used existing it infrastructure and existing databases. If links or documents need to be made/uploaded for all 10,000 establishments and it will take an hour for each establishment, the total set-up costs would be around 0.5 and one million EUR. The operation and maintenance costs would depend on how frequent the database should be checked - probably half to a full man year per year would sufficient which could cost about 50,000 to 100,000 EUR per year.

In addition to the benefits of option (b), it has the added benefit that it will make sharing of relevant information more efficient. Not only will it provide easier public access to the information, it will also support the competent authorities in their activities.

Costs and benefits of Option (d): central EU wide database version 2

The option of centralised database with all information integrated within it would be a more resource intensive solution and would necessitate Member States adapting their existing systems.

The specific costs of such an approach cannot be estimated without a detailed analysis of the system requirements, but are likely to be very substantial.

The benefits of this option would be the same as option (c).

Other impacts

Options (b) to (d) would provide a structure that could help to simplify and streamline Member States' implementation reporting pursuant to article 19.4 of the Directive.

ANNEX XI

Costs and benefits of options for Policy Issue 6: clarifications to facilitate effective implementation

A) Closer coordination, integration of information and procedures, etc

See section 5.6.2 of this report

B) Other issues where clarifications are needed

Safety performance indicators

For further information about SPIs and the effects of using them, cots etc please refer to section 5.6.1 of the COWI impact assessment study (7).

Costs and benefits of Option (a): Unchanged policy

This would have no impact on costs or the level of protection compared with the current situation.

Costs and benefits of Option (b): Mandatory requirements

Making SPIs mandatory will lead to costs of developing and implementing the right SPIs at each site. If it is possible to define a standard set of the right SPI that can be immediately applied these costs for each site could be reduced but then there will be costs for CAs and the Commission in developing such a standard set of the right SPIs. There could be some benefit in terms of improving protection levels, by increasing the focus on safety culture and management. *Costs and benefits of Option (c): Non-binding requirements*

This option would be less costly since the use of SPIs would be optional. It could potentially have the same benefits as option (b) but would provide flexibility to Member States.

Costs and benefits of Option (d): Guidance

This option would not be costly as the work could be contained within existing administrative costs. Guidance could help to improve the use of SPIs and help contribute towards improved protection levels

Domino effects

Costs and benefits of Option (a): Unchanged policy

There would be no impact on costs or protection levels, which would however be less than optimal.

Costs and benefits of Option (b): Include additional requirements

Under this option, there would be clearer obligations in Article 13, relevant provisions in Article 6(notifications) and Annex II (safety report) to take account of external factors and possible domino effects.

The costs are likely to be low assuming that operators already consider external factors. Improved dissemination of information to non-Seveso sites should not be resource demanding and will be part of the general improvement to the provision of information to the public.

The impact on the protection level is difficult to assess due to the lack of data in relation to domino situations, but is likely to be positive.

Underground gas storage sites

Costs and benefits of Option (a): Unchanged policy

The no-change option would have no impacts in terms of costs or benefits. The present uncertainty over whether such sites are caught by the Directive would remain, resulting in differences of treatment between Member States.

Costs and benefits of Option (b): Include within scope of Directive

According to a Commission survey in 2008, in total there are about 150 underground gas sites in the EU, of which 100 are already covered national legislation implementing the Directive.

The economic impact of including the remaining 50 sites would be in order of EUR 1.5 million annually assuming that all sites would become upper tier establishments. (Currently around 90 per cent of the sites qualify as upper tier establishments).

The benefits of this option are there would be a level playing field for all establishments. Furthermore the protection level would be increased given the significant major accident hazard potential associated with underground gas storage facilities.

Environmental effects

Costs and benefits of Option (a): Unchanged policy

The no-change option would have no impact on costs or benefits. There would remain a potential gap in terms of the level of protection.

Costs and benefits of Option (b): Include more details in Annex II, Annex IV and Article 12 (land-use planning)

This option has three separate components involving inclusion of more specific references to environmental aspects as follows: in the safety report (Annex II); in emergency planning (Annex IV) and land-use planning (Article 12).

These options are not alternatives and are assessed together.

To the extent that environmental aspects are not already being addressed, there could be slight increases in costs as regards developing and updating safety reports and emergency plans. The impact on costs in relation to land-use planning could be higher in terms of additional time and resources needed to make environmental assessments and possible physical mitigation measures, but these cannot be quantified.

All the components would increase the protection level in relation to environmental impacts.

Deadlines for External emergency plans

Costs and benefits of Option (a): Unchanged policy

The no-change option would have no cost implications or impact on the existing level of protection. However the lack of any specific deadline for completion of the plans has give rise to delays which could have a major adverse impact on as a result of reporting.

Costs and benefits of Option (b): Specify a 12 months deadline

This would not involve any additional costs since external emergency plans have to be developed in any case. There would be a positive impact on the level of protection.

Reporting of accidents

Costs and benefits of Option (a): Unchanged policy

No clear data are available on the costs to operators and competent authorities of reporting accidents, but these are not significant. The no-change option would have no impact on these costs or the existing level of protection as a result of reporting.

Costs and benefits of Option (b): Deadline for reports

Since reports have to be submitted anyway, imposing a deadline would not have any impact on costs. This option has the benefit that it would speed up reporting and could lead to improvements in the protection level through early dissemination of lessons learned from accidents.

Costs and benefits of Option (c): Reduced reporting threshold

If the current threshold were to be reduced to 5% of the lower tier thresholds or 1% of the upper tier thresholds, it would reduce the threshold by a factor of 4-5. For example, the difference between LT and UT thresholds varies by a factor of 2 to 10; for most hazard categories it is around 4. It is estimated that such a reduction could lead to an additional 20 major accidents being reported (compared with an annual average of around 30 at present), with a corresponding increase in costs, though overall these would remain moderate(according to the administrative burdens study the total annual costs for operators of reporting accidents is 47,000 EUR)

The benefit of this option is that if more accidents are being reported, this will increase knowledge and lessons learned, which should ultimately help to improve prevention of similar accidents and lead to higher levels of protection.

Safety management requirements for lower-tier establishments

Costs and benefits of Option (a): Unchanged policy

The no-change option would have no impacts in terms of costs or benefits. The present uncertainty over interpretation of Annex III would remain, resulting in differences of treatment between Member States.

Costs and benefits of Option (b): Clarify existing text of Annex III

This option would clarify that an SMS should be proportionate to the hazards (and that this should be reflected in the underlying documentation and procedures). This is unlikely to have much impact on costs. It should make implementation easier and could reduce for competent authorities and industry by avoiding questions and clarifications about the content of the MAPP and its relationship to the SMS. However it would also allow those Member States who impose stricter rules to continue to do so. There is unlikely to be any impact on protection levels.

Costs and benefits of Option (c): Require full safety management system

There are no data available on the specific costs of introducing a SMS so it is difficult to quantify the costs of this option. However these could be quite substantial.

It is estimated that about two thirds of the Member States already have requirements similar to SMS for lower tier establishments. However these requirements are often proportionate to the size of the establishment, degree of risks etc. Moreover the level of safety management systems varies across establishments. This means that those that might already have formulated a SMS could incur limited additional costs, whereas those that do not have any formalised safety system would need to set up and document a SMS, which could take a lot of time and resources.

The benefit of this option is that protection levels would increase since safety management systems make a significant contribution towards enhancing safety. However extending the requirements for lower-tier establishments in this way would undermine the principle of proportionality in the existing two-tier approach of the Directive.

Costs and benefits of Option (d) mini-safety report, including internal emergency plan

Preparing a safety report is one of the most expensive administrative requirements. One of the important elements of the safety report is the work of defining and analysing major accidents scenarios, which can be a resource-intensive exercise.

As a minimum, to be of use a min-safety report would need to be based on one or two major accident scenarios.

It is roughly estimated that the costs of such "mini" safety report would be between 25% and 50% of the costs of a full safety report (the average cost of which is estimated as 35,000 EUR). If the lower percentage is used, the best estimate for the average costs of preparing a mini SR is about 8,750 EUR. An equivalent "mini" internal emergency plan is estimated at EUR 2000. In total these administrative costs will be 10,750 EUR per lower tier site. Based on a survey of existing national requirements, it is assumed that 50% of the Member States (and establishments) already have similar requirements for lower tier. So the estimated total additional one-off cots of this option are 25 million EUR.

There would be increased benefits in terms of the level of protection compared with option (c). However it would also have the same disadvantage of undermining the existing two-tier approach.

Costs and benefits of Option (e): Combination of options (c) and (d)

This would imply significant additional costs compared with the other two options.

Protection levels would be even further increased, but the existing two-tier approach would be completely nullified, there being effectively no longer any distinction between upper- and lower-tier sites.

The following table summarises the impacts of alternative options (b) to (e):

Overview of impacts of lower tier options

	LT in %[1] of full	Cost per lower tier in EUR	Total costs in EUR	Protection level
Clarify the text in the Directive	Na		Possible marginal savings	No impact
Extend full SMS requirement (as described in Annex III) into LT	100%	Potentially high	Potentially high	Increased
Require 'Mini' safety report including IEP for LT	25%	10,750	25 million one-off	Increased
Require SMS, IEP and mini SR for the LTs (combination of the second and third options).	25%	> 11,000	> 25 million one-off	Increased

1 Note 1): The costs of the LT requirement in % of the costs of the upper tier requirement e.g. costs of "mini" SR in % of SR.

The impact on the protection level from increasing lower-tier requirements is difficult to quantify. There is no consensus among Member States experts about whether risks are less for lower tier - some see little difference. As for the economic impacts where it is assumed that about 50% of the Member States already have additional requirement, also for the protection level some of the effect should already be realised and impact will be less than if no Member States had additional requirements. Overall an increase in requirements that prompt better safety culture and systems should have an impact on the risks of major accidents, though it can not be quantified.

ANNEX XII

Summary table options:

Option component	Economic impacts, inc change of scope for policy issue 1[22]	Protection level[23]	Other impacts including simplification, administrative efforts, etc
Policy Issue 1: Alignment of Annex I	% Change of scope (economic impact)		
C	-2% (Costs up to +2.5 million EUR)	Small decrease (Exclusion of the dermal and inhalation vapour exposure routes)	Higher administrative costs due to differentiated exposure routes
D	+0.3% (Costs up to 4.9 million EUR per year)	Small increase (Inclusion of Acute Toxic 3 complete)	No change (Acute Toxicity categories 1,2,3 intact)
E	-4.2% (Savings up to 1.1 million EUR per year)	Decrease (Exclusion oral and dermal exposure route	Slightly higher due to partly differentiated exposure routes
E*	-1.9% (Costs up to 2.4 million EUR per year)	Small decrease (Exclusion oral exposure route for Acute Toxic 3)	Slightly higher due to partly differentiated exposure routes
Policy Issue 2: other technical amendments to Annex I			
Hydrogen: a) do nothing	Neutral	Unchanged	
Hydrogen: b) to grant an alleviation by doubling the threshold	Neutral/limited impacts	Unchanged/slight decrease	
Heavy fuel oil: a) accept possible re-classification effect	Neutral/limited impacts	Unchanged/possible slight increase	
Heavy fuel oil: b) avoid the possible effect by listing as named substance with other petroleum products	Neutral	Unchanged	

[22] Economic impacts are administrative costs. Non-administrative compliance costs, for example related to such physical modifications have not been considered as they are very site specific and it has not been possible to quantify these.

[23] The protection level aspect covers protection against environmental damage, against damage to human health and against damage to public and private property. Therefore the environmental and part of the social impacts follow directly the results regarding the protection level.

Option component	Economic impacts, inc change of scope for policy issue 1[22]	Protection level[23]	Other impacts including simplification, administrative efforts, etc
Aerosols: a) the CLP approximation proposal of 150/500)	+ App. 0. 5 million EUR per year	Unchanged/ slightly increased	
Aerosols: b) higher threshold	- 3 to 4 million EUR		
Sodium hypochlorite: a) accept CLP re-classification effect for mixtures	+ Up to 3.5 to 4 million EUR per year	Increased	
Sodium hypochlorite: b) exemption	Neutral/limited impacts	Unchanged	Sets a precedent
Policy Issue 3:Procedure for changing Annex 1			
3 a) Do nothing – no extension of existing derogation provision	No impact	No impact	Unwarranted CLP effects not correctable
3 b)/d: Allow Member States to grant derogations from some or all Seveso requirements based on harmonised criteria	Potential savings for industry and CAs	No or low impact (condition for derogation)	Potential risk of market distortion
3 c): Allow EU wide substance derogations from some or all Seveso requirements based on harmonised criteria	Potential significant savings for industry and CAs	No impact (condition for derogation)	Allows flexibility in light of CLP
3 e) Introduce Safeguard clause	Potential increase in scope	Potential increase	Allows flexibility in light of CLP
Policy Issue 4A – Type of information to the public[24]			
a) Do nothing – Information as currently required by Annex V	No additional costs	No impacts	
b) Annex V information on-line	One-off costs around 0.5 to 1 million EUR 50,000-100,000 per year in maintenance plus some Member State costs	Slight increase	Better access to information
c) Additional information on basic data for all sites plus	One-off costs around 2-4 million	Increase. Improvement in	Better access to information. Less

[24] Confidentiality issues will be considered (see discussion in section 2.4)

Option component	Economic impacts, inc change of scope for policy issue 1[22]	Protection level[23]	Other impacts including simplification, administrative efforts, etc
accident scenarios and key information from external emergency planfor upper tier (revised Annex V) on line	EUR Annual costs up 0.5 million EUR	information available	consequences in event of accident Aids lessons-learning and exchange of best practices, monitoring of actual implementation etc. Improved, transparency.
d) Additional information plus non-technical summaries of SR and EEP on line	One-off costs from up to 20 million EUR Annual costs of up to 2 million EUR	Increase. Significant Improvement of information available	As above
Policy Issue 4B: management of information			
a) Do nothing – continue with current Member States systems	No additional costs	No improvements in Member States provisions	
b) Member States databases (same databases/costs as in 4 A)b), repetition)	One-off costs around 0.5 to 1 million EUR 50,000-100,000 per year in maintenance plus some Member State costs	Slight increase	Better access to information
c) Information management: Simple website with links to documents either directed uploaded on the EU site or links to Member States websites with the information/documents	50,000-100,000 per year in maintenance plus some Member State costs One-off costs of 1 million to set up link/upload documents	Increase. Significant Improvement in information available	As above. Plus more harmonisation, less fragmentation, streamlining and simplification
d) fully integrated central EU database	Substantial costs to adapt all existing systems to one database format	As above	As above
Policy issue 5: land-use planning			
a) do nothing	No costs	No impacts	

Option component	Economic impacts, inc change of scope for policy issue 1[22]	Protection level[23]	Other impacts including simplification, administrative efforts, etc
b) minor clarifications	No costs or potential savings	Limited impacts	
c) extend requirements	Potentially very costly with one-off costs of several hundred million or billions EUR	Significant increase	
Policy issue 6A: Closer coordination, integration of information and procedures, etc	Cost savings of approx 0.5 million EUR per year (coordination of inspections). No additional costs	No impact or slight increase in protection level	Simplification. Greater efficiency. More harmonised implementation
Policy issue 6B: other improvements/clarifications			
Safety performance indicators			
a) mandatory requirement to use SPI	Potential significant costs	Potential increase	
b)Include reference to the use of SPI for internal safety	No additional costs	Potential increase	
c) Guidance	No additional costs	Potential increase	
Safety management requirements for LT sites			
a) Clarify existing provisions	No significant change/potential small savings	No change	
b) Increase safety management requirements for lower tier to include SMS	Potential significant costs	Some increase	Many Member States already have such requirements. two-tier approach
c) Require mini-safety report and internal emergency plan for LT sites	25 million EUR one-off costs	Increase	As above. Further undermines two-tier approach
d) Require SMS, mini- safety report and IEP	More than 25 million EUR one-off costs + app. 1 million EUR annually		
Other clarifications (such as underground gas storage, domino effects, environmental aspects, deadlines for emergency plans, and deadlines and thresholds for accident reporting	Limited additional costs (1.5 million EUR annual cots for underground gas storage)	Increase	

ANNEX XIII

GLOSSARY:

ATE	Acute Toxicity Estimates
CA	Competent Authority
CCA	Committee of competent authorities for the implementation of the Seveso II Directive
CCS	Carbon Capture and Storage
CLP	Classification, labelling and packaging, stands for Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures
CLWP	Commission Legislative and Work Programme
CO_2	Carbon Dioxide
COM	European Commission
COWI	COWI A/S Consultancy, DK-2800 Kongens Lyngby, www.cowi.com
DPD	Dangerous Preparations Directive (DPD)
EEP	External Emergency Plan
EIA	Environmental Impact Assessment
GHS	UN **G**lobally **H**armonized **S**ystem of Classification and Labelling of Chemicals
H_2	Hydrogen
HSE	Health and Safety Executive (UK authority)
IEP	Internal Emergency Plan
IPPC	Integrated Pollution Prevention and Control Directive
INSPIRE	Infrastructure for Spatial Information in the European Community (Directive 2007/2/EC)
ISSG	Inter-Service Steering Group
KPI	Key Performance Indicator (CostKPI)
LPG	Liquefied Petroleum Gas
LT	Lower Tier Seveso establishment (Article 6 and 7)

MARS	Major Accident Retrieval System (Seveso accidents database, 2009: eMARS)
MAPP	Major Accident Prevention Policy
MJV	Mutual Joint Visits (Seveso Inspection Programme)
MS	Member State
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation 1907/2006)
SEA	Strategic Environmental Assessment'
SEVESO	Directive 96/82/EC (Seveso II Directive)
SEIS	Shared Environmental Information System
SMEs	Small and Medium sized Enterprises
SMS	Safety Management System
SPI	Safety Performance Indicator
SPIRS	Seveso Plants Information and Retrieval System (Seveso sites database)
SR	Safety Report (Article 9 Seveso obligation)
TWG	Technical Working Group, here TWG "Seveso and GHS"
UT	Upper Tier Seveso establishment (Article 9)