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**COMMISSION STAFF WORKING DOCUMENT**

**SUMMARY OF THE 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**

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## 1. PROBLEM DEFINITION

### *Problem addressed by the Seveso Directive*

Chemical accidents often have serious, even devastating, consequences. Some well-known major accidents like Seveso, Bhopal, Schweizerhalle, Enschede, Toulouse and Buncefield have taken many lives and cost up to billions of euro. The Seveso legislation addresses accident prevention and preparedness and lessons learned from such accidents. The current Seveso II Directive 96/82/EC was adopted in 1996 and amended by Directive 2003/105/EC. 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 human health 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 frequency of major accidents has fallen by some 20% between 2000 and 2008. This suggests that the Directive is meeting its objectives. Furthermore, the fact that the Seveso approach has been copied worldwide attests to its success.

### *Problem addressed by this Impact Assessment Report*

The Directive has to be amended due to changes in the EU system of classification of dangerous substances to which Annex I refers. That system has been replaced by the Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP), which becomes definitive on 1 June 2015. The alignment to the CLP Regulation raises three main issues. The key issue is how the alignment of Annex I to the CLP Regulation is implemented (policy issue 1). Related to that issue are possible other technical amendments to Annex I defining the scope (policy issue 2) and the procedures for adapting Annex I in the future (policy issue 3) to specific cases requiring more flexible solutions than are offered by the reference to the CLP Regulation.

Given the need to make this amendment, it was decided to undertake a wider review of the Directive since it has remained essentially unchanged since its adoption. While the review has confirmed that the Directive has been instrumental in reducing the likelihood and consequences of chemical accidents and the existing provisions are fit for purpose, a number of areas were identified where limited amendments would be appropriate to clarify and update certain provisions. The most significant of these relate to information to the public and information managements systems (policy issue 4) and land-use planning (policy issue 5), where some opportunities for improvements may exist. The other issue relates to relatively minor changes to a number of detailed provisions which could usefully be clarified or updated (policy issue 6).

## 2. ANALYSIS OF SUBSIDIARITY

Action at EU level is needed to amend the Directive, to ensure that existing high levels of protection of human health and the environment throughout the EU are maintained, and to promote greater harmonisation in implementation. This will help to 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.

### **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. 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. The Directive should also be clear, coherent and easy to understand to help increase consistency of implementation.

The main specific objective is to align Annex I to the CLP while maintaining existing levels of protection. The other specific aims are to clarify certain provisions to improve implementation and enforceability. Other provisions should be updated to take account of technological and regulatory developments since the current Directive's adoption. In addition, where possible requirements should be streamlined or simplified to reduce the administrative burden for operators and competent authorities without compromising safety.

### **4. POLICY OPTIONS, INCLUDING ANALYSIS OF IMPACTS AND COMPARISON**

#### ***Policy issue 1: alignment of Annex I to the CLP Regulation***

This is the core of the impact assessment.

This alignment must be made for a series of hazard classification categories of dangerous substances, but is only problematic for toxicity. This is due to the fact that the CLP Regulation introduces three new toxicity categories that do not completely correspond to the previous two categories that they replace, with different thresholds or cut-off values. Moreover the new toxicity categories are divided into three exposure routes (oral, dermal, inhalation). Therefore the options considered vary with respect to which categories and exposure routes are taken into account.

Although there is some uncertainty as regards the impacts over time, the overall assessment is that the impact of all of the options, as well as the difference of impacts between them, is limited.

The impact would be to slightly modify the scope of the Directive. Depending on the option, up to 405 of the establishments currently covered could fall out of the scope (-4.2%) and up to 342 new establishments could be caught (+3.4%). This would cause impacts of a comparable magnitude on administrative compliance costs and the protection level. The overall cost impact is low compared with the overall administrative costs of the Directive. There would be one-off costs for adjustment to the CLP (which all operators would have to make whatever option is chosen) estimated as 1.7 million EUR. There would also be option-related costs (or savings) for industry ranging from a cost increase of 4.9 million EUR per year to cost savings of 1.1 million EUR depending on the option chosen. The cost impact for authorities is estimated at about 10% of the costs/savings to industry. This compares with

estimated total administrative costs of the Directive for industry of about 52 million EUR per year for industry and authorities together of at least 100 million EUR. Other aspects evaluated qualitatively, which relate to practical implementation and administrative complexity/effort and will run beyond the initial alignment exercise, also need to be taken into account.

In the light of this assessment one option is preferable as, in addition to having a limited impact on scope, shared with other options, it maintains a high level of protection taking into account the most likely exposure routes in the event of a major accident..

### ***Policy issue 2: other technical amendments to Annex I***

The options relate to whether specific product categories or substances are appropriately covered by the Directive, including certain products/substances affected by the CLP. The options range from maintaining the status quo to defining specific higher thresholds for the substances concerned or derogations for packaged products.

The different options are likely to have marginal overall impact. Options involving increased thresholds, etc could bring limited costs savings for the affected industries, but could reduce the protection levels.

The preferred options are those maintaining or increasing the level of protection.

### ***Policy issue 3: future adaptation of Annex I***

As mentioned under policy issue 1, there are uncertainties about the longer term impacts of the initial alignment of Annex I, and in particular its automatic adaptation to future changes in classifications of substances and mixtures in the future. This suggests a need to be able to adapt Annex I as necessary via delegated acts. The option is a package of tools including EU-wide substance derogations and establishment-specific derogations at Member State level, with as a counterpart a safeguard clause enabling the inclusion of non-captured hazards.

Such a package, together with the use of delegated acts to amend Annex I, would provide the necessary flexibility to deal with situations arising from the CLP alignment where substances are included/excluded under the Directive that do/do not present a major-accident hazard. This would have a positive effect on protection levels and a net positive effect on costs.

The options assessed under this policy issue are all complementary and are preferred options.

### ***Policy issue 4: information to the public and information management systems***

The aim is to improve the information provided to the public, including that reported to the competent authorities. This would be in the interest of transparency and ensure that the public is aware of the dangers and appropriate action to take in the event of an accident. The different options represent a scaled approach, starting from business as usual to including much more detailed information.

It is also important that the information is collected, managed and shared in an efficient and streamlined way, thereby facilitating reporting and monitoring of implementation. The options for this range from the establishment of databases at Member State level to a fully integrated central EU database. The assessment shows

that the more information has to be made available, the greater the costs. However the more the level of the information is improved, the greater the potential benefits in terms of protection levels. Similarly, the more information management is improved, the greater would be the costs and benefits.

On the basis of cost benefit considerations, the preferred options are those improving the availability of relevant information level whilst entailing only moderate costs.

#### ***Policy issue 5: land-use planning***

The aim is to consider how major-accident hazards could be better considered in land-use planning. The Directive includes requirements that Member States should control the siting of new establishments, modifications to existing establishments and new developments in their vicinity through appropriate safety distances or, in the case of existing establishments, additional technical measures. Further clarifications and improvements may warrant consideration. Options are to maintain but clarify the existing provisions, emphasising environmental protection and making references to possible integration of procedures with those under similar legislation; or to extend the provisions in relation to new establishments to existing sites.

The latter option could have significant cost implications, but would also lead to significant increases in protection levels. However there is too little experience with practical implementation of such an approach to support a concrete proposal at this stage.

Therefore the first option is preferred. This is not expected to have any major impacts on costs, but may improve protection levels.

#### ***Policy issue 6: other clarifications***

The aim is closer coordination between different authorities, better integration of information and procedures to facilitate more consistent implementation and streamlining and simplification to reduce administrative burdens. The aim is also to clarify a number of provisions to improve enforceability and the effectiveness of implementation. A raft of possible option components is assessed. Those that would contribute towards closer coordination, etc are likely to have a positive overall impact in terms of implementation, simplification and reduction of administrative burdens (although it is difficult to quantify this), with possibly some improvements in existing levels of protection. Likewise, the elements aimed at clarifying and improving certain provisions will lead to clearer and better regulation, and improve protection levels without imposing significant additional costs.

The sub-options retained in this package include (1) the sub-options potentially providing savings with no reduction of protection, and (2) the sub-options providing an increase in protection at the lowest cost.

#### ***General observations on the impacts***

Overall, the potential changes considered represent a moderate adaptation of the Directive and would not significantly affect the level of protection or the Directive's costs. The costs of the various different options are low compared with the Directive's total costs.

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 Directive's tiered approach, with only basic requirements for lower-tier establishments, which take into account SMEs' capacities.

The available information suggests that the proportion of the establishments that are SMEs that would newly fall under the scope of the Directive as a result of the alignment to CLP would not be different from the proportion of establishments currently covered by the Directive that are SMEs – however, uncertainties remain due to the limited information available for mixtures. 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. However 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, as SMEs are by their nature more sensitive to an increase in costs than larger businesses. However, the options considered under policy issue 3 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.

Sections 5 and 6 of the main report compare all the main options within the different policy issues, including their costs/impacts and benefits. The following table summarises the preferred options.

Option component	Economic impacts, inc change of scope for policy issue 1 <sup>1</sup>	Protection level <sup>2</sup>	Other impacts including simplification, administrative efforts, etc
Policy Issue 1: Alignment of Annex I			
E*	Costs up to 2.4 million EUR per year	Small decrease (exclusion of oral exposure route for Acute Toxic 3 category)	Slightly higher due to differentiated exposure routes
Policy Issue 2: other technical amendments to Annex I			
Hydrogen: a) do nothing	Neutral	Unchanged	
Heavy fuel oil: b) avoid the	Neutral	Unchanged	

<sup>1</sup> 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.

<sup>2</sup> 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 <sup>1</sup>	Protection level <sup>2</sup>	Other impacts including simplification, administrative efforts, etc
possible effect by listing as named substance with other petroleum products			
Aerosols: a) the CLP approximation proposal of 150/500)	+ App. 0. 5 million EUR per year	Unchanged/ slightly increased	
Sodium hypochlorite: a) accept CLP re-classification effect for mixtures	+ Up to 3.5 to 4 million EUR per year	Increased	
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 <sup>3</sup>			
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	One-off costs around 2-4 million EUR  Annual costs up 0.5 million EUR	Increase. Improvement in information available	Better access to information. Less consequences in event of accident Aids lessons-learning and exchange of best practices, monitoring of actual implementation etc. Improved, transparency.

<sup>3</sup> Confidentiality issues will be considered

Option component	Economic impacts, inc change of scope for policy issue 1 <sup>1</sup>	Protection level <sup>2</sup>	Other impacts including simplification, administrative efforts, etc
Policy issue 4B: management of information			
c) 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 EUR per year in maintenance plus some Member State costs  One-off costs of 1 million EUR to set up link/upload documents	Increase. Significant Improvement in information available	As above. Plus more harmonisation, less fragmentation, streamlining and simplification
Policy issue 5: land-use planning			
b) minor clarifications	No costs or potential savings	Limited impacts	
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			
b) Include reference to the use of SPI for internal safety	No significant 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	
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 costs for underground gas storage)	Increase	

## **5. MONITORING AND EVALUATION**

Monitoring and evaluation of the Directive at EU level will continue to be based on specific indicators. The main core indicators include the number of major accidents reported, the number of establishments covered by the Directive and the provision of plans and reports. Existing monitoring and reporting tools will be simplified and streamlined as outlined under policy issue 4. Monitoring the impact of the CLP alignment of Annex I in practice and the effectiveness of envisaged correction mechanisms, the indicators will be based on the number of lower-tier and upper-tier establishments, and information about their activities and the main dangerous substances concerned, plus the number of derogations granted and the reasons for these.