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Interim, final and ex-post evaluations of policies, programmes and other activities

Evaluation of the Pressure Equipment Directive

Executive Summary

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**List of Acronyms**

<table>
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<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADCO</td>
<td>Market Surveillance Cooperation Group</td>
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<tr>
<td>ADR</td>
<td>European Agreement for the International Carriage of Dangerous Goods</td>
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<td>ASME</td>
<td>American Society of Mechanical Engineers</td>
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<td>CABF</td>
<td>Conformity Assessment Bodies Forum</td>
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<td>CEECs</td>
<td>Central and Eastern European Countries</td>
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<td>CLP</td>
<td>Classification, Labelling and Packaging Directive</td>
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<td>DG ENTR</td>
<td>DG Enterprise and Industry, European Commission</td>
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<td>DG MOVE</td>
<td>DG Mobility and Transport, European Commission</td>
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<td>ESRs</td>
<td>Essential Safety Requirements</td>
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<td>CEN</td>
<td>European Committee for Standardisation</td>
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<td>EN</td>
<td>European Harmonised Standard</td>
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<td>ECUI</td>
<td>European Committee of User Inspectorates</td>
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<td>IA</td>
<td>Impact Assessments</td>
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<td>ICSMS</td>
<td>The Internet-Supported Information and Communication System for Pan-European Market Surveillance.</td>
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<td>ILD</td>
<td>Intervention Logic Diagram</td>
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<td>NBs</td>
<td>Notified Bodies</td>
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<td>NLF</td>
<td>New Legislative Framework</td>
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<td>NDT</td>
<td>Non-Destructive Testing</td>
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<td>MD</td>
<td>Machinery Directive</td>
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<td>PED</td>
<td>Pressure Equipment Directive</td>
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<td>PWHT</td>
<td>Post Weld Heat Treatment</td>
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<td>PS</td>
<td>Maximum Allowable Pressure</td>
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<td>OJ</td>
<td>Official Journal of the European Union</td>
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<td>RAPEX</td>
<td>Rapid Information Exchange System Between Member States</td>
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<td>RTPO</td>
<td>Recognised Third Party Organisation</td>
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<td>SPVD</td>
<td>Simple Pressure Vessels Directive</td>
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<td>TC</td>
<td>Technical Committee</td>
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<td>TPED</td>
<td>Transportable Pressure Equipment Directive</td>
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<td>UIs</td>
<td>User Inspectorates</td>
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<td>WGP</td>
<td>Working Group Pressure</td>
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<td>WPG</td>
<td>Working Party Guidelines</td>
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<td>WPM</td>
<td>Working Party Materials</td>
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This summary contains an abbreviated account of the main findings, conclusions and recommendations of the study ‘Evaluation of the Pressure Equipment Directive’. The study was conducted for the European Commission’s DG Enterprise and industry, by the Centre for Strategy and Evaluation Services (CSES) during the period November 2011 to October 2012.

1. Executive Summary

1.1 Background to the Evaluation and Pressure Equipment Sector

The Pressure Equipment Directive (97/23/EC) (PED)\(^1\) was adopted by the European Parliament and the European Council in May 1997 and entered fully into force in May 2002. The purpose of the evaluation has been to assess how, and to what extent, the Directive has met its objective of guaranteeing free circulation of stationary pressure equipment within the EU while ensuring a high degree of safety.

In order to carry out the evaluation, CSES developed a methodological framework on the basis of the standard evaluation questions of the relevance, efficiency, effectiveness, utility, sustainability and European value added of the legislation. Guided by a set of specific evaluation questions, CSES used a combination of research tools including a review of relevant documents and publications, collection and analysis of data from published sources, analysis of 179 survey responses and 90 interviews with the main stakeholders related to the Pressure Equipment Directive (Member State authorities, notified bodies, industry associations, firms in the pressure equipment industry, standardisation experts, notified bodies, User Inspectorates and academics) in thirteen EU Member States.

Previous research undertaken in 1996 on the ‘Global Competitiveness of the European Union Pressure Equipment Industry’ identified the existence of trade barriers within the Internal Market. In many Member States, pressure equipment had to be designed according to the requirements of national standards and these were perceived as limiting cross-border business activities. Given the industry’s economic importance, which is represented in the vast array of industrial and consumer products that constitute pressure equipment, EU-level interventions were recommended in order to facilitate intra-EU trade and to strengthen the pressure equipment sector more broadly.

After ten years of implementation, the evaluation has been well positioned to assess the performance of the PED since its introduction and to make a judgement of the Directive’s continuing relevance.

1.2 Main conclusions

Relevance

- In comparison with the previous system of national regulation, the introduction of the PED has proven relevant for the improved functioning of the Internal Market. The Directive has removed barriers to trade since the placing on the market of pressure equipment now operates under a harmonised regulatory framework.

- At the same time, the introduction of the PED has successfully combined market integration with maintaining the high levels of product safety that Europe was already accustomed to.

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- In relation to other pieces of European legislation, the scope of the PED is generally clear and the Directive fits into a relatively stable and coherent regulatory environment. However, the majority of national authorities interviewed indicated a preference for merging the Simple Pressure Vessels Directive (SPVD) with the PED in order to simplify the administrative enforcement of the Directives. Nevertheless, industry associations stated their preference to maintain the status quo in order to provide industry with the flexibility of selecting either the SPVD or PED, as appropriate.

Relevance – Economic Performance of the Industry

- The evaluation assessed the economic performance of the industry before and after the introduction of the Directive (i.e. between 1995 and 2010). Data were analysed from the PRODCOM and COMEXT databases and industry research reports. Given the scope of the study, certain methodological difficulties were encountered in developing a consistent account from the data. However, as far as can be judged, a number of promising results were identified. Output in value terms at constant 2005 prices has shown strong growth (the weighted average for the industry is 57%). Over the same period, the EU 27 economy grew by 32.1%.

- Likewise, the integration of the Internal Market appears to have developed at a strong rate with a weighted average growth in intra-EU exports of 123.2% at constant 2005 prices over the 1995 to 2010 period. A breakdown of the data at Member State level reveals the leading role that the German and Italian producers play within the industry.

- In 2010, the value of extra-EU exports was more than double the value of extra-EU imports. However, over the 1995 to 2010 period, the growth rate of extra-EU imports (127%) was greater than extra-EU exports (105%). Over the short to medium term, whilst competition is increasing, the data indicate that European industry is in a relatively strong position compared with that of other world regions.

- However, the economic data analysed did not entirely reflect the perceptions of certain industry associations and businesses. Although unevenly felt across sectors, subsectors and firms, it was reported that there has been significant delocalisation of manufacturing units to low cost centres such as Asia and that this trend was set to intensify. It may be that the data frame used in the quantitative research has not been able to fully capture these trends.

Effectiveness

- To a significant extent, one of the core objectives of the Directive, the removal of barriers to trade and improving the effectiveness and efficiency of the Internal Market, has been realised. The PED has opened up trading opportunities across the Internal Market with the benefit of providing users with greater levels of choice.

- The classification of pressure equipment according to the fluid that it contains and stored energy is regarded as having been a sensible system to adopt. It has maintained existing safety standards in well regulated Member States and added transparency and consistency to the conformity assessment process. It has improved safety standards in some Member States that previously regulated pressure equipment under very different approaches.

- However, there are a number of barriers that continue to hinder the performance of the Directive. Whilst in some specific cases these have serious implications, they should not be considered as constituting a widespread failure with the Directive;
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- As an overall observation, it appears that the New Approach framework is not entirely sufficient to guarantee the safety performance of pressure equipment in line with the Essential Safety Requirements of the PED. The actors (manufacturers, Notified Bodies and national and European authorities) that operate under the New Approach framework are sometimes not fully able to hold each other to account or to perform their duties to the extent that the objectives of the New Approach are fulfilled. The extent to which this occurs varies across the Member States which has led to an uneven enforcement of the Directive and PED Guidelines.

- One concern is that the management of the conformity assessment process differs markedly between the Member States and between Notified Bodies (NBs). This is in terms of the type and quality of the applied techniques which in some cases have led to unsatisfactory outcomes. Scientific research has revealed the existence of non-conforming pressure equipment that carries the CE marking on the Internal Market. In addition, the withdrawal of certificates by NBs from manufacturers with a view to withdrawing approval of design and production processes has rarely occurred.

- Similarly, the quality of market surveillance varies across Europe. In some cases, this may be explained by the fact that Member State resources to test products on a sufficient scale can be limited. Finding suitably qualified personnel may prove problematic. Customs authorities may prioritise the examination of other products such as toys. According to a number of national authorities, cooperation between officials across Europe in terms of sufficiently sharing information is limited. The extent to which market surveillance authorities use web based tools to communicate problems related to non-conforming products such as RAPEX (for consumer products) or ICSMS (for industrial products) was perceived as partial. External stakeholders commented that overall the system is underperforming.

- Difficulties may arise for market surveillance authorities in developing a coordinated response to removing non-conforming products from the Internal Market. The safeguard clause (that provides market surveillance authorities with the means to take action against non-confirming products, subject to Commission verification on whether such national measures restricting the free movement are justified or not) has been used on roughly 5 occasions. This is surprising given the apparent volume of non-conforming products on the market.

- The delocalisation of production to low cost centres presents a number of heightened challenges for the consistent implementation of the PED. Market surveillance authorities are presented with an increasing number of imported products from third countries that may not have been appropriately conformity assessed. Subsidiaries of NBs may not be performing as intended. The framework in place to address the perceived scale of these challenges appears to be insufficient;

- A significant minority of firms commented that some legislative barriers that hamper the smooth functioning of the Internal Market remain. This is particularly in relation to national in-service inspection legislation.

- Furthermore, it was surprising to some that to date not a single manufacturer of non-conforming products that carried serious safety failings has been convicted through legal processes;
• CEN has played a key role in developing a significant number of European harmonised standards (EN) that provide economic and technically innovative advantages when compared with other standards and codes (such as resource efficiencies). A significant amount of time and effort has been invested in the standardisation process in order to achieve this outcome. However, the process is limited by the fact that the process is driven by a small number of volunteers mainly from industry;

• Despite the perceived advantages of EN standards their uptake by European industry has so far been partial. Whilst for certain products and in certain countries there has been a relatively positive uptake, there remain large and significant segments of the pressure equipment sector that have not adopted EN standards. This outcome can be partly explained by certain key Member States continuing to support their former national standards. In addition, users may prefer to procure pressure equipment built according to other standards and codes as result of in-service inspection costs and other issues;

• The Conformity Assessment Bodies Forum (CABF) plays a critical role in encouraging Notified Bodies (NBs) to provide consistent implementation of the Directive. However, only a small proportion of the PED NBs attends the meetings or are informed by national mirror group meetings. This has led to the emergence of an inner core of NBs that is technically more coherent and knowledgeable than their counterparts.

Utility, Sustainability and European Value Added

• The PED has been well formulated and meets the needs of the target beneficiaries. To a significant extent, this has led to the harmonisation of the Internal Market for pressure equipment and has produced tangible results for manufacturers and users;

• However, the ongoing sustainability of the Directive hinges upon stronger and more consistent enforcement of the rules with a view to ensuring that the same conformity assessment procedures are correctly applied to the same types of pressure equipment;

• Overall, the PED has achieved European added value. The largely harmonised legislative framework has had a positive impact on the European pressure equipment sector. This outcome could not have been achieved through Member States acting alone or bilaterally;

1.3 Main recommendations

Non-legislative Recommendations

• Member States should ensure that national market surveillance authorities fulfil the expectation that they make use of the safeguard procedure when non-conforming products are identified. This could be supported through strengthened ADCO discussions on the matter. The European Commission could play a supporting role when and where appropriate;

• The European Commission should encourage national authorities to make greater use of existing web based tools such as RAPEX and ICSMS in order to identify and communicate problems with non-conforming consumer and industrial pressure equipment;

• With a view to supporting the harmonisation of conformity assessment practices, the management of the CABF could be strengthened. The chair and co-chair could form an
executive body that has a strong management approach to finalising CABF common agreements, encouraging NB compliance with common agreements, monitoring the performance of CABF members and reporting on such activities. The executive body could draw upon the assistance of relevant Member States authorities in terms of sharing information on common CABF agreements and the performance of NBs in meeting those agreements and their performance generally. Member States authorities should draw upon the insights gained from the CABF in order to appropriately monitor the NB market and take actions where necessary. The European Commission could play a supporting role when and where relevant, in particular by ensuring that common agreements taken by the CABF do not hinder the free and fair competition of the NB market.

- The EC standardisation process would be better supported through greater involvement of a wider variety and larger number of pressure equipment stakeholders. Ideally, this would include national standardisation bodies, NBs, industry, users and other relevant experts and individuals. CEN, the European Commission and Member States could encourage greater involvement in the process by relevant groups.

- CEN, Member States and NBs should promote the uptake of EN standards by users. CEN should remind national standardisation bodies of their legal obligation to cease publishing former national standards. CEN could engage with national standardisation bodies to learn if EN standards have reached the stage of sufficiently covering the manufacturing processes of national industry. Member States should promote the use of EN standards within public procurement documents.

- To enhance the sustainability of the Directive, efforts to enforce the rules of the Directive in full should be increased. The Commission and Member States need to consider the use of appropriate legal action, where serious failings are discovered.

Further research/study:

- We recommend conducting further research with a view to assessing the technical feasibility of potentially merging the SPVD and PED. In particular, the research should examine the implications of having a single set of Essential Safety Requirements for pressure equipment - including simple pressure vessels - within a merged Directive. This should be supported by an impact assessment in order to determine the implications of the potential merger on industry.

- It appears that national in-service legislation may have aspects that impinge upon the correct functioning of the Internal Market for pressure equipment. However further study is required to map out the existing national legislative regimes and to identify with certainty any deficient features. It is anticipated that such research would be very resource intensive if it would cover all Member States. It could be envisaged to conduct a pilot study examining the situation in a limited number of Member States.

\[2\] Alignment of the SPVD and PED to the NLF will facilitate merger of certain provisions of these Directives but there are some problems with the nature of the technical scope and requirements which require more detailed study. One such matter is the differences in classification by pressure and volume so that the thresholds are aligned in a way which is meaningful in relation to the pressure hazard. Another matter for more detailed study is where the SPVD applies to pressure equipment for vehicles but this application to vehicles is excluded from the PED. Further consideration would also be necessary for the application of simple pressure equipment in assemblies such as compressor units where the SPVD, PED and MD may apply.
Alignment to the New Legislative Framework

- The alignment to the NLF provides an excellent opportunity to strengthen the PED’s legal basis for conformity assessment and other areas. The strengthened system of accreditation could provide greater oversight of the NB market and it would be beneficial to have harmonised selection and monitoring accreditation criteria across all Member States. The European Commission should carefully assess this point during the alignment.

- New and existing NBs should be monitored in line with the requirements of the PED and accreditation bodies should exercise their powers of withholding or suspending operating certificates if problems are identified. Extra emphasis should be placed on the role of accreditation bodies in monitoring the performance of subsidiaries of NBs that are located outside Europe;

- As suggested by the NLF, the system for market surveillance requires strengthening. This includes Member States providing adequate resources for market surveillance activities, ensuring that products are checked on an adequate scale, better coordination and information sharing between bodies, developing joint responses, streamlining the safeguard procedure, the joint development and coordination of appropriate programmes, and market surveillance activities being conducted outside Europe. Article 25 of the NLF Regulation also suggests that the Commission in coordination with Member States should develop and organise training programmes and exchanges of national officials. All of these activities should be rolled out and tailored to address the needs of the market surveillance system in the pressure equipment area.

- It is recommended that the alignment to the NLF should in particular oblige NBs to participate in either EU or national mirror group meetings (with the support of national authorities, national mirror group meetings may have to be established in certain countries). This requirement could be made clear in the relevant accreditation documentation and the extent of attendance at meetings could be monitored by accreditation bodies (and the CABF) as part of their enhanced role outlined by the alignment to the NLF.

Legislative Recommendations

- To encourage greater consistency between stakeholders and Member States in the enforcement of the PED Guidelines, Member States could develop a similar legislative measure to the Decree adopted by the French government that legally commits stakeholders to apply the PED Guidelines;

- If the results of further research prove positive, the Commission should carefully consider a potential merger between the PED and SPVD;

- If it is confirmed that national in-service inspection regimes discriminate against the full application of the principles of the PED and the New Approach, the European Commission should seek to include appropriate measures in the PED (one possibility could be the requirement for the equal treatment of EN and other standards by relevant national legislation);

- As indicated by the main findings, there is currently no urgent need to revise the Directive given its strong performance. However a future revision of the Directive should assess the relevant areas indicated in the main report such as the automatic provision of declarations of conformity, the definition of assemblies, the wording for pressure accessories, specific

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quantitative requirements for materials while recognising the safety implications of changing such requirements, the mandatory adoption of User Inspectorates, the revision of the procedure for the European Approval of Materials with view to encouraging more efficient approval of materials, inclusion of a small number of relevant PED Guidelines, extending the scope of the Directive to offshore pressure equipment, examining the concept of Sound Engineering Practices with a view to increasing the safety of pressure equipment, and including an additional objective for the PED in order to reflect its role of regulating products produced in third countries that are intended for the Internal Market.