Framework Service Contract for the Procurement of Studies and other Supporting Services on Commission Impact Assessments and Evaluations

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Evaluation of the Pressure Equipment Directive

Final Report

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List of Acronyms

ADCO  Market Surveillance Cooperation Group
ADR  European Agreement for the International Carriage of Dangerous Goods
ASME  American Society of Mechanical Engineers
CABF  Conformity Assessment Bodies Forum
CEECs  Central and Eastern European Countries
CLP  Classification, Labelling and Packaging Directive
DG ENTR  DG Enterprise and Industry, European Commission
DG MOVE  DG Mobility and Transport, European Commission
ESRs  Essential Safety Requirements
CEN  European Committee for Standardisation
EN  European Harmonised Standard
ECUI  European Committee of User Inspectorates
IA  Impact Assessments
ICSMS  The Internet-Supported Information and Communication System for Pan-European Market Surveillance.
ILD  Intervention Logic Diagram
NBs  Notified Bodies
NLF  New Legislative Framework
NDT  Non-Destructive Testing
MD  Machinery Directive
PED  Pressure Equipment Directive
PWHT  Post Weld Heat Treatment
PS  Maximum Allowable Pressure
OJ  Official Journal of the European Union
RAPEX  Rapid Information Exchange System Between Member States
RTPO  Recognised Third Party Organisation
SPVD  Simple Pressure Vessels Directive
TC  Technical Committee
TPED  Transportable Pressure Equipment Directive
UIs  User Inspectorates
WGP  Working Group Pressure
WPG  Working Party Guidelines
WPM  Working Party Materials
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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Executive Summary

• 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;
Executive Summary

- 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;

Efficiency
Executive Summary

- 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 Summary

The 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\(^2\). 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.
**Executive Summary**

**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.

2. Methodological Approach

2.1 Resume of Assignment Aims

This evaluation has been commissioned by the Construction, Pressure Equipment and Metrology Unit (G5) of DG Enterprise and Industry (DG ENTR) with the support of the Evaluation function of the Planning and Management Unit. Other Commission Services have been involved notably staff from the Road Safety and Transport of Dangerous Goods Unit (D3) of DG Mobility and Transport (DG MOVE).

The Pressure Equipment Directive (97/23/EC) (PED) was adopted by the European Parliament and the European Council in May 1997 and entered into force in May 2002. Hence, the purpose of the evaluation is to assess, after 10 years of implementation, 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 addressing this question, the evaluation has aimed to:

- Review the relevance of the PED, in particular by gaining a better understanding of the structure of the stationary pressure equipment market in Europe and identifying the main trends in international trade;
- Identify difficulties in the Directive’s implementation that may require the need for regulatory and/or non-regulatory measures;
- Provide recommendations to improve the effectiveness of the Directive;
- Identify areas requiring further study.

These aims have been pursued within the standard framework established by the European Commission for conducting evaluations and has included an assessment of the operation of the Directive against the standard evaluation criteria (relevance, effectiveness, efficiency, utility, sustainability and European value added).

Within the framework of the evaluation, appropriate methodologies have been applied for assessing the observable results and impacts arising from the Directive’s implementation, particularly in evaluating the effectiveness, efficiency and utility of the Directive. This has involved a review of the coherence of the Directive’s Intervention Logic and the relationship between expressed objectives and the means for implementing them, especially in the context of evolving markets and international trade in the relevant product groups. Obstacles inhibiting an optimal application of the Directive in terms of both free circulation of the equipment and technical aspects have been identified. In response, conclusions on the current performance of the PED have been

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Methodological Approach

formulated, and recommendations have been put forward that aim to overcome barriers and strengthen implementation\(^5\).

**Evaluation Tasks**

The specified evaluation tasks have been carried out within a defined methodology and required the collection and analysis of both primary and secondary data, analysis and the formulation of conclusions and recommendations. The specified tasks included:

- Elaborate, refine and validate the evaluation methodology, subject to the approval of the project Steering Group;
- Consult with the relevant services of the Commission in order to identify the means whereby specific evaluation questions can be addressed;
- Elaborate further evaluation questions, if necessary;
- Identify, test and apply methodologies for evaluating the results and impacts of the Directive;
- Identify, collect and analyse data that will provide the information to answer the agreed set of evaluation questions. These are designed to assist an assessment of the legislation against the main evaluation criteria;
- Within this, identify, collect and analyse information that will allow a characterisation of the evolution of the markets for products covered by the PED;
- Identify the obstacles inhibiting an optimal application of the Directive in terms of both free circulation of the equipment and technical aspects;
- Define actions which may need to be taken to eliminate these obstacles;
- Formulate robust and useable conclusions;
- Make recommendations on actions that could help improve the implementation of the Directive or any future activities in this area;
- Develop a set of appropriate indicators.

**Evaluation Questions**

Whilst undertaking the tasks set out above, the following questions have been addressed:

*The Relevance and Coherence of the Directive*

- Does the PED represent a consistent approach to the development of the Internal Market for stationary pressure equipment?
- How does the PED interact with other related legislation and could any improvements in this regard be made (such as the Simple Pressure Vessels Directive 2009/105/EC and Transportable Pressure Equipment Directive 2010/35/EC)?

\(^5\) It should be pointed out that it has not been the evaluators intention to provide detailed technical and engineering guidance on highly technical areas (such as on the Essential Safety Requirements). Rather, the recommendations seek to address the identified legislative and policy gaps and deficiencies and provide initial suggestions on how these can be ameliorated.
Methodological Approach

- Are the provisions of the PED consistent with ensuring a high degree of safety and with meeting the needs of industrial users (mainly) and the concerns of Member States and European citizens?

The Relevance of the Directive In Relation to the Economic Importance of the Sector

- What are the main trends in the structural characteristics of the sector (in which countries is the industry concentrated, what are the main trends in terms of intra-EU and external trade, what is the overall size of the market EUR?)
- Is the sector across the EU suffering from a skills deficit both in the number of staff and their degree of qualification? Are training and education adapted to the needs of the sector?

Effectiveness

- To what extent has the Directive contributed to an efficiently operating Internal Market for stationary pressure equipment in its scope?
- Has the current classification of pressure equipment based on the fluid that it contains and the stored energy been adequate?
- What is the impact of the delocalisation of production? Is this trend causing new challenges in relation to the implementation of the Directive?
- To what extent has the new approach concept, including the third party conformity assessment and market surveillance, been successful? Are there any aspects or actors that render certain aspects of the Directive more or less effective than other comparable Directives?
- Are you aware of any problems that manufacturers have experienced in placing pressure equipment on the market in another MS than the one where it was produced? If yes, in which Member States did this take place and what was the reason?
- What, if any, are the barriers to an effective application of the Directive? How could any such barriers be overcome?

Efficiency

- What aspects of the Pressure Equipment Directive are the most efficient or inefficient, especially in terms of resources that are mobilised by the stakeholders (manufacturers, users, conformity assessment bodies, standardisers and public authorities)?
- What does this represent in terms of administrative and reporting burdens on stakeholders or other actors?
- How successful has the development of harmonised European product and material standards been for pressure equipment? How do these standards compare with private, international or former national codes?
- How successful has the take-up of these harmonised European product and material standards been? What are the main barriers to the uptake of harmonised European standards?
- What has been the experience of the Directive’s provisions for user inspectorates?
Methodological Approach

Utility

- Is the Directive delivering identifiable benefits to the sector including both manufacturers and users? What have been the results for manufacturers and users?

Sustainability

- Will any changes brought about by the Directive continue to have an effect? What will be the results and impacts in the medium term (5 to 10 years)?

- If relevant, what measures might be envisaged to further support the competitiveness and sustainability of the Internal Market in this sector?

European Added Value

- What is the European added value of the Directive?

It should be pointed out that some of the evaluation questions have been addressed at a relatively cursory level. For example, it has not been possible to conduct a full analysis of the training needs and skills endowment of the sector. Rather the intention has been to consider the extent to which evidence on training and skills availability impacts on the relevance and effectiveness of the Directive. Similarly, this has been the case in other areas.

2.2 Methodological Approach

The specific questions addressed by the evaluation have already been stated. However, there are broader considerations that have shaped the conduct of the evaluation and helped direct its focus and empirical investigations. These fall into two areas, one concerns the evaluation framework, and the other concerns the sectoral issues that are specific to the Pressure Equipment Directive.

The Evaluation Framework

The conduct of an evaluation of existing legislation (especially in view of the recent developments that have stressed the importance of reviewing legislation to see if it continues to be ‘fit for purpose) needs to conform to the standard procedures that have been developed in the Commission since the late 1980’s. These see evaluation as part of a cycle that these days accompanies the initial development of legislative proposals with an impact assessment, continues through its early and subsequent implementation with monitoring processes and eventually arrives at a point where an ex-post evaluation aims to establish what legislation has achieved and how far it has progressed towards its initial objectives. The current evaluation is of the latter kind, although given that the legislation under consideration dates from 1997, when it was not usual to conduct a widely based impact assessment, it is not possible to refer back to anticipated outcomes in any detail.

It will nonetheless be useful, in the course of the current evaluation to review the earlier stages in the legislative cycle and any work that has been conducted that has contributed to its overall assessment. To this extent, it will be useful to review the report for the Commission on the ‘Global Competitiveness of the EU Pressure Equipment Industry’ that was published in 1996. This report provides something of a baseline against which to judge the development of the industry and the performance of the PED since its introduction. There will also need to be reference to intermediary developments, such as the ‘Evaluation of the User Inspectorates’ (97/23/EC)6 under the PED and the ‘Review of the Application of the Simple Pressure Vessels Directive (87/404/EEC) in relation to the

Evaluation of the Pressure Equipment Directive Section

Pressure Equipment Directive (97/23/EC)\(^7\).

Equally, the standard framework indicates that the evaluation will need to look across a range of criteria in coming to a conclusion on the legislation under review. These criteria can be summarised as follows:

<table>
<thead>
<tr>
<th>Key Evaluation Criteria</th>
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<tbody>
<tr>
<td><strong>Relevance</strong> - the extent to which the objectives and implementing measures of a Directive are relevant to the identified needs of the intended beneficiaries, or to the achievement of key policy objectives.</td>
</tr>
<tr>
<td><strong>Effectiveness</strong> - the extent to which a given Directive is achieving its operational, specific and global objectives, in terms of the outputs, results and longer term outcomes.</td>
</tr>
<tr>
<td><strong>Efficiency</strong> - the relationship between financial inputs and identifiable outcomes and how economically the Directive’s provisions have been converted into outputs and results. Linked to this is value for money; could more be achieved with the same level of financial inputs or, conversely, could the same outputs be achieved with reduced inputs? And how efficiently managed is the policy in a wider sense?</td>
</tr>
<tr>
<td><strong>Utility</strong> – the extent to which a Directive’s impacts respond to the initial needs and problems of the target beneficiaries.</td>
</tr>
<tr>
<td><strong>Sustainability</strong> - the extent to which positive changes attributable to the implementation of a given Directive may be expected to last beyond the period of their implementation. This includes financial sustainability i.e. are impacts achieved to date likely to be sustainable within current or planned EU and national public funding regimes?</td>
</tr>
<tr>
<td><strong>European added value</strong> – the extent to which intervention or activities supported at an EU level brings about changes that would not have occurred through Member States acting on their own or cooperating bilaterally.</td>
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</table>

The relationship between these issues may be illustrated by the following diagram:

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Methodological Approach

It can be seen that while the central questions in any evaluation relate to effectiveness and efficiency of the legislation or programme under review, there are other aspects for consideration relating to the relationships between the needs of beneficiaries, legislative objectives, the processes of implementation and the success or otherwise of the policy, as evidenced in its short term outputs, the results and the longer term outcomes. The various criteria used in standard evaluations have been framed to highlight these different aspects and have been used to inform the framing of the evaluation questions.

The Sectoral Context

There are also a series of key points that arise because of the particular nature of the legislation under review and the context in which it has its effects.

Central to these issues are the questions of how well the Internal Market for pressure equipment is actually functioning, to what extent the safety aspects have been achieved, how far the legislation is supporting or hindering market mechanisms, and what are the main continuing barriers to the effective and efficient operation of the Internal Market?

The relationship between these various questions had to be explored and linked back to the specific evaluation questions that have already been raised. Exploring these relationships has been a central methodological concern for the study.

With this in mind, it is useful to view the PED in the framework of an Intervention Logic diagram. Following the New Approach, the Intervention Logic takes into account the operation of Internal Market legislation and starting with the initial statement of identified needs follows through the policy logic to the objectives at an operational level. The outputs and longer term outcomes of its implementation, not presented here, can be defined as the achievement of the stated objectives that should ultimately lead to an effective and efficient Internal Market able to encourage the strengthening of European industry whilst maintaining high safety standards. See diagram below:

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8 The New Approach is explained in section 3.2.
2.3 Overall Approach

The study adopted the following overall approach for the implementation of the specified tasks:

- **Phase 1: Preparatory Tasks** – set up meetings and various preparatory tasks including an initial survey of relevant documents and data, review of current objectives and indicators; the refining of evaluation questions and the preparation of research tools, leading to an Inception Report;

- **Phase 2: Implementation of the desk research and interview programme and analysis** – continuing desk research and the conduct of an interview programme with a range of stakeholders. Collection and assessment of market data. The submission of a Progress Report and subsequently a First Findings and Recommendations Report;

- **Phase 3: Further analysis and Final Report** – completion of interview programme and further analysis, especially in the light of comments made by the Steering Group on the First
Methodological Approach


The following sections highlight the approach and structure of some of the key activities that have fed into the work undertaken over the duration of the evaluation.

Analysis of Documentation and Background Research

Analysis of documentation and background research has informed the development of the methodology and, our understanding of the policy framework, and the structure and dynamics of the pressure equipment market. This has included examining legislative and policy documents, standardisation documents and industry reviews.

In addition to assessing the PED itself, the background research has considered the relationship between the PED and other related Directives, such as the Simple Pressure Vessels Directive and the Transportable Pressure Equipment Directive. However, rather than a conducting a technical comparison, the research has set the scene for assessing stakeholder perceptions of how the PED interacts and relates to other Directives.

Although the PED has not been immediately aligned with the New Legislative Framework, the review has taken into account in what ways the NLF seeks to ameliorate the performance of New Approach Directives. This has supported the development of appropriate recommendations.

A significant area for the evaluation has been the nature and role of the harmonised European standards that enable presumption of conformity with the Directive. Rather than simply focusing on technical aspects, this analysis has taken into account the rationale of European standards in comparison with other comparable standards and their intended impact in terms of enhancing market performance. A recent survey on the uptake of European standards has also been taken into account.

Although not within the scope of the PED, there has also been consideration of the impact of national in-service inspection regimes on the pressure equipment industry. Despite the fact that legislation in this area is solely developed and overseen by national authorities, there have been comments that certain types of regime have significant implications for manufacturers when designing and placing products on the market.

Identification and Analysis of Relevant Market Data

Over the course of the evaluation, a range of data sources were examined concerning the pressure equipment market and the extent to which they would prove useful for the purposes of the study.

Given that for some product groups, specific information is available through commercial sources, selected data from industry reports are included. It should be pointed out that the commercially available data do not extend to a complete overview of the PED sector and the type of data available varies from product group to product group.

The PRODCOM⁹ database was screened for relevant data. However, there were already recognised limitations with using PRODCOM for PED market assessments. In particular, certain product groups overestimate the size of the market since they do not take into account the boundary between

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⁹ PRODCOM is an EU database that provides statistics on roughly 4500 different types of manufactured goods. It can be accessed through the Eurostat website: http://epp.eurostat.ec.europa.eu/portal/page/portal/prodcom/introduction
Methodological Approach

those products that fall under the scope of the PED and those that do not. Moreover, PRODCOM
does not have complete coverage of all of the products that fall under the PED sector.

Similarly, data was extracted from the COMEXT\textsuperscript{10} statistical database where similar limitations were identified.

The structure of the assessment of the PED market has been largely based on the overarching
product categories that have been identified for regulation by the Directive. However, there have been two modifications to the product categories in order to take into account important features of the assemblies market. Firstly, with a view to assessing industry trends, industrial assemblies and consumer assemblies have been separated into two separate groups. Secondly, boilers have been selected as a standalone group given the prominent role they play within the assemblies market.

Table 2.1: Overarching PED product categories and corresponding subgroups

<table>
<thead>
<tr>
<th>Vessels</th>
<th>Piping</th>
<th>Safety Accessories</th>
<th>Pressure Accessories</th>
<th>Industrial Assemblies</th>
<th>Boilers (Industrial and Consumer assemblies)</th>
<th>Consumer Assemblies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product subgroups</td>
<td>Product subgroups</td>
<td>Product subgroups</td>
<td>Product subgroups</td>
<td>Product subgroups</td>
<td>Product subgroups</td>
<td>Product subgroups</td>
</tr>
</tbody>
</table>

The analysis of the market data is outlined in the \textit{relevance quantitative} section.

\textbf{Establishment of the Baseline}

To enable a clear understanding of the evolution of the PED sector over time, a baseline of the market for each of the product categories before the introduction of the PED has been provided in the \textit{relevance quantitative} section. This has been largely been supported by the analysis of data from the PRODCOM database. The baseline facilitates clear comparison between the former and current market conditions on the basis of constant 2005 prices.

\textbf{Identification of Indicators}

Based on the data that is available, suitable indicators have been selected that are closely associated with the PED market assessment and baseline, and these have been outlined in Chapter 4. These form part of a broader set of indicators that also take into account variables that can illustrate developments in the processes and procedures associated with the Directive. The selection of indicators has been carefully considered to ensure that monitoring processes and future evaluations can collect the same information for comparison purposes. The PED indicators are built on and are compatible with the broader indicator framework used by DG ENTR and aim to assist Unit (G5) to establish on-going and practical monitoring of the PED and its implementation.

\textbf{The Framework for the Interview Programme}

The interview programme was designed to take into account views from an appropriate range of old and new Member States, and to strike the right balance between important producer and user countries. The selected countries were as follows:

\textbf{Table 2.2: PED Interview Programme – Participating Member States}

\textsuperscript{10} COMEXT is an EU database that provides statistics on intra and extra EU trade according to different types of nomenclature. It can be accessed through the Eurostat website: \url{http://epp.eurostat.ec.europa.eu/newxtweb/}
Methodological Approach

<table>
<thead>
<tr>
<th>Member States Participating in the Interview Programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Austria</td>
</tr>
<tr>
<td>2 Czech Republic</td>
</tr>
<tr>
<td>3 Finland</td>
</tr>
<tr>
<td>4 France</td>
</tr>
<tr>
<td>5 Germany</td>
</tr>
<tr>
<td>6 Italy</td>
</tr>
<tr>
<td>7 Netherlands</td>
</tr>
</tbody>
</table>

In total, 90 stakeholders have been interviewed. The distribution of stakeholders was based on the need to reflect the position of different groups whilst allowing the collection of detailed information on the actual impacts of the PED. Businesses (material suppliers, designers, manufacturers and users of pressure equipment) therefore make-up the largest group, national public authorities the second largest, followed by Notified Bodies (NBs) and a range of other important stakeholders such as business associations, standardisation experts, academics and relevant officials from the European Commission.

Table 2.3: PED Interview Programme - Stakeholder Groups and Number of Interviewees

<table>
<thead>
<tr>
<th>Stakeholder Groups</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Commission officials</td>
<td>2</td>
</tr>
<tr>
<td>Standardisation specialists / bodies (European and national)</td>
<td>8</td>
</tr>
<tr>
<td>European associations</td>
<td>6</td>
</tr>
<tr>
<td>Member State officials (including officials responsible for market surveillance / safety)</td>
<td>23</td>
</tr>
<tr>
<td>Notified Bodies (including 2 with subsidiaries outside of the EU)</td>
<td>10</td>
</tr>
<tr>
<td>National business associations</td>
<td>9</td>
</tr>
<tr>
<td>Academics</td>
<td>3</td>
</tr>
<tr>
<td>Businesses (materials suppliers, designers, manufacturers, users of pressure equipment and User Inspectorates)</td>
<td>29</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>90</strong></td>
</tr>
</tbody>
</table>

The analysis of the responses from stakeholders has supported the identification of the main evaluation findings and the development of recommendations.

**Delivery and Analysis of Business and Stakeholders Surveys**

In order to collect information and gauge responses from a wide range of stakeholders, two online surveys were broadly disseminated. The first survey was designed to specifically target businesses and the second was designed in order to collect the views from other types of pressure equipment stakeholders such as national authorities, notified bodies and experts in the field of standards. The survey questions generally covered the type of issues that were raised and examined during the interview programme.

Responses to specific survey questions have been inserted into the relevant sections of the report and have the role of clarifying the views of stakeholders on certain matters. During the course of the evaluation, a national industry association that mainly represents the views of SMEs that install items that contain pressure equipment (such as air conditioning equipment) received responses to the survey from a relatively large number of its members. Given the specific focus of this association, the results from this group have been provided separately in order not to distort the results of the business survey.

The responses to the surveys can be found in Annex 3 (which contains the Business Survey – 96 responses were received in total) Annex 4 (which contains the Stakeholder Survey – 53 responses...
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were received in total) and Annex 5 (which contains the PED Installation Industry Survey – 30 responses were received in total).
3. Background and Key Issues

3.1 Background to the Sector before the Introduction of the PED

Prior to the introduction of the PED, a significant study was published in 1996 on the ‘Global Competitiveness of the European Union Pressure Equipment Industry’\(^\text{11}\). Given the limited amount of research in this field, the study provides something of a baseline for assessing subsequent changes in the pressure equipment industry as a whole, especially those brought about by European legislation, EU enlargement and globalisation\(^\text{12}\).

The study initially illustrated that the pressure equipment industry was (and continues to be) comprised of an eclectic sectoral and product mix, and makes it clear that it’s almost impossible to produce an all-encompassing picture of such a large and varied sector (which at that time was restricted to 15 Member States). Nonetheless, it provides a number of useful market assessments based on product classifications along the lines of those traditionally used by the industry. Reference is made to pressure vessels (containers, tanks, cylinders, reactors, columns), boilers and steam generators, heat exchangers, industrial piping and safety devices.

From assessing the economic data, it’s clear that the pressure equipment industry could only be regarded as strategically significant for Europe. For example, the data for 1994 indicates that the EU was the world’s leading exporter of pressure vessels (£660m per year), it was the world’s leading exporter of boilers (£760m per year) and the world’s leading exporter of fire extinguishers (£68m per year). The combined workforce for the pressure vessel and boiler sectors was 200,678. Overall, considering the data presented for other sectors as well, Europe held a significant global position in the manufacturing of pressure equipment.

The pressure equipment industry was also regarded as important given the sector’s provision of ongoing expertise, services and products to strategic industrial users. So much so, that the industry is often characterised by reference to the end-users, in sectors such as chemicals, food and drink, automotive, energy, oil and gas, and the iron and steel industries. However, this traditional market was seen to be moving production outside of Europe and the report recommended that pressure equipment manufacturers needed to follow their existing clients in a process of delocalisation.

However, since the sector was characterised as having a large SME base (with firms often with fewer than 100 employees), delocalisation presented a challenge for those firms that could not afford to develop their commercial networks internationally. In response, many firms had to direct their efforts towards becoming part of the supply chain of larger engineering companies.

Another major concern was that product design capability was limited and orientated to the safety legislation and requirements of specific Member State markets. Generally speaking, each Member State had its own set of laws and standards derived from its particular client base and historical traditions. It was pointed out therefore that the fragmented framework of national legislation and standards across Europe acted as a barrier to trade which consequently imposed significant burdens and costs on industry.

According to the study, ASME standards (American Society of Mechanical Engineers) such as the ASME VII standard tended to dominate the export market to third countries. This was the result of the global reach of American industry and their subsidiaries, the use of ASME standards as the de facto standards for the US / Canadian market, and the long-standing global recognition of ASME.

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\(^{12}\) Not all product groups that fall under the scope of the PED are included in the study and in addition the research includes assessments of product groups that subsequently were not regulated under the PED.
Background and Key Issues

In certain Member States, market surveillance and control authorities were also assessed as impacting negatively on the Internal Market. For example, some intra-EU exporters experienced difficulties in placing products on the market if their products did not conform to the standards or other requirements of the destination Member State even though the same product was fully acceptable in their own Member State.

In general, it was considered that the European pressure equipment industry demonstrated a number of competitive advantages. These included good educational levels, experience, capability, manpower, intelligent design skills and quality management systems. Yet gaps in the industry were also identified including the limited capacity of a large number SMEs. It was recommended therefore that the industry should continue to differentiate itself on the basis of a number of factors including exploiting performance based specifications and innovative and cost effective materials.

The combined identification of the economic importance and competitiveness of the sector and the recognition that the Internal Market was hindered via a fragmented framework of national standards, led the authors of the study to conclude that the introduction of European standards would be highly advantageous for the industry. In terms of economic advantages, it was perceived that European standards would be a significant factor in strengthening intra-EU trade, facilitating economies of scale through larger series in production and reducing control costs. It was also perceived that the potential acceptance of European standards by third country markets would strengthen opportunities for European exporters. Moreover, it was considered that European standards would improve the safety, quality and reliability of equipment and encourage the uniform implementation of simplified rules.

As far as it is possible to tell, it appears that there has not been a comparable study since then. Thus, whilst the study provided a useful insight into the conditions that led to the development of the PED, it was necessary as part of the evaluation to develop a current characterisation of the sector. This helps the evaluation to make an assessment of the performance of the PED (whilst simultaneously considering other trends that may have driven changes within the industry) and to make a judgement on the Directive’s continuing relevance.

3.2 The PED, New Approach, and the New Legislative Framework

To overcome some of the abovementioned trade barriers and to support the strengthening of the Internal Market, the Pressure Equipment Directive (97/23/EC) came into force in November 1999. From this point forward, the PED has meant that harmonised legislative requirements are in place that apply to the design, manufacture, testing and conformity assessment of stationary pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar.

The PED establishes regulatory requirements for a broad range of products that constitute stationary pressure equipment including vessels, piping, safety accessories and pressure accessories. The

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13 The Directive initially provided a transitional phase until May 2002 to allow manufactures to opt for either the requirements of the Pressure Equipment Directive or to continue with national regulations.
14 ‘Vessel’ means a housing designed and built to contain fluids and gases under pressure.
15 ‘Piping’ means components intended for the transport of fluids and gases integrated in a pressure system.
16 ‘Safety accessories’ means devices designed to protect pressure equipment against allowable pressure limits being exceeded.
17 ‘Pressure accessories’ means devices with an operational function and having pressure-bearing housings.
PED also regulates assemblies\textsuperscript{18} that are partly or wholly composed of pressure equipment. Consequently, the scope of the PED covers a particularly heterogeneous and complex product range which includes products for industrial use such as chemical installations, boilers, heat exchangers, storage vessels, but also, although to a lesser extent, consumer items such as pressure cookers and fire extinguishers.

One of the key objectives of the PED is to enhance the competitiveness of European industry by ensuring the free movement within the Internal Market of stationary pressure equipment that meet specified Essential Safety Requirements (ESRs). This means that Member States are unable to prohibit, restrict or impede the placing on the market and/or putting into service of pressure equipment that complies with the ESRs outlined by the PED. In particular, Member States are unable to employ national controls or restrictions that are based on identified pressure hazards that may restrict intra-EU trade and imports from third countries.

\textit{The New Approach and the PED}

The PED was initiated through the European Community’s Programme for the Elimination of the Technical Barriers to Trade and was selected for formulation under the \textit{New Approach to Technical Harmonisation and Standards (1985)}.

The New Approach was developed to address weaknesses in the traditional method of legislating for products within the Internal Market. The traditional method produced harmonised rules to meet the specific requirements for each type of product, but it was often slow and cumbersome in achieving agreement by all the Member States and created volumes of detailed and specific legislative texts. Occasionally, the legislation became outdated soon after implementation as a result of technological advancements.

To address these failures, the New Approach was introduced to provide a regulatory technique for technical harmonisation whereby product legislation is restricted to protecting the public goals of health and safety. In addition, rather than specifying requirements through traditional legislation, the New Approach emphasised the use of harmonised European standards to enable presumed conformity with the Essential Safety Requirements (ESRs) of the related Directive. Using standards as opposed to traditional legislation has been linked with offering firms and stakeholders ownership of key technical decisions through their participation in the standardisation process, allowing greater regulatory flexibility and opportunities for enhanced competitiveness and innovation. The New Approach therefore has the following key features:

- Legislative harmonisation is limited to Essential Safety Requirements that products placed on the Internal Market must meet if they are to benefit from free movement within the Internal Market;
- The technical solutions that meet the ESRs are laid down in harmonised European standards;
- Application of harmonised or other standards remains voluntary, and the manufacturer may apply other technical solutions to meet the ESRs;
- Products manufactured according to the harmonised European standards benefit from a presumption of conformity with the ESRs of a specified Directive;

After two decades of operation, the New Approach, broadly speaking, has gained recognition and acceptance from many sectors. However, the experience of implementation of a number of New

\textsuperscript{18} ‘Assemblies’ means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole.
Approach Directives has revealed several common weaknesses that have sometimes resulted in an insufficient level of confidence in the marketplace for products manufactured in the EU or imports from third countries. The consequence of this has been that firms that have abided by the rules have felt that there isn’t a level playing field, issues regarding the safety of products have been raised and consumers have considered that they haven’t been sufficiently protected.

The New Legislative Framework (NLF)

Given that a number of different Directives are facing similar problems, the New Approach was subject to a revision recently in the form of the New Legislative Framework for the marketing of products. The aim of the New Legislative Framework (NLF) is to keep intact the central tenets of the New Approach but to reinforce the effectiveness of the system, improve its transparency, and ultimately remove the remaining obstacles to the free movement of products within the Internal Market.

The NLF is being delivered through a broad package of measures and is composed of the following legal texts:


Although it was initially planned to include the PED in the NLF package (adopted by the Commission on 21/11/2011), it has since been decided that a separate proposal for the PED would be prepared, also taking into account the alignment of the Directive with the CLP Regulation on classification, labelling and packaging of substances and mixtures. Nevertheless, given that some of the key features that support the implementation of the New Approach Directives need to be set out in order to clarify the Intervention Logic of the PED, it is useful to keep in mind some of the provisions under the NLF that seek to strengthen its performance. Moreover, during the course of the evaluation, it has been detected that aspects of the PED’s implementation framework would benefit from features prescribed by the New Legislative Framework. This has supported the development of evaluation recommendations that are outlined in the Effectiveness section.

Key Features of the New Approach and the Measures to Strengthen its Operation under the New Legislative Framework

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To ensure the free circulation of products, the New Approach\textsuperscript{20} put in place a number of checks and balances that facilitate intra-EU trade in products that comply with ESRs, together with mechanisms to detect and remove products that do not conform. This system is built around a number of key features:

- Manufacturers are responsible for ensuring that products are properly designed and manufactured to meet the Essential Safety Requirements;
- Before being placed on the market, products should undergo a conformity assessment that is often overseen by a Notified Body\textsuperscript{21};
- To indicate that the Essential Safety Requirements have been met and the conformity assessment has been successfully completed, manufacturers issue an EC declaration of conformity and place a CE marking on the product;
- Member States should undertake market surveillance activities to guarantee that only products meeting the requirements of the Directive are available on the market;
- If it is believed that a product does not conform to the Essential Safety Requirements, it may be removed from the market. A \textit{safeguard clause} enables Member States to inform the Commission of any action they have taken to remove the product from market, and if approved, the Commission may recommend a similar Internal Market-wide response.

The following section will look at each of these key features in more detail and will make clear some of the provisions under the NLF that are intended to strengthen their operation.

\textit{Manufacturer Responsibility}

Under the New Approach, a manufacturer is the person responsible for designing and manufacturing a product with a view to placing it on the Internal Market. Manufacturers therefore have an obligation to ensure that a product is designed, manufactured and conformity assessed to the ESRs in accordance with the provisions of the relevant Directive. Manufacturers may use finished products, ready-made parts or may subcontract these tasks but must retain overall control and have the necessary competence to take responsibility for the product.

The NLF reinforces this approach by setting-out a proportionate set of obligations for economic operators within the supply chain (this includes manufacturers, distributors and importers of products from third countries) that underscore that they should only place on the market products that conform with harmonised legislation. As such, it is recommended that manufacturers and importers that have placed non-compliant products on the market are liable for damages under the EU Product Liability Directive (85/374/EEC).

\textit{Conformity Assessment}

Conformity assessments are undertaken by the manufacturer and, in the majority of the cases, by a third party organisation, known as a Notified Body (NBs) which provides independent analysis of the products being assessed. NBs are appointed by national authorities or by their delegated agents, and notified to the EC.

\textsuperscript{20} The New Approach is supported by the rules outlined by the Global Approach in relation to testing and certification.

\textsuperscript{21} However, in relation to the PED for category I pressure equipment, the manufacturer can independently declare that the product satisfies the requirements of the Directive.
Under the NLF, it has been recognised that NBs have not demonstrated consistent performance across the EU and would benefit from a mandatory accreditation system in line with EN ISO 17000. It is recommended therefore that quality requirements and standards are established to ensure that NBs and accreditation bodies perform their responsibilities to the same robust level. For example, if an accreditation body identifies that a NB is no longer competent to carry out a specific activity, the accreditation body should suspend or withdraw the NB’s accreditation certificate. Accreditation bodies should also assess the competence of subsidiaries and subcontractors of NBs, and should monitor the competence of their own personnel.

CE Marking

Manufacturers must place a CE marking on their products as a declaration to the authorities and consumers of the product’s conformity with the harmonised legislation. This should be based on the satisfactory completion of a conformity assessment procedure that demonstrates compliance with the ESRs.

Hence, given that the CE marking represents a formal indication of compliance, Member States are not allowed to restrict the placing on the market or the putting into service of CE marked products unless such measures can be justified on the basis of non-compliance.

Under the NLF, the position of the CE marking has been clarified. It is recommended that the Commission should monitor the implementation of the CE marking and report the findings to the European Parliament. In response to the misleading application of the CE marking, Member States should take appropriate action that may include criminal sanctions for serious infringements in order to provide a deterrent against improper use.

Market Surveillance

To ensure that only products that are compliant with the harmonised legislation are placed on the market, Member States must perform market surveillance activities. Member States have therefore been required to establish appropriate activities to guarantee that only products meeting the requirements of the applicable Directive(s) are available to consumers whilst those that are not are removed from the market.

The NLF follows a similar logic by requiring Member States to conduct market surveillance activities for products covered by harmonised legislation. It is required that products should be removed from the market if they are a risk to health and safety, if they don’t comply with the relevant harmonised legislation and if the CE marking has been misleadingly fixed to the product. Market surveillance authorities must therefore perform appropriate product checks on an adequate scale.

To support the work of market surveillance authorities, the Commission is requested to develop and maintain a general information support system that provides information on non-compliance with harmonised legislation. Market surveillance authorities should also develop programmes for sharing experiences and resources, and cooperate with competent authorities in the third counties on relevant issues.

Safeguard Clause

A safeguard clause requests Member States to inform the Commission when they take action against a product that does not conform such as removing the product from the market. If this action is considered to be an appropriate response, the Commission informs all other Member States who must adopt similar actions to ensure the enforcement of EU legislation.
Under the New Legislative Framework, a similar approach is requested of Member States. This reaffirms the importance of providing written notice to economic operators when they take action against a product that includes the grounds for which the decision is based and appropriate remedies.

3.3 Specific Features of the Pressure Equipment Directive

In line with the key features of the New Approach, the PED has put in place a number of specific features for the design, manufacture, testing and conformity assessment of stationary pressure equipment. This section explains in more detail a number of the specific feature of the PED relating to four different areas; the ESRs, classification of pressure equipment, the conformity assessment procedures and the role of User Inspectorates (UIs). It should be recognised that this section is for illustrative purposes only and is designed to inform those with limited knowledge of the PED. Please see the Directive itself for full information (the links are provided at the bottom of the page).

**PED Essential Safety Requirements**

In terms of the PED ESRs, at a general level, the Directive stipulates that pressure equipment must be designed, manufactured and checked, and if applicable equipped and installed, in such a way as to ensure its safety when put into service in accordance with the manufacturer’s instructions and in reasonably foreseeable conditions. Manufacturers are therefore obliged to:

- Eliminate or reduce hazards as far as is reasonably practicable;
- Apply appropriate protection measures against hazards which cannot be eliminated;
- Where appropriate, inform users of residual hazards and indicate whether it is necessary to take appropriate special measures to reduce the risks at the time of installation and/or use.

The description below explains some of the ESRs without being exhaustive (see Annex 1 of the PED for more details):

<table>
<thead>
<tr>
<th>Pressure Equipment Directive (97/23/EC)</th>
<th>Essential Safety Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design requirements</strong></td>
<td></td>
</tr>
<tr>
<td>Manufacturers must ensure that pressure equipment is properly designed to enable safe use of the product throughout its intended life. Consideration of a large range of design factors must be demonstrated and ensure that:</td>
<td></td>
</tr>
<tr>
<td>• The design strengths of pressure equipment are adequate for the loadings (e.g. pressure, temperature, fatigue etc.) related to their intended use and other reasonably foreseeable conditions;</td>
<td></td>
</tr>
<tr>
<td>• There are provisions made for the safe handling and operation of pressure equipment and that attention has been paid to the design of closures and openings, discharges, surface temperature etc.;</td>
<td></td>
</tr>
</tbody>
</table>

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• Pressure equipment has been designed and constructed so that all necessary examinations to ensure safety can be carried out;
• Adequate means have been provided for draining and venting;
• Adequate allowance or protection against corrosion or other chemical attack have been provided;
• Adequate measures have been taken to address conditions of erosion or abrasion;
• The design of assemblies are suitable and reliable for their intended purpose and the components can be readily integrated in an appropriate manner;
• Where appropriate, pressure equipment must be designed and provided with accessories, or provisions made for their fitting, so as to ensure safe filling and discharge;
• Protection against exceeding the allowable limits of pressure equipment under foreseeable conditions is made through the fitting of, or provisions made for, protective devices;
• Safety accessories must be designed and constructed so that they are reliable and suitable for their intended purpose and be independent of other functions;
• Pressure equipment must be designed to meet damage-limitation requirements in the event of an external fire.

Manufacturing requirements
• Manufacturers must ensure the competent execution of the provisions set out at the design stage by applying appropriate techniques and relevant procedures especially in view of preparation of the component parts, permanent joining, non-destructive tests, heat treatment and traceability;
• Pressure equipment must be subjected to a final assessment including an appropriate final inspection, proof test and inspection of safety devices;
• Pressure equipment must be appropriately marked and labelled. This includes the CE marking, further information for safe installation, maintenance and inspection and appropriate warnings where necessary.
• Pressure equipment must be accompanied with user instructions and contain relevant safety information;

Materials
• Materials used for the manufacture of pressure equipment must be suitable for such applications and for their scheduled lifetime unless replacement is foreseen. Similarly, welding consumables must be appropriate both individually and in a joined structure;

Specific Pressure Equipment Requirements
• Fired or heated pressure equipment with a risk of overheating must be designed and constructed to minimise risks from a significant loss of containment from overheating;
• Piping must be appropriately designed and constructed and ensure that the risks of overstressing are adequately controlled, provisions have been made for drainage and corrosion, consideration has been made of potential damage from turbulence, etc.;
Specific quantitative requirements for certain pressure equipment should be considered as a general rule, or in areas where they are not applied, measures should be taken to achieve an overall equivalent level of safety. The quantitative requirements cover allowable stresses, joint coefficients, pressure limiting devices, hydrostatic tests pressure and material characteristics (e.g. a steel is considered sufficiently ductile if its elongation after rupture is no less than 14% and its bending rupture energy measured on an ISO V test-piece is no less than 27 J).

Classification of Pressure Equipment

Under the PED, pressure equipment is classified by category according to an ascending level of hazard. As explained below, this is based on the type of the fluid that is contained in the pressure equipment, the type of container (i.e. pipes or vessels) and the volume and pressure (or stored energy) that the pipe or vessel operates at.

To begin with, the fluids that pressure equipment contains are divided into two different groups:

- Group 1 comprises dangerous fluids and includes fluids defined as explosive, extremely flammable, highly flammable, flammable, very toxic, toxic and oxidizing (as covered by the Dangerous Substances Directive 67/548/EEC 23 (DSD));
- Group 2 comprises all other fluids not referred to above.

To determine the classification of the pressure equipment, the PED includes 9 conformity assessment tables that correspond with certain types of equipment (i.e. pipes or vessels) based on the maximum allowable pressure (PS), the volume (V) and the state of the fluid (gas/liquid) and type of fluid it will contain (either Group 1 or Group 2). The conformity assessment tables therefore provide the framework for determining the category of pressure equipment that a given item will fall into. An example is provided below:

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In relation to the specific type of pipe or vessels, the conformity assessment table indicates the categorisation of the corresponding pressure equipment by four different categories (and a group that falls under Article 3 paragraph 3 of the Directive) and is based on their related pressure and volume.

The pressure equipment that falls under Article 3 paragraph 3 of the Directive is the least hazardous and is not subject to a conformity assessment procedure. Nor is the CE marking applied by the manufacturer. Rather, this category is subject to the sound engineering practices of a Member State in order for it to be placed on the market and to ensure its safe use.

Following that, the conformity assessment table indicates four different categories based on an ascending level of hazard (from Category I to Category IV). Category I is the least hazardous category and as indicated in the above table the range is from PS.V equal to or greater than 25 bar.L up to less than 50 bar.L. Category IV covers the most hazardous range and as indicated in the table above the range is from PS.V equal to or greater than 1000 bar.L.

By taking into account the stored energy of pressure equipment (based on the product of PS.V), the Directive has recognised that in certain cases a small vessel operating at very high pressure is as dangerous as a large vessel at operating at a lower pressure. This ensures that the most suitable conformity assessment procedures are selected in order to appropriately assess the design and manufacturing measures that are intended to contain the identified hazard.

Conformity Assessment Procedures, CE marking and Declaration of Conformity

Pressure equipment must undergo a number of conformity assessment procedures before being placed on the market. The conformity assessment procedures are implemented at various stages of the design and manufacturing process and enable manufacturers to demonstrate product conformity particularly in relation to safety aspects against the provisions of the Directive.

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24 This diagram specifically refers to vessels containing gaseous fluids in Group 1 with a volume greater than 1L and a product of PS and V greater than 25 bar L or with a pressure PS greater than 200 bar.
In the same way as all New Approach Directives, the PED conformity assessment procedures operate on the basis of a modular approach. Satisfactory completion of the modules is linked to the input and approval from a NB apart from module A (Category 1 pressure equipment) which is based on manufacturer examination alone and requires the manufacturer to ensure that the pressure equipment satisfies the requirements of the Directive.

In total, there are 13 different modules which apply to the different Categories of pressure equipment as indicated below:

Table 3.1: Conformity assessment procedures applied to the different Categories of pressure equipment

<table>
<thead>
<tr>
<th>Category</th>
<th>Module(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat I</td>
<td>Module A (internal production control)</td>
</tr>
</tbody>
</table>
| Cat II   | Module A1 (internal manufacturing checks with monitoring of the final assessment)  
           Module D1 (Production quality assurance)  
           Module E1 (Product quality assurance) |
| Cat III  | Module B1 (EC design examination) + D (Production quality assurance)  
           Module B1 (EC design examination) + F (Product verification)  
           Module B (EC type-examination) + E (Product quality assurance)  
           Module B (EC type-examination) + C1 (Conformity to type)  
           Module H (Full quality assurance) |
| Cat IV   | Module B (EC type-examination) + D (Production quality assurance)  
           Module B (EC type-examination) + F (Product verification)  
           Module G (EC unit verification)  
           Module H1 (Full quality assurance with design examination and special surveillance of the final assessment) |

Upon successful completion of the relevant module, the manufacturer fixes the CE marking to the pressure equipment in this way declaring, on his sole responsibility, conformity with all legal requirements. When requested, the manufacturer must supply a signed EC declaration of conformity (the PED does not demand that the declaration of conformity is automatically supplied with the pressure equipment). The declaration of conformity describes amongst other things the pressure equipment, the conformity assessment procedures that have been followed, references to the type-examination and design-examination certificates issued by the NB and the harmonised or other standards that have been adopted.

Recognised Third Party Organisations

Recognised Third Party Organisations (RTPO) are outlined by Article 13 of the PED and have the aim of supporting the delivery of key tasks that are outlined in the ESRs. Namely, RTPOs are appointed by national authorities to approve personnel (through examinations) that undertake conformity assessment activities relating to permanent joining and non-destructive tests.

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26 Permanent joining tests assess the safety of material joints that are intended to last the life-time of a product.
User Inspectorates

The PED deviates from other New Approach Directives through a feature which Member States may chose to adopt known as User Inspectorates (UIs). UIs are independent bodies that are part of a company or group and have the remit of performing conformity assessment activities (specifically modules A1, C1, F and G). By performing this role, they enable firms to take advantage of their in-house technical know-how and avoid using NBs, and are particularly advantageous for users of highly complex pressure equipment (such as major installations and plants).

The PED requires that each UI must be organisationally identifiable and have reporting methods to ensure and demonstrate their impartiality and independence of judgement. However, UIs cannot apply the CE marking, and UI approved pressure equipment can only be used in establishments operated by the group of which the UI is a part.

3.4 Harmonised European Standards and Other Pressure Equipment Standards

The European Committee for Standardisation (CEN) has been authorised under the Directive to develop and adopt harmonised European standards (known as EN standards) that enable presumption of conformity with the ESRs. Since the introduction of the PED, a large number of EN standards for pressure equipment and harmonised standards for materials used in pressure equipment have been developed through a variety of CEN Technical Committees (TCs) and subsequently published in the Official Journal of the European Union (OJ).

The list of EN standards published in the OJ largely covers three main product groups and variants of them namely pressure vessels\(^{28}\), piping\(^{29}\) and boilers\(^{30}\). Other standards that are essential for the manufacture of pressure equipment have also been developed and include materials\(^{31}\), valves\(^{32}\) and techniques such as welding\(^{33}\). A proportion of the EN standards have been initially developed at an international level through the International Organisation for Standardisation (ISO)\(^{34}\) and have been integrated within the CEN Technical Committees to form EN ISO standards. Occasionally, an EN standard has formed the basis of an ISO standard.

EN Standards and their Technically Innovative Design Philosophy

Following the logic of the PED, the approach taken by CEN has been to develop standards through a comparatively different design philosophy in relation to the approach taken by some of the other major standards and codes bodies. For many, this is largely perceived as a more technically innovative but more demanding design approach given that safety factors for EN standards are achieved through goal setting (i.e. specifying responsibilities and what is required to be achieved) as opposed to other approaches that actually prescribes the goal to be achieved. As such, to comply with EN standards, manufacturers need to undertake specific analytical design techniques to

\(^{27}\) Non-destructive testing is the branch of engineering concerned with all methods of detecting and evaluating flaws in materials.

\(^{28}\) For example EN 13445 (Unfired Pressure Vessels)

\(^{29}\) For example EN 13480 (Metallic Industrial Piping)

\(^{30}\) For example EN 12953-1 (Shell Boilers) and EN 12952-1 (Water Tube Boilers and Auxiliary Installations)

\(^{31}\) For example EN 10028-1 (Flat Products Made of Steel for Pressure Purposes)

\(^{32}\) For example EN 1983 (Industrial Valves – Steel Ball Valves)

\(^{33}\) For example EN ISO 9606-2 (Qualification Test of Welders - Fusion Welding)

\(^{34}\) For example EN ISO 16136 (Industrial Valves – Butterfly Valves of Thermoplastic Materials)
determine the guaranteed performance of materials, whereas other types of standards and codes tend to emphasise the enhancement of materials to a specified thickness to enable compliance\textsuperscript{35}. By way of example, these diverging approaches can be determined in relation to mechanical testing of steel for pressure equipment. In the EN system, it is required that the maximum design stresses to be used in construction appear in the material specifications and are based on the measured proof stress as a function of temperature. The material manufacturer is therefore required to ensure that the proof stress values adequately support the design allowable stresses. Whereas in other approaches, the standard or code establishes the design allowable stresses based on data analysed by the standardisation body. Given that the manufacturer is not party to the development of the allowable stresses, he is not in a position to certify that the design meets the safety demands of the application in question and only needs to demonstrate that the material meets the room temperature properties mentioned in the specification.

Research funded by a private standardisation body (ASME)\textsuperscript{36} that provides codes that contain design allowable stresses, indicated that pressure equipment designed in this way has a strong safety performance and is comparable to the safety performance of pressure equipment designed according to the EN system. However, it needs to be kept in mind that pressure equipment that has not been designed under the EN approach may not necessarily meet the ESRs of the PED given that it has been built according to a different design philosophy. In such case, the pressure equipment manufacturer has to take additional measures to ensure compliance of the pressure equipment with the PED.

**Benefits of EN Standards**

To encourage their uptake by industry, the aims of EN standards go beyond simply enabling presumption of conformity with the ESRs. By determining the guaranteed performance of materials, they are designed with the intention of offering a number of economic and technically innovative advantages (in comparison with other standards and codes) including:

- Reducing material and manufacturing costs through the use of thinner walls within manufactured pressure equipment;
- Potentially reducing the costs of in-service inspection and maintenance (depending on the approach of the country concerned);
- Deferring replacement by increasing life expectancy.

To further illustrate this point, a study was undertaken to assess the economic advantages in terms of costs of using EN standards for design calculations, materials and conformity assessment\textsuperscript{37}. The study was delivered by two NBs with the assistance of pressure equipment manufacturers from Italy, France, Germany and Austria. The research considered the application of the European harmonised standard for unfired pressure vessels known as EN 13445 compared with ASME VIII design procedures relating to a set of 9 manufacturing example cases which covered a wide range of pressure vessel types, designs, materials and fabrications. As such, as well as considering EN 13445 in relation to the PED conformity assessment route, ASME Section VIII was considered in relation to


both the ASME (U-stamp or U2 stamp 2) and PED conformity assessment routes\(^{38}\). The following table summarises the mean values of the relative design calculations, materials and related conformity assessment costs of each example i.e. the mean of the relative costs quoted by the different manufacturers for each vessel and code route considered:

### Table 3.2: Overall Production Costs for 9 Example Products Developed Through Three Different Standard and Conformity Assessment Routes

<table>
<thead>
<tr>
<th>Example</th>
<th>EN 13445 DBF</th>
<th>EN 13445 DBA</th>
<th>ASME VIII Div. 1</th>
<th>ASME VIII Div. 1 + PED</th>
<th>ASME VIII Div. 2</th>
<th>ASME VIII Div. 2 + PED</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) CNG storage tank</td>
<td>100.0%</td>
<td>95.6%</td>
<td>130.4%</td>
<td>138.5%</td>
<td>118.1%</td>
<td>117.9%</td>
</tr>
<tr>
<td>(2a) Hydrogen reactor (welded course)</td>
<td>100.0%</td>
<td>No benefit</td>
<td>115.9%</td>
<td>122.6%</td>
<td>106.5%</td>
<td>110.5%</td>
</tr>
<tr>
<td>(2b) Hydrogen reactor (forged course)</td>
<td>100.0%</td>
<td>No benefit</td>
<td>94.3%</td>
<td>94.9%</td>
<td>84.9%</td>
<td>85.3%</td>
</tr>
<tr>
<td>(3) Jacketed autoclave(^1)</td>
<td>100.0%</td>
<td>Not required</td>
<td>97.9%</td>
<td>98.6%</td>
<td>Not required</td>
<td>Not required</td>
</tr>
<tr>
<td>(4) Steam vessel(^5)</td>
<td>100.0%</td>
<td>No benefit</td>
<td>110.6%</td>
<td>110.6%</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>(5) AES heat exchanger(^3)</td>
<td>100.0%</td>
<td>Not required</td>
<td>100.3%</td>
<td>101.8%</td>
<td>Not required</td>
<td>Not required</td>
</tr>
<tr>
<td>(6) EEM heat exchanger(^3)</td>
<td>100.0%</td>
<td>Not required</td>
<td>99.0%</td>
<td>101.9%</td>
<td>Not required</td>
<td>Not required</td>
</tr>
<tr>
<td>(7) NEN heat exchanger(^3)</td>
<td>100.0%</td>
<td>Not required</td>
<td>108.2%</td>
<td>106.9%</td>
<td>Not required</td>
<td>Not required</td>
</tr>
<tr>
<td>(8) Water separator</td>
<td>100.0%</td>
<td>Not required</td>
<td>105.6%</td>
<td>110.1%</td>
<td>Not required</td>
<td>Not required</td>
</tr>
<tr>
<td>(9) Air cooler</td>
<td>100.0%</td>
<td>88.1%</td>
<td>106.7%</td>
<td>108.2%</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

\(^1\) with fatigue analysis according to EN 13445 and ASME VIII Div. 1, respectively.  
\(^2\) the minimum plate thickness according to TEMA – applied on both EN and ASME approach – tends to equalize the designs.

Overall, the research demonstrated that EN 13445 offers a technically and economically competitive design route for unfired pressure vessels. Out of the 9 examples, 6/7 (depending on the manufacturing approach for hydrogen reactors) indicated that using EN 13445 was the most economically efficient route. The main reason was that ASME VIII designs require thicker materials in comparison to EN designed pressure equipment. This leads to overall lower material costs for EN

\(^{38}\) For the estimation of the costs, the study used the following combinations of codes and conformity assessment routes:  
- EN 13445 and conformity assessment according to the PED (CE-marking).  
- ASME Section VIII (Division 1, Division 2 if applied) and conformity assessment according to ASME (U-stamp, or U2-stamp), presuming that the manufacturers already held these stamps and were entitled to use them.  
- ASME Section VIII (Division 1, Division 2 if applied) and conformity assessment according to the PED (CE-marking).

The exercise was based on compliance with the corresponding requirements assuming no pre-existing qualifications or supplementary data from other similar equipment.
Background and Key Issues

designed products. However, it was noted that some of the cost benefits of thinner EN designed materials is offset by higher EN design costs when compared with ASME VIII approaches e.g. weld testing and Non-Destructive Testing (NDT). However, Post Weld Heat Treatment (PWHT) requirements carry greater costs for ASME designs since PWHT requirements are greater as wall thickness increases.

In addition, although not specifically referring to EN standards, the environmental benefits of using design approaches that lead to thinner materials for pressure equipment have also been tentatively recognised. Through the use of light weight design techniques such as design by analysis and reducing safety factors, greater resource efficiency can be achieved when manufacturing pressure equipment. Moreover, comments have been made by academics about the use of such standards in relation to future market demands. Given that pressure equipment installations will become increasingly complex, a new genre of extreme pressure equipment have been identified that would benefit from technically advanced standards as a result of their associated hazards.

3.5 Other Procedures that Assess Conformity of Materials with the ESRs

In addition to the standardisation procedure for materials, the PED contains another two procedures that have similar goals for approving materials in lines with the ESRs namely the European Approval of Materials (EAM) and the Particular Material Appraisal (PMA).

European Approval of Materials (EAM)

The EAM procedure has been developed with a view to achieving approval for potential new materials that may be used for the manufacture of pressure equipment. Given that new materials are often not initially widely recognised or used by industry, a procedure outside the normal standardisation process was seen to be the most relevant and effective way to support the functioning of the Directive.

In order to receive an EAM, a manufacturer must issue a request to a NB with a view to performing appropriate tests in order to certify the conformity of the material with the corresponding requirements of the Directive. The NB then informs the Commission and Member States by submitting an EAM application including the material characteristics and the underlying test results. The Commission and/or the Member States may object within three months and refer the case to the Standing Committee set up by Article 5 of Directive 83/189/EEC (otherwise known as the 98-34 Committee). The Standing Committee will examine the case considering the advice of the sectoral expert group (Working Group Pressure). Given the highly technical nature of this process, the WGP has setup a subgroup Working Party Materials (WPM) that has the role of examining the EAM application in detail. After an assessment of the comments received, the EAM application is either rejected or accepted. In the latter case, the NB may issue the European approval of the materials to the manufacturer. The Commission accordingly publishes the references of the EAM in the OJ with the European approval of the material concerned.

Particular Material Appraisal (PMA)

A PMA is the result of a process by which a pressure equipment manufacturer demonstrates that a proposed material that is not referenced in an EN standard or covered by an EAM conforms to the applicable ESRs. Although there aren’t any specific legislative requirements regarding how a PMA should be executed, the PED makes it clear that for Category III and IV equipment the PMA must be delivered by the pressure equipment manufacturer and assessed by the NB that is responsible for

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the delivery of the conformity assessment procedures by which the pressure equipment is being assessed. There are also a number of PED Guidelines (see further information of PED Guidelines below) on the matter among which it is recommended that PMA documents are drawn up by the manufacturer alone. Further support on developing PMAs has been provided in a document on the “Principles for the contents of Particular Materials Appraisals”40.

3.6 PED Guidelines that Support the Enforcement of the Directive

To support the even enforcement of the PED, non-statutory PED Guidelines have been produced and are continually updated at a European level. The PED Guidelines are developed through the Working Group Pressure (WGP) and Working Party Guidelines (WPG) and consist of a range of authoritative responses to questions submitted to the WGP by industry and other stakeholders. To date, just less than 200 PED Guidelines have been developed that cover a range of issues that include the scope and exclusions of the Directive, classification and categories, assemblies, evaluation assessment procedures, interpretation of the ESRs for design, manufacturing materials and other areas, miscellaneous items and horizontal areas41. It should be noted that proposals for new guidelines are submitted by stakeholders such as national industry associations, Member State authorities and NBs. Normally proposals made by individual firms are submitted via industry associations / national authorities and are screened prior to submission. The procedure for the development of the PED Guidelines is set out below.

Figure: 3.2: Procedure for the Development of the Guidelines (proposals for new guidelines are submitted by stakeholders)


42 Please find the diagram at: http://www.netinform.net/Vorschriften/DG/ped_en/go.htm Please note that the further information available at this site is now out of date (The diagram is not out of date).
Background and Key Issues

Although non-statutory in nature, the PED Guidelines are widely understood as being the correct interpretation of the Directive and for the most part are voluntarily applied. There are only a small number of PED Guidelines that are objected to by the Member States. In general they are adopted by Working Group Pressure unanimously thereby giving them an authoritative status.\(^{43}\)

In addition to the European level PED Guidelines, numerous non-statutory guidelines have been developed at national level by relevant government authorities and NBs. The main purpose of these guidelines is to provide stakeholders with an accessible interpretation of the Directive and to ensure a consistent application of the Directive by all stakeholders in all Member States and EEA countries.

3.7 PED Conformity Assessment and Market Surveillance Meetings

The enforcement of the Directive is further supported through the work and meetings of conformity assessment and market surveillance bodies.

**Conformity Assessment Bodies Forum (CABF)**

The Conformity Assessment Bodies Forum (CABF) is composed of the PED NBs and Users Inspectorates and as well as supporting the process for the development of the PED Guidelines, a range of other issues and best practices are discussed which aim to encourage the consistent implementation of the Directive.

**Market Surveillance Cooperation Group (ADCO)**

In addition, market surveillance issues are discussed through the Market Surveillance Cooperation Group (ADCO) which is composed of relevant national authorities from the Member States. The main aim of ADCO is to exchange information and best practices based on national findings with the intention that this leads to the consistent enforcement of the Directive and limiting of non-compliant products on the European market.

3.8 Relationship with Related European Legislation for Pressure Equipment

The EU has other pieces of legislation that regulate specific areas of the pressure equipment market or govern the use of pressure equipment within certain types of products. During the course of the evaluation, stakeholders have commented that these require assessment given their interaction in some areas with the PED. This section will present the most significant of these as indicated below:

- The Simple Pressure Vessels Directive (SPVD)\(^{44}\)
- The Transportable Pressure Equipment Directive (TPED)\(^{45}\)
- The Machinery Directive\(^{46}\)

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\(^{43}\) As noted in the introductory online text to the guidelines the ‘status of the guidelines’ is as follows: ‘The PED Guidelines are not a legally binding interpretation of the Directive. The legally binding text remains that of the Directive. However, the PED Guidelines represent a reference for ensuring consistent application of the Directive. They represent, unless indicated differently in the respective guideline text, the unanimous opinion of the Member States’.


Evaluation of the Pressure Equipment Directive

Background and Key Issues

An assessment of how they interact with the PED is presented in the relevance section.

**The Simple Pressure Vessel Directive (SPVD)**

The SPVD was formulated under the New Approach and follows the logic of supporting the free movement of CE approved goods within the Internal Market. However, the SPVD specifically provides regulation for ‘simple pressure vessels’ that are produced in series, are produced from steel or aluminium (alloys), are not intended to be fired, are subject to an internal gauge pressure of over 0.5 bar but lower than 30 bar and are intended to contain air or nitrogen. With this definition of simple pressure vessels in mind, the SPVD provides regulation for a very precise and relatively small area of the pressure equipment market.

**Transportable Pressure Equipment Directive (TPED)**

The TPED is one of a series of measures that provides the legal framework to enforce the European Agreement for the International Carriage of Dangerous Goods (ADR)\(^{47}\). The TPED covers all pressure equipment designed for transport including pressure receptacles, valves and other accessories, tanks, battery vehicles / wagons, multiple element gas containers and gas cartridges.

The main purpose of the TPED is to support the placing of transportable pressure equipment on the Internal Market through the application of conformity assessment procedures overseen by NBs. However, in contrast with the PED, the TPED has been formulated according to a very different style of rule making as manufacturers are not provided with the option of selecting standards which they deem to be the most appropriate in order to meet specified safety requirements. Alternatively, the TPED is highly prescriptive as manufacturers of transportable pressure equipment must adopt specific ISO standards as outlined in the “European Agreement Concerning the International Carriage of Goods by Road (Volume II)”\(^{48}\). Moreover, in terms of safety measures, in a significant number of cases the TPED ISO standards contain a range of safety criteria, thresholds and tests that when considered as a whole do not correspond entirely with the safety measures in comparable PED standards. Finally, a further key difference is that the TPED provides standards to support the in-service inspection of transportable pressure equipment. The regulation therefore considers the use-phase of the product that occurs after the product has been placed on the market.

**Machinery Directive**

The Machinery Directive was formulated under the New Approach and likewise facilitates the free movement of goods that meet Essential Health and Safety Requirements (EHSRs) and is supported by EN standards.\(^{46}\) The Machinery Directive, regulates machinery one of the applications of which are defined as ‘assemblies fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application’.

In terms of the requirements for pressure equipment, the Machinery Directive does not provide a great deal of detail but there are some ESRs applicable to equipment subject to an internal pressure such as:


47 The ADR is overseen by the United Nations.

**Background and Key Issues**

- Both rigid and flexible pipes, particularly those that operate under pressure must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected to ensure that no risk is posed by rupture;

- Where machinery are powered by a source of energy other than electricity, they must be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy;

- The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used;

- The durability of the materials used must be adequate for the nature of the working environment foreseen by the manufacturer or his authorised representative, in particular as regards to the phenomena of fatigue, ageing, corrosion and abrasion;

- Finally, some of the safety components covered by the Machinery Directive may be subject to an internal pressure and must meet safety requirements.

**3.9 Relationship between the PED and National In-service Inspection Regimes**

Whilst the scope of the PED does not cover in-service inspection, national legislation in this area is applied across many industrial sectors in Europe and often has the goal of ensuring that pressure equipment meets specified safety requirements during the use phase of the product. Normally, in-service inspection legislation establishes a number of assessments and tests either during the installation of pressure equipment and/or at subsequent intervals after it has been put into service. In addition, given that the legislation is formulated and overseen by national bodies, national regimes differ in their nature and scope. Whilst existing research in the area is limited, certain types of national in-service inspection regimes can affect the placing on the market and/or putting into service of pressure equipment.

A survey\(^\text{49}\) conducted by the European Committee for User Inspectorates (ECUI) noted that Member States had in-service inspection requirements relating to the scope, nature and frequency of inspections and the authorisation of Inspection Bodies. These were based on parameters relating to the history, size and complexity of plant, pressure, volume, stored energy and temperature of equipment, and inspection and testing methods. An analysis of the degree of flexibility of the requirements and parameters led the ECUI to conclude that broadly speaking two types of inspection regime operated in Europe:

- In some countries, *de facto* responsibility is taken by the government authority through prescriptive requirements which limit the role of firms in making independent judgements;

- In other countries, more flexible regimes are in operation which place the primary responsibility for the safe management of pressure equipment, subject to safeguards, on the user.

The ECUI concluded that flexible regimes could be successfully introduced across Europe and would incur greater benefits for the pressure equipment industry than the current ‘fragmented’ approach.

An example of an in-service inspection approach that is slightly different from other national regimes is the ‘Putting into Service Inspection’ (KVI) that is conducted in the Netherlands and is delivered by

\(^{49}\) EUCI (2007) Position Paper: In-service Inspection of Pressure Equipment:
the Appointed Inspection Agency (AKI). The inspection takes place after the pressure equipment has been placed on the market but before being put into use and has four main aspects:

- Verification of equipment through technical documentation and markings;
- Inspection of the external condition of pressure equipment, assemblies and pressure systems;
- Inspection of the operation of safety and pressure accessories;
- Inspection of the arrangement and integration of pressure equipment.

Whilst research undertaken by a prominent NB found that this type of legislation is useful for ensuring that pressure equipment meets the PED and guaranteeing the safe and sound assembly and/or installation of different types of pressure equipment at the premises of the user, it does provide an example of how in some cases distinct national legislation has a role in determining the placing on the market of pressure equipment.

**Summary of Background and Key Issues**

- 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. Given the industry’s economic importance, EU-level interventions were recommended in order to facilitate intra-EU trade and to strengthen the sector broadly speaking. With this backdrop in mind, the evaluation has been well positioned for assessing the performance of the PED since its introduction and to make a judgement of the Directive’s continuing relevance;

- Other pieces of EU legislation (namely the SPVD, TPED, and Machinery Directive) that have been designed to regulate pressure equipment or govern the use of pressure equipment within certain types of products have been said to interact in some areas with the PED. The areas of interaction are analysed in the relevance section.

- The Commission intends to make a proposal that will align the PED with the NLF (and at the same time take into account the alignment with the CLP). The emergence of the NLF as a means of addressing problems with the New Approach Directives broadly suggests that the PED framework may require strengthening in certain areas. Identification of problems in this area and recommendations to support the performance of the PED that parallel key features of the NLF are outlined in the effectiveness section;

- The PED provides a rigorous approach to classifying and conformity assessing pressure equipment. Given that this is one of the cornerstones of the Directive, the effectiveness section investigates stakeholder perceptions of the performance of this important aspect.

- Non-statutory PED Guidelines and national guidelines have been developed in order to provide stakeholders with appropriate interpretations of the Directive. Their intended role of ensuring consistent application of the PED by stakeholders is examined in the effectiveness section.

- Although outside of the legislative scope of the PED, national in-service inspection regimes are believed to affect the placing on the market of pressure equipment. The reaction from stakeholders with regard to this issue is examined in the effectiveness section.

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• Significant levels of resources have been invested in developing EN standards that offer presumption of conformity with the PED and provide a number of economic and technically innovative advantages (in comparison with other standards and codes). Within the efficiency section, the extent of their uptake by industry is assessed along with an assessment of stakeholder perceptions of their intended benefits.

• The process of ensuring that materials used in pressure equipment meet the ESRs has been supported through the introduction of two procedures (EAM and PMA) that operate outside of the standardisation route. These procedures will be assessed within the efficiency section.
4. Relevance

4.1 Introduction to the Evaluation Thematic Assessment

The evaluation has taken place almost 10 years after the Directive replaced national legislation. During the course of the study, the PED has been said to reach a stage of maturity along with a range of supporting policy processes and implementing activities. The targeted stakeholders that supplied qualitative and quantitative feedback to support the evaluation were consequently well placed to provide insightful comments on the workings of the Directive, its relative strengths and weaknesses and the impact that it has had on the marketplace. However, given that the evaluation represents a relatively original piece of research in the pressure equipment field, a number of the findings are based on qualitative statements from stakeholders alone. Given the complexity of the subject matter, in some areas the evaluation may be regarded as providing the basis from which further investigation will undoubtedly add to the on-going assessment and monitoring of the legislation.

In order to appropriately structure and assess the research findings, the following sections offer an analysis in the context of the standard evaluation framework with particular reference to the thematic areas of relevance, effectiveness, efficiency, utility, sustainability and European added value.

4.2 The Concept of Relevance in Relation to the PED

One of the key themes of the evaluation framework is to determine the relevance of the Directive for tackling the needs of users and other beneficiaries and the nature and scope of activities that it has been designed to address. In particular, the approach seeks to uncover whether the implementing measures of the Directive have led to the realisation of its key policy objectives and whether the legislation comfortably fits into the broader policy landscape of which it is part. The overall coherence and consistency of the legislation is therefore a major consideration.

This section will assess in detail the PED’s efforts to support the development of the Internal Market for pressure equipment and its aim to ensure a high degree of safety for industrial users and consumers. It will also examine how the PED interacts with other related legislation such as the SPVD, Machinery Directive and TPED, and will determine whether any improvements can be made in this regard.

4.3 The Consistent Development of the Internal Market for Pressure Equipment in Relation to Governance and Economic Performance Aspects

The PED was introduced to address the identified shortcomings of the Internal Market in ensuring the free movement of pressure equipment. As mentioned, prior to the PED being introduced, previous research indicated that the sector was characterised by regulatory fragmentation which hindered intra-EU trade and the unimpeded placing of products on the market. With this backdrop in mind, the stakeholders that provided comments on whether the PED has led to a consistent development of the Internal Market were able to compare the earlier situation, where there was an absence of European legislation, with the current context.

At this level of analysis, the introduction of the PED, compared with the prior system of national legislation, has led to a greatly improved and much more consistent regulatory framework for facilitating the free movement of pressure equipment. Comments have been made that it has taken some time for certain stakeholders to adapt to the requirements of the PED, and for certain supporting mechanisms and complementing features to be introduced and function well. Despite
these initial challenges, the Directive, at this stage of maturity, has now made it possible for firms to execute an approach to the marketing of pressure equipment across Europe with significantly higher levels of uniformity.

This has meant that the characterisation of the pressure equipment market as being fragmented in regulatory terms no longer holds in a number of key areas. In fact, it has been noted that a cultural shift has occurred. As a result, European industry, NBs and public authorities now operate within an environment that is framed by a number of common key principles and practices that allow for a largely common understanding of the steps necessary for the placing of pressure equipment on the European market. Consequently, by making serious efforts to introduce and follow the PED framework, such as the classification of pressure equipment, oversight of the conformity assessment modules by NBs, application of the CE marking and the issuing of declarations of conformity, the pressure equipment community have made great steps towards achieving the PED goal of removing the identified barriers to trade within the Internal Market.

Industry associations and individual firms have pointed out that the enhanced consistency of the Internal Market has led to a number of commercial benefits which have helped to open-up opportunities and lowered the costs of conducting business in Europe. In particular;

- The replacement of national legislation with the PED framework has opened up intra-EU trading opportunities as manufacturers have improved their understanding of the rules they need to follow to access Member State markets;
- When looking at the EU as a whole, the role of national authorities in governing the placing on the market of pressure equipment according to national requirements has been reduced and this has itself overcome some of the barriers to enhanced market entry opportunities;
- In some countries, it has been noticed that the number of companies from other Member States that are competing for contracts has increased since the introduction of the PED;
- Consequently, the level of competition has increased between firms within the Internal Market;
- According to some, manufacturers from outside Europe that follow the PED approach are in an enhanced commercial position as they can target the EU as a whole rather than adopting a country by country strategy;
- The costs for NB approvals have been significantly reduced for some firms as pressure equipment can be conformity assessed according to a single set of requirements and uniformly marketed across all Member States. This is particularly true for firms that frequently trade across the EU and design equipment according to the harmonised European standards;
- Given that pressure equipment need to meet ESRs rather than specified technical requirements, the Directive provides significant scope for product innovation;

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51 A number of intra-EU export orientated firms noted significant reductions in regulatory costs compared to the previous system of designing equipment to meet national safety requirements but were unable to provide exact figures or shares. However, one large firm that makes use of the harmonised European standards and exports pressure equipment to multiple Member States mentioned savings in the region of 80% and a figure of roughly €0.5m. It is considered unlikely that this is representative of the industry as a whole but it could be stated that significant savings have been made across industry in particular for firms exporting to numerous countries and particularly those using the harmonised European standards.
4. Relevance

Finally, the amount of time it takes for firms to consider regulatory issues has been reduced in relation to conformity assessment procedures and Member State market entry requirements. This has again led to cost savings.

However, although one can point to the benefits that the Directive has encouraged from a longitudinal perspective, a large number of issues remain when considering the functioning of the Directive in the current time period alone. As will be explored in more detail in the sections examining the effectiveness and efficiency of the Directive, the initial conclusions need to be qualified by factors that hamper the current performance of the Directive or limit the achievement of its ultimate objectives. These include a range of different issues including a number of problems that are common to a large number of New Approach Directives, unclear or possibly unnecessary aspects of the PED, uneven Member State implementation practices, the limited uptake of the harmonised European standards and the negative impact that the fragmented national in-service inspection regimes have on ensuring the smooth functioning of the Internal Market for pressure equipment. All of these issues will be examined individually in the forthcoming sections.

4.4 The Consistent Development of the Internal Market for Pressure Equipment in Relation to Safety Performance Aspects

Combined with their overall positive response relating to the PED’s objective of facilitating an improved Internal Market, stakeholders also commented that the Directive’s provisions for ensuring a high degree of safety have also been largely met. Generally speaking, when reflecting on the safety of pressure equipment that conforms to the PED, no reason was given to believe that the ESRs were in anyway inferior to the measures that had previously existed under national requirements. In addition, no accidents or incidents were mentioned that could be directly attributed to a failing or a lack of focus on safety in relation to the ESRs. If accidents had occurred, it was more of question of inappropriate maintenance practices or failed systems rather than problems associated with the ESRs. It appears therefore that the PED has successfully combined market integration with maintaining the high levels of safety that Europe was already accustomed to.

It should be acknowledged however that the positive safety performance of the PED is a result of the requirement for the utilisation of standards that conform to the ESRs (the ESRs only provide the safety objectives that pressure equipment are expected to meet whereas relevant standards provide the technical details that are designed with the aim of meeting the ESRs). In terms of the harmonised European standards, their solid safety performance, according to a small number of standardisation experts, rests upon the inclusion and development of ‘safe design philosophies’ that already existed in certain Member States. The development of the specified safety requirements within EN standards were therefore based on combining and enhancing the experiences of former national standards. Although the most stringent national requirements were not always selected for adoption, stakeholders commented that EN standards have maintained a satisfactory level of safety for the placing of pressure equipment on the market.

However, whilst the PED and complementing EN standards have attained a satisfactory overall level of safety in Europe, a broad number of potential safety issues have been detected. Although these issues are not directly connected to a failing of the PED or harmonised European standards, they pose issues for the PED when considering its goals of achieving an even level of safety across Europe. These issues include the uneven application of the conformity assessment modules, varying NB capacity levels and in certain cases the import of pressure equipment and use of
materials that have been unsatisfactorily manufactured outside Europe. These issues will be explored in more detail in the effectiveness section and have been summarised in table 6.4.


In terms of the interaction and overlap of the PED with other pieces of European legislation, a number of comments were made in relation to the SPVD, TPED and Machinery Directive. Before these comments are assessed in detail, a short summary of the "Review of the Application of the SPVD in Relation to the PED" is provided.

Summary of the Review of the Application of the SPVD in Relation to the PED

The SPVD was adopted long before the introduction of the PED and is highly specific in scope. Given the simultaneous implementation of the PED and SPVD, in certain cases manufacturers are provided with two legislative options which they can select from in order to meet EU requirements. As a result, the PED contains a clause that obliged the Commission to undertake a review in order to ascertain the relationship between the SPVD and the PED and to determine their suitability for integration. However, based on an assessment of safety and technical issues, the review found that the two Directives should not be merged as a result of number of findings:

- In terms of assemblies, given that the PED provides regulation for assemblies as a whole and the SPVD only the vessel concerned within an assembly, it was considered that a merger would increase the administrative burden on certain product groups;
- In terms of the response to the identified manufacturing problems within inexpensive consumer products that contain simple pressure vessels, it was found that a merger would not be suitable since the safety standards for such items would not be raised given that the PED has less specific requirements than the SPVD for simple pressure vessels;
- With regard to standardisation, it was suggested that specific standards would still be required for simple pressure vessels under a merged Directive and that significant standardisation work would therefore have to be undertaken that would involve an unjustifiable transition phase for manufacturers;
- In relation to PED product group exemptions, by merging the Directives the current long list of PED exemptions that do not apply to the SPVD would need to be corrected and would entail a complicated and lengthy process;
- It was thought that it would be inappropriate to include special provisions for simple vessels in a merged Directive, since this would negatively impact on other serially produced items;
- Finally, with regard to the administrative workload and competitiveness aspects, no additional benefits were identified and merging the Directives would result in limiting the choice currently offered to manufacturers for ensuring compliance with legislative requirements.

Overall, from the viewpoint of the reviewer and consultation responses, the decision not to merge the Directives appeared to be well-founded.

Current Findings In Relation to the Simple Pressure Vessels Directive

In terms of the current perception of the operation of the SPVD and its interaction with the PED, the situation seems to be relatively stable with manufacturers generally understanding the remits of both Directives and the types of vessel that the Directives apply to. In addition, a number of Member States officials were confident that if a problem of interaction emerges then these can be rapidly dealt with through cooperation with their relevant colleagues or SPVD counterparts.

The case was also made by European and national industry associations that the findings of the review continue to be relevant. In particular, given that there is limited conflict between the two Directives, firms should be offered the flexibility to select the most appropriate piece of legislation according to their manufacturing requirements. In addition, it was also made clear that a merger of the legislation would unsettle firms that were already accustomed to working with the SPVD which in their mind is functioning well. Moreover, certain SMEs were concerned that merging the Directives would increase the regulatory burden on manufacturers as a result of the more stringent PED requirements. Comments were also made that a merger would not solve the problem of regulating the two distinct types of pressure vessel and that if merged the same complexities would remain but within a single document. The investment in terms of time and effort of merging the Directives would consequently not result in a more relevant, effective and efficient regulatory landscape.

However, during the course of the evaluation it was found that in a limited number of cases there have been issues with manufacturers incorrectly applying the SPVD with products that should be regulated by the PED. For the most part, these issues should not be interpreted as a problem with the Directive as such but rather a misapplication of the rules by manufacturers. Such instances could be dealt with through stronger market surveillance and conformity assessment procedures which are discussed in more detail in the effectiveness section. However, some national authorities have considered that the Directives aren’t particularly clear in relation to assemblies that include simple pressure vessels.

In addition, a number of businesses that manufacture both simple pressure vessels and complex pressure equipment commented that although it may be possible for them to use the SPVD in certain cases, they actually treat all of their production processes according to the PED. In such cases, the PED was considered as a more robust and clearer legislative tool that provided them with a simpler approach than having to use the two Directives.

Moreover, a significant number of national authorities made a case for merging the Directives. Their rationale was largely based on reducing administrative burdens and increasing the safety of pressure equipment. A number of them pointed out that the SPVD could not be justified given that the document is almost as lengthy as the PED but covers a much smaller proportion of the market. The PED is also regarded as placing stronger emphasis on safety aspects and it is felt that simple pressure vessels could be readily incorporated into existing PED concepts and processes. Merging the Directives would therefore result in higher levels of safety, greater administrative efficiency and certainty, and greater levels of clarity for European and international manufacturers.

Other findings indicated that simple pressure vessels are now largely manufactured outside Europe (although Italy is still active on the market) and that safety issues with imported equipment have been identified. In this context, a merger of the Directives was considered appropriate as the PED framework would be potentially more effective in regulating products that originate from third countries.

Recent policy proposals will also make conditions more feasible for facilitating a merger between the Directives. Given that the SPVD will be aligned to the New Legislative Framework, a number of
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new conformity assessment modules will be introduced to the SPVD that are similar in nature to the PED modules. A potential merger between the Directives would therefore be easier to manage.

Having considered these results, the conclusions made by the previous review that there are overwhelming advantages for keeping the two Directives separated appear to be less certain in today’s environment. Whilst similar arguments were again made by industry for maintaining the status quo, there were also arguments by certain groups that merging the two Directives would reduce administrative burdens for public authorities and establish a more appropriate regulation of pressure equipment originating from third countries.

A decision to go ahead (or not) with a merger should be based on detailed investigation. It is recommended that research should be initiated to investigate whether merging the Directives is technically feasible (in particular examining the implications of having a single set of classification tables, conformity assessment procedures ESRs for pressure equipment - including simple pressure vessels - within a merged Directive). The delivery of an Impact Assessment would support the process in terms of assessing the implications of the merger for industry.

Transportable Pressure Equipment Directive

Evidence was also put forward regarding the poor interaction in a very small number of areas between the TPED and the PED. In this particular case, the inconsistencies emerged as a result of a small number of products that are poorly defined in terms of which Directive they correspond to. Manufacturers and public authorities have stated that this includes certain types of cylinders (such as cylinders used in breathing apparatus) and stationary assemblies that include transportable cylinders. For the most part, these products may be used as either transportable pressure equipment or stationary pressure equipment.

From the point of view of some manufacturers, the two different regulatory routes have caused confusion. They argue that for the small group of products mentioned above, there is no certainty about the regulatory approach that they are obliged to adopt. This is because in some cases, the manufacturer may not know how the product will eventually be used or how the ‘nature of the use’ should be interpreted (as either transportable or stationary pressure equipment or both) and therefore it may not be known which piece of legislation to apply. This has led to both academic / legalistic problems of interpretation (for manufacturers, NBs and officials) but also practical problems in applying the Directives (for manufacturers and NBs). However, there is also the point that manufacturers may not wish to apply both Directives to their manufacturing processes since this would have the effect of increasing their manufacturing costs.

In addition, according to one manufacturer, the regulatory course pursued often depends on the national context and in certain countries firms may design a product according the PED whereas in others the TPED is selected for the same product. Similarly, NBs in some countries may be more open to conformity assessing a certain product to either the TPED or PED, whereas in other countries a stricter interpretation is applied. However, this may be a national problem of regulatory interpretation rather than an issue with the Directives as such.

The extent to which national authorities can deal with these complexities varies across the Member States. Some authorities mentioned that if problems arise between the TPED and PED, then through cooperation with the relevant stakeholders, problems can for the most part be dealt with. On the other hand, other authorities tended to emphasise that the complexities create a great deal of confusion for themselves and the manufacturers involved.
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Whilst the problem is restricted to a small number of products, for representatives of certain industries such as the LPG sector, the uncertainty on this matter creates significant confusion. By way of remedy, a limited number of comments suggested that the TPED and the PED should be merged or that a ‘mutual recognition’ approach should be adopted. However, for those familiar with the requirements of both Directives in detail this is not technically feasible. Given that the basis of the TPED rests upon the Agreement for the International Carriage of Dangerous Goods (ADR) and that for transportable pressure equipment ISO standards only must be applied, the TPED’s conformity and safety assessment requirements are very different from those of the PED. Merging the Directives or providing ‘mutual recognition’ would be impossible given that their technical foundations are markedly different. Moreover, although an item of equipment may be ‘perfectly safe’ given that it conforms to one of the Directives, strictly speaking certain technical requirements might not be met if it is used in a way contrary to the intention of the manufacturer.

Overall, a limited number of products have received a lot of attention given that in some cases there is a lack of clarity on the matter. As mentioned, breathing cylinders are one such example. Although excluded from the TPED and explicitly referred to in Article 3 paragraph 1.1(a) of the PED, some Member States have commented that the breathing cylinders market is unsure about which Directive to apply given that the ADR is regarded as unclear in certain areas. This subject is currently under discussion within the Working Group Pressure (WGP).

It is recommended that the European Commission speed up the process for clarifying with legal certainty the scope of the Directives and how they should be applied. Going forward, emerging markets that may fall into this category such as fuel cells need to be properly considered in order to provide clear regulatory guidance to manufacturers.

Machinery Directive

References to the Machinery Directive (MD) were raised much less frequently than with the other two pressure Directives. However, a limited number of issues were mentioned.

The MD is informed by the PED’s categorisation of pressure equipment. Under the Directive, Category I pressure equipment or below must demonstrate conformity with the MD only. However, if a manufacturer develops a piece of machinery that contains Category II pressure equipment or above then the items of pressure equipment need to be conformity assessed according to the requirements of the PED.\(^{53}\)

With regard to machinery that contain Category I pressure equipment or below there were a limited number of concerns that the Essential Safety and Health Requirements of the Machinery Directive are not sufficient to guarantee that appropriate safety measures are taken to address the pressure hazard for certain types of machine. In addition, under the Machinery Directive, Category I pressure equipment and below are excluded from approval processes overseen by NBs which was a concern to some. As a result, for a limited number of pressure equipment stakeholders, the specifications and procedures for Category I pressure equipment within the Machinery Directive were said to be inadequate and the safest option for manufacturers would be to apply the PED to all items of pressure equipment within machinery.

\(^{53}\) If a machine is classified as containing Category II pressure equipment or above then both the PED and Machinery Directive apply. A NB should be involved in overseeing the PED conformity assessment procedures for this type of product.
However, comments received from an expert in the Machinery Directive field outlined that as the Machinery Directive does not contain well developed specifications for Category I pressure equipment, manufacturers often understand that they should apply the PED and relating PED standards in appropriate cases. In addition, given the current regulatory framework, the manufacturer has the right to simply apply the MD to the specified products if he wishes (or both the MD and PED if he chooses). This approach was seen to better meet the needs of machinery manufacturers. Finally, the MD requires that all safety hazards are sufficiently dealt with. The CE marking cannot be affixed to the machinery without having dealt with the pressure hazard in a satisfactory way.

The evaluation did not collect any direct evidence to indicate that machines that include Category I pressure equipment or below are unsafe. It should also be recognised that extending the scope of the PED to cover Category I pressure equipment within machines would have an enormous impact given the number and range of machines that contain Category I pressure equipment or below. It is suggested that no further action is taken on this matter.

A further issue that was occasionally identified was the weak market surveillance of products that are covered by both the PED and the Machinery Directive (such as machinery that are combined with Category II pressure equipment or above). In some cases, pressure equipment may not have been conformity assessed in the appropriate manner under the PED and is circulating on the Internal Market. Moreover, machinery that may have been produced at one time in Europe specifically for the industrial market, such as leaf blowers or sandblasters, are now being produced outside of Europe at much lower costs and are entering European consumer markets. Similarly, safety issues have been raised as such items may not have been conformity assessed according to the PED. Given these findings, it is recommended that stronger enforcement of the rules by market surveillance authorities and NBs should help to improve the implementation of the Directives. The issue of market surveillance and the corresponding recommendations are expanded upon in the effectiveness section.

The PED’s Coherent Interaction with Other Directives

An assessment of the comments made by stakeholders suggest that on the whole the PED’s problematic areas of interaction with other Directives are relatively partial and confined to a small number of specific examples (such as the products that fall in a grey area between the PED and TPED). Where other problems have occurred, these appear to be related to the issue of inconsistent or incorrect application of the rules by either manufacturers or NBs. To a certain extent, this could be remedied through stronger approaches to market surveillance which are explored further in the effectiveness section. Overall, one could say in relation to coherence with other pieces of European legislation, that after 10 years of implementation, the scope of the PED is mainly clear and that the Directive fits into a relatively stable and coherent regulatory environment.

4.6 Economic Importance of the Sector

Within the context of the examination of the Directive under the theme of relevance, there are a number of questions regarding the extent of the economic importance of the sector and its structural characteristics, including intra and extra-EU trade. The qualitative findings are complemented by a quantitative examination of the economic trends within the relevance – quantitative analysis section.

Economic Transformation within the Pressure Equipment Industry
Responses from the interviewed stakeholders mainly indicated that the European pressure equipment sector was experiencing economic transformation. There is a strong perception that manufacturing units are moving from sites in Europe to low cost centres such as Asia but also to other world regions. However, whilst general trends can be observed, which were largely unsurprising given the parallel trends in comparable sectors, it is clear that the situation is highly complex and shaped by longstanding historical factors. This means that the extent of transformation across the pressure equipment sectors and sub-sectors varies considerably. Those pessimistic about the situation commented that Europe on the whole is in the process of a slow industrial decline and the economic importance of the sector has been fading gradually since roughly 1995.

In recent years, one issue is that major investments in large scale assemblies tend to take place in Asia whereas in Europe investments tend to serve the needs of existing users and/or sites. Drivers of demand may therefore be particularly intensive outside of Europe. However, some stakeholders mentioned that demand for assemblies is cyclical and that with some assemblies becoming due for replacement, there is a prospect of demand picking up in Europe, while, as mentioned by some firms the situation in Asia presents opportunities for Western companies to widen their client base and rather the issue is that local suppliers often require additional managerial and technical support to meet the needs of projects and users.

A number of foundries, casting and fabrication units have now moved outside of Europe mainly to Asia and these supply producers of a range of pressure equipment in both local and international markets. Certain ‘low-end’ products were said to be mainly or extensively produced in Asia including valves, less sophisticated vessels and consumer goods such as pressure cookers.

Larger European companies are changing their organisational structures in order to remain competitive. For example, units that serve existing European clients on a technical level remained in place but the companies have otherwise experienced downsizing. Production units have often moved outside of Europe but these are overseen by Western professionals whose main goals are to ensure quality in production processes and to enhance the capacity of local staff.

Rather than undertaking production themselves, firms based in Europe may have simply moved onto installation work and consequently rely upon agents based in Europe to search for and select low cost products that are produced outside of Europe but that adhere to the specified quality requirements.

Moreover, competition was also said to be intensifying with ‘old competitors’. For example, the US was said to be a longstanding and active player on the market whose position in a number of areas including in terms of exporting to Europe was strengthening.

However, whilst across a number of sectors change was significantly or identifiably underway, in other areas, Europe has retained its competitive edge. These are mainly in high end or technically advanced parts of the market or in niche products that require advanced skill-sets (although there are emerging signs of high end products being produced outside of Europe). In addition, it was mentioned that existing European clients will continue be serviced well into the future by European firms given their intimate knowledge of the PED.

At the same time, some firms appeared to be much less affected by competition from Asia. The boiler manufacturing sector was said to be going strong and was operating within and exporting to a large number of EU countries and also to third country markets. Those working in the oil and gas sectors mentioned that the markets were serviced by traditional home country players and the
situation was not likely to change. Production of certain instruments to control pressure are still produced in Europe given that transportation costs from Asia cancelled out competitive advantages from low labour costs. Also, some firms from sectors that experienced competition from outside of Europe, such as the heat exchanges market, felt that their ability to maintain quality levels had helped them to retain existing industrial clients.

Yet, competition from Asia aside, the economic crises that have led to dips in global demand was felt by some to be the most significant immediate threat to the sector and that finding ways to address this issue was the most pressing concern for policy makers and industry.

To sum up, the general view was that economic transformations have taken place across various products groups, although to varying extents, and that the sector’s economic position had weakened from a manufacturing perspective. Moreover, it was suggested that although certain sectors currently remain competitive and can manufacture in Europe, the pressure from low cost competitors in other world regions would have a negative long term impact on the sector. Combined with this, comments were made that the positive advantages brought about through improved Internal Market functioning by the PED are not enough in the long term to ensure the sustainability of the manufacturing side of the pressure equipment industry.

In addition, with these comments in mind, the future relevance of the PED to the operation of the Internal Market may change as a result of industry moving its manufacturing units outside Europe. It could be envisaged that in the future, the PED may be mainly regulating the pressure equipment (intended for the Internal Market) produced in third countries. The implications of this potential transformation from a regulatory perspective need to be monitored by the European Commission. The issue of the impact of the delocalisation of production on the PED is explored further in the effectiveness section.

The Extent of the Availability of Engineering Skill-Sets

There are further questions relating to the availability of suitable engineering skills that are significant for the economic performance of the sector. A number of differing perspectives were offered by stakeholders but it was generally recognised that the availability of relevant skill-sets are not as abundant as they used to be and that there is a shortage in their supply. Difficulties in identifying new and suitable recruits were therefore identified.

One aspect is that engineering is not perceived as such an attractive career choice as it used to be and it has a poor (environmental) image. This is in terms of the manual areas of the work such as welding and also more design-led aspects which require university qualifications. In addition, there appears to a problem with the extent to which the PED is covered in general engineering courses and a shortage of dedicated post-graduate courses that is met to varying degrees with in-house training. There is also a general problem that those initially opting for an engineering education may select ‘softer industries’ such as financial services at career entry level.

In a bid to maintain the incoming flow of engineering graduates, some firms seek young engineers from outside of Europe such as China. Although these graduates tend to be technically stronger than their European counterparts they often lack managerial and leadership skills. In certain cases, firms have set up design focused offices in Asia in order to identify (low cost) graduates. However, in some European countries such as Sweden and Germany, the supply of graduates was felt to be at a reasonable level and much stronger than in other countries such as the UK.

The academics interviewed confirmed that few courses currently focus on training graduates specifically in pressure equipment engineering or in relation to the EN or other design codes.
Consequently, highly specialised graduates are not immediately fed into the market and companies need to deliver graduate training programmes in order to ensure that new recruits develop the appropriate skill-sets.

The situation does of course vary and some firms did report that they do not face skill shortages in the manufacturing of products designed under the PED.

There appears to be a generational problem as those particularly high end skill-sets are at the later stages of their career and it was frequently mentioned that questions remain about who will replace them at an equally qualified level. There are also broader questions about the replacing of manual skill-sets for hands-on manufacturing work and welding.

In terms of solutions to these problems, it was suggested by industry association leaders that training issues should be given a higher profile, especially in that environmentally focused engineering degrees are emerging that cover a wide range of subject matters that are essential to basic engineering functions and these could be tailored to include course content for an area that continues to have considerable economic significance. To a certain extent, traditional engineering degrees may have to re-brand themselves in order to adapt to the interests of a new generation of students. Links with the resource efficiency aspects of the harmonised European standards within these courses could be made.

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**Relevance**

**Main Findings and Conclusions**

- The PED has proved to be highly relevant for the improved functioning of the Internal Market. The introduction of the PED, compared with the previous system of national legislation, has led to a greatly improved and much more consistent regulatory framework for facilitating the free movement of pressure equipment.

- The introduction of the PED has opened up intra-EU trading opportunities as manufacturers have an improved understanding of the rules they need to follow to access Member State markets. This appears to have resulted in lower costs for industry and reduced barriers to trading across the Internal Market.

- The introduction of the PED has successfully combined market integration whilst maintaining the high levels of safety that Europe was already accustomed to.

- In relation to other pieces of European legislation, the scope of the PED is mainly clear and the Directive fits into a relatively stable and coherent regulatory environment.

- The results of the earlier review that rejected the viability of a potential merger between the SPVD and PED appear to be less certain in today’s context. A number of national bodies believe that a merger between the Directives would reduce the administrative burden for public authorities and would better regulate (in terms of guaranteeing safety standards) the changing conditions of the market place for simple pressure vessels. However, industry associations suggested that the two Directives should remain as separate items.

- The small number of TPED and PED regulatory overlaps for certain types of products that may be used in either transportable or stationary settings are confusing for the manufacturers concerned. The Commission is in the process of clarifying the Directives in the small area of overlap related to cylinders for breathing apparatus.
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- A limited number of pressure equipment stakeholders consider that Category I pressure equipment within machinery would attain higher levels of guaranteed safety if such items were conformity assessed according to the PED. However, the evaluation has not identified evidence that indicates that machinery that contains Category I pressure equipment is unsafe. In addition, it should be recognised that extending the scope of the PED to such products would have a massive regulatory impact. It is suggested that the issue should not be examined further.

- The qualitative research regarding the economic importance of the sector has indicated that the pressure equipment sector is undergoing transformation. The perception is that segments of the pressure equipment sector have now shifted to low cost centres outside Europe and the trends suggest that this will be an ongoing process. In the future, the relevance of the PED to the Internal Market may change given that the Directive may be mainly regulating products manufactured in third countries.

- Qualified manual workers and engineering graduates are in short supply. This may in the near future have negative consequences given that many European engineers in the industry are in the later stages of their careers. It is important to raise the profile of this issue.
5. Relevance – Quantitative Assessment

5.1 Introduction

A key feature of the evaluation’s assessment of the relevance of the PED is a consideration of the evolving structure of the pressure equipment industry and the appropriateness of the Directive’s provisions in respect to the changes taking place. This section therefore provides an economic analysis of some of the most significant product groups that fall under the regulatory scope of the PED with data that has been collected from a number of sources.

One of the aims of this exercise is to provide an evidence base for the current and future evaluations of the PED. In this way, it is intended that it will add substantially to the methodological framework for such efforts. The exercise will provide a baseline from a period before the introduction of the PED that will allow a comparison to be made with the current period and the impact of the Directive to be considered. This assessment will then support the examination of the question of how relevant the Directive is for its key target groups in the context of other important potential drivers for growth such as EU enlargement and globalisation.

5.2 Description of the Industry

Before the methodological approach to this section is outlined, it would be useful to provide a brief description of the industry. It is worthwhile to point out that the evaluation has not been tasked to provide an in-depth market study that would include a detailed analysis of the structure of the various sectors and subsectors. The main focus of the analysis is to determine market performance before and after the introduction of the PED. However, given the diverse product range that the sector covers, it is useful to outline some of its key features.

The pressure equipment sector covers a broad range of industrial and (to a much lower extent) consumer products. Whilst not always the case, pressure equipment often includes pressure vessels which are containers of rigid construction that contain or are intended to contain a liquid or gas under pressure. Pressure equipment is often part of complex systems that operate under pressure and include pipes and piping components (such as flanges), pressure accessories (such as valves) and safety accessories (such as bursting discs).

Consumer products that fall under the category of pressure equipment include items such fire extinguishers and pressure cookers. Industrial items include industrial boilers, cryogenic vessels, heat exchangers, steam generators, stationary storage cylinders for liquefied gases, industrial refrigeration and air conditioning, machinery such as sand blasters or vaporisers and complex industrial assemblies such as chemical plants.

Previous research conducted in 1996 on the pressure equipment sector indicated that the industry is fragmented and consists of a vast number of specialised SMEs with an average of 100 employees or less. However, the interview programme for the evaluation revealed consolidation in the industry with the sector containing a significant proportion of large companies and multinational firms. Such companies contained units that design and manufacture pressure equipment both within and outside Europe. However, they tend to be part of larger groups that develop a vast array of engineering and technology products and provide supplementary support services to a wide range of sectors such as the food, chemicals, health care, energy and pharmaceutical industries. At the same time, the industry continues to contain a number of SMEs. These appear to be focused on the development of particular products such as heat exchangers or components such as valves. The sector also contains SMEs and large firms that provide onsite installation and maintenance services.

Finally, it was noted there was substantial SME growth and new entrants to the market in low costs centres outside Europe.

5.3 Methodological Approach

An initial problem in characterising the ‘pressure equipment industry’ is that it consists of a diverse range of products that do not correspond directly to any of the categories used in standard industrial classifications. There are no Eurostat data, for instance, on the size of the sector’s output. A picture has to be built up using partial data, available in official sources or in market studies and this characterisation has to begin with a classification of the industry’s component elements.

The approach adopted to structuring the market information has been based on the general product categories that have been targeted for regulation by the PED. However, there have been two modifications to these product categories in order to take into account important features of the assemblies market. Firstly, with a view to assessing industry trends, industrial assemblies and consumer assemblies have been separated into two separate groups. Secondly, boilers have been selected as a standalone group given their prominence within the assemblies market.

Under each PED product category, a number of product subgroups have then been identified that form the backbone of analysis. The data on these product subgroups have been built up from a number of EU databases and commercially available sources.

In terms of the EU databases available, all of the PRODCOM\textsuperscript{55} and SITC\textsuperscript{56} product codes from the PRODCOM and COMEXT databases were screened in order to select suitable products that fall within the scope of the PED. For a number of cases, the product subgroups are an aggregate of several PRODCOM or SITC codes. For example, one of the product subgroups, ‘Boilers’, is based on 7 PRODCOM codes, each one of them referring to a single segment of the boilers market.

In addition, data from commercially available and industry studies have been used to provide further indications of the trends in the product subgroups. In these cases, the product subgroups have not been independently constructed for this assessment but rather the categories in the existing study have been used. However, data from separate tables within each existing study have been brought together to present graphs and bar charts that compare market performance in different world regions. Moreover, the figures from these existing studies have been converted from USD $ to EUR € on the basis of the relevant annual average exchange rates provided by Eurostat\textsuperscript{57}.

The following table defines the product categories and subgroups that have been selected, together with an indication of the available data sources and where relevant the corresponding statistical codes:

<table>
<thead>
<tr>
<th>PED Category</th>
<th>Product Subgroups</th>
</tr>
</thead>
</table>
|Vessels      | • Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases. PRODCOM codes: 25291110 25291120 25291130 25291170 25291200;  
             | • Metal Containers and Containers for Liquids and Gases. SITC Codes: 69211 69212 |

\textsuperscript{55} PRODCOM Codes are maintained by the EU. NACE Rev 2 has been used for the evaluation.
\textsuperscript{56} SITC Codes are maintained by the UN.
\textsuperscript{57} Eurostat provide estimated exchange rates up to 2013 only. Data presented for forecasts for 2014 onwards have therefore been converted with the use of the 2013 exchange rate.
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| **69243 69244;** | • Ferrous Metal Pressure Vessels and Tanks of More Than 61cm External Diameter and 0.14 Cubic Metres Capacity *(Commercially Available Market Data)*; |
| **Piping** | • Metal Tubes and Pipes. PRODCOM Codes: 2420130 24201330 24201350 24201370 24201400 24202300 24202340 24203340 24203370 24203410 24203430 24203450 24203470 24203500; |
| | • Metal Tubes and Pipes, SITC Codes: 67911 67914 67915 67916 67917 68426; |
| | • Steel Pressure Tubing *(Commercially Available Market Data)*; |
| | • Metal Tubes and Pipes Fittings. PRODCOM Codes: 24513030 24513050 24523000; |
| | • Metal Tube and Pipe Fittings. SITC Codes: 67951 67952 67953 67956 67955 67959; |
| | • Plastic Pipes with a Minimum Burst Pressure of 27.6 Mpa. PRODCOM Code: 22212935; |
| **Safety Accessories** | • Safety or Relief Valves. PRODCOM Code: 28141180; |
| | • Safety or Relief Valves, SITC Code: 74740; |
| | • Safety of Relief Valves *(Commercially Available Market Data)*; |
| | • Pressure Monitoring and Measuring Instruments. PRODCOM code: 26515271, 26515274, 26515279; |
| | • Pressure Regulators and Controllers. SITC Code: 87463; |
| | • Pressure Regulators, Controllers and Monostats *(Commercially Available Market Data)*; |
| | • Pressure Sensors and Transmitters *(Commercially Available Market Data)*; |
| **Pressure Accessories** | • Valves. PRODCOM Codes: 28121450 28121480 28141120 28141140 28141160 28141313 28141315 28141333 28141335 28141353 28141355 28141357 28141373 28141375 28141377; |
| | • Industrial Valves. SITC Codes: 74710 74720 74730 74780 74790; |
| | • Valves *(Commercially Available Market Data)*. |
| **Industrial Assemblies** | • Reciprocating Displacement Compressors. PRODCOM Code: 28132630 28132650 28132670 28132690; |
| | • Machinery for Liquefying Air and Gases. PRODCOM Codes: 28251150; |
| | • Steam and Sandblasting Machines. PRODCOM Code: 28292230; |
| | • Condensers for Steam or Other Vapour Power Units. PRODCOM Code: 25301250; |
| | • Sample of Industrial Assemblies (Condensers for Steam or Other Vapour Power Units / Steam Turbines and Other Vapour Turbines / Machinery for Liquefying Air or Other Gases / Steam and Sandblasting Machines) SITC Code: 7112 712 74175 74563; |
| | • Heat Exchange Units. PRODCOM Code: 28251130; |
| | • Heat Exchange Units. SITC Code: 74174; |
| | • Heat Exchangers *(Commercially Available Market Data)*; |
| | • Investment in Pharmaceutical Chemical Plant Construction *(Commercially Available Market Data)*; |
| | • Custom Fabricated and Field Erected Ferrous Metal Pressure Vessels and Tanks for Refineries, Paper Mills And Chemical Plants *(Commercially Available Market Data)*; |
Relevance – Quantitative Assessment

5.4 Methodological Limitations

**Limitations in Assessing Data from Different Sources and Variables**

There are significant limitations that one should consider when assessing data in relation to the various sources and variables that have been included in this section. The first is that the data from each source have been assembled using different methodologies, which suffers from the fact that data from one source are not immediately comparable with data provided by another. This is also the case when assessing variables from the same source such as the figures for intra and extra-EU trade, since separate methodologies have been used to collect data in each case. Similarly, the PRODCOM and SITC codes have been designed for different purposes and should not be seen as providing parallel market coverage for the product subgroup concerned. In addition, although in theory the figures for total flows in intra-EU exports and imports should be the same, in practice this is not the case as a result of a series of methodological issues.

**Difficulties in Determining the Proportion of the Product Subgroup Market that Falls Under the Regulatory Scope of the PED**

A further issue to consider is the extent that the product subgroup market is required to conform to PED requirements. Even though the products selected for this study are those that could be

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58 For certain product subgroups one would expect that the market coverage of the PRODCOM and SITC codes to be relatively comparable e.g. Fire Extinguishers. However, for other product subgroups where a different number of codes from both sources have been used to develop aggregate product subgroups, it’s likely that coverage of the market diverges. Reconciling all the detail of the data is beyond the scope of the evaluation, so the data should be regarded as providing broad indications rather than reliable statistics.

59 Explanations for asymmetries in intra-EU import and export data include: the system of thresholds (this system makes it possible to exempt ca.80% of operators from statistical formalities. For a given transaction, therefore a company might be required to provide statistical information in one Member State, whereas its supplier or customer in another Member State is exempted) late or non-response by certain companies, different national practices on statistical confidentiality, misapplication of the rules and delays, the use of different methods for calculating the statistical value of dispatches (FOB value) and arrivals (CIF value) and triangular trade. In the intra-EU context, triangular trade is said to exist in the case of a company in Member State A which sells goods to a company in Member State B, which in turn sells them to a company in Member State C, although the goods are “physically” forwarded only once - from A to C. In cases such as this, intra-Community trade statistics should record a dispatch from A bound for C, and an arrival in C of goods from A. There is, however, a considerable risk that A or C will regard Member State B as its trading partner bound for C, and an arrival in C of goods from A.
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expected to be covered by the PED provisions, it has not been possible to precisely determine the proportion of the market for each product subgroup that is required to conform to the Directive. It would be possible to assume that for say fire extinguishers to be placed on the Internal Market, the vast proportion would have to be manufactured with the aim of meeting the PED’s requirements. However, for broader product subgroups, such as piping or valves, given the multiple applications for such items, it is much more difficult to determine the extent to which they have been used in applications that are covered by the Directive. Moreover, although during the course of the interview programme it has been acknowledged by a limited number of European manufacturers that they develop pressure equipment according to EN standards for extra-EU markets, it’s likely that the majority of pressure equipment products placed on the market outside of the EU have been developed in line with the requirements of other regulatory regimes.

Overall Coverage of the Market Identified By Each Product Category

When assessing the data in the tables below, further issue needs to be recognised. For certain PED product categories, such as vessels, piping and boilers, the evaluation team is confident that it has data for the whole market. However, not all the products will be covered by the PED, since not all of them are used in products that are within the scope of the Directive. It is not known what proportion of the PED market is covered, but the figures do give a clear indication of the general market for these products.

In the case of other PED product categories, especially in the area of industrial and consumer assemblies, it has only been possible to collect data for a small sample of specific product subgroups. It is not known what proportion of the total market is represented by the data. It is likely that the coverage of the overall market is relatively small.

Shortcomings in the Perceived Accuracy of the Data Collected

Discussion with pressure equipment experts after the initial assessment of the data collected in line with the approach set out above identified a number of possible shortcomings that should be borne in mind in the sections below. These mainly relate to the findings that have been based on the data extracted from PRODCOM and COMEXT. Some of those interviewed, for instance, have raised questions about the relative scale of certain product groups. The data show, for example, that the value of production for metal reservoirs and containers for liquids and gases are lower than sectors such as valves and this is surprising for some experts. Clearly, it is not possible to go beyond the published data in this study, but issues such as these should mean that there should be some caution when assessing the figures.

5.5 The Performance of the Pressure Equipment Industry

Within the limitations set out above, the performance of the Pressure Equipment industry can be assessed in relation to its growth record across the EU, since the introduction of the Directive and also in relation to its position at a global level. It will be seen that the various sub-sectors of the industry have performed differently although there is an overall positive trend towards continued growth. The sections below provide data against different indicators in order to assess the underlying economic trends of the product subgroups.

Economic Output (Production Value)

Production output data in value terms is provided for each of the product subgroups. The production value variable is defined as the annual value (EUR) of goods sold. Production value data from PRODCOM are for 1995, the earliest year that data are available, and the most recent year
2010. It should be pointed out that the data for 1995 are based on figures for the EU 15, whereas data for 2010 correspond with the EU 27. It is recognised that for comparison purposes an assessment between the EU 15 in 1995 and 2010 would be more direct. However in many cases the data available for the EU 15 in 2010 are unreliable, since there are no aggregate figures available and there are a number of gaps in the data for individual Member States (Annex 2 provides our estimates of the EU 15 2010 data, but some of the figures could be very misleading).

A baseline from 1995 has been presented below, showing the situation before the introduction of the PED, and compared with the figures for 2010. In order to take inflation into account, the GDP Deflator provided by Eurostat has been used. Based on Constant 2005 prices, a real growth figure is presented.

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Future research may wish to investigate the rates of inflation within the specific sectors and develop a sector specific deflator.
### Relevance – Quantitative Assessment

Table: 5.2 EU Economic Output (€m Production Value) 1995 and 2010 in Current and Constant 2005 Prices

<table>
<thead>
<tr>
<th>Product Category and Product Subgroup</th>
<th>€m Production Value</th>
<th>Real Growth % Between 1995 and 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Current Prices</td>
<td>Constant 2005 prices</td>
</tr>
<tr>
<td></td>
<td>EU 15 1995</td>
<td>EU 27 2010</td>
</tr>
<tr>
<td><strong>VESSELS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases</td>
<td>2,374</td>
<td>5,720</td>
</tr>
<tr>
<td><strong>PIPING</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Tubes and Pipes</td>
<td>Data are not available</td>
<td>13,997</td>
</tr>
<tr>
<td>Metal Tube and Pipe Fittings</td>
<td>Data are not available</td>
<td>704</td>
</tr>
<tr>
<td>Plastic Tubes and Pipes with a Minimum Burst Pressure of 27.6 Mpa</td>
<td>804</td>
<td>1,372</td>
</tr>
<tr>
<td><strong>SAFETY ACCESSORIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety Valves</td>
<td>Data are not available</td>
<td>610</td>
</tr>
<tr>
<td>Pressure Measuring and Monitoring Instruments</td>
<td>454</td>
<td>1,224</td>
</tr>
<tr>
<td><strong>PRESSURE ACCESSORIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valves</td>
<td>6,501</td>
<td>13,487</td>
</tr>
<tr>
<td><strong>INDUSTRIAL ASSEMBLIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reciprocating Displacement Compressors</td>
<td>499</td>
<td>865</td>
</tr>
<tr>
<td>Machinery for Liquefying Air and Gases</td>
<td>536</td>
<td>2,400</td>
</tr>
<tr>
<td>Steam and Sandblasting Machines</td>
<td>613</td>
<td>787</td>
</tr>
<tr>
<td>Condensers for Steam or Other Vapour Power Units</td>
<td>60</td>
<td>112</td>
</tr>
<tr>
<td>Heat Exchange Units</td>
<td>1,741</td>
<td>5,040</td>
</tr>
<tr>
<td><strong>CONSUMER ASSEMBLIES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fire Extinguishers</td>
<td>450</td>
<td>521</td>
</tr>
<tr>
<td><strong>BOILERS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boilers</td>
<td>5,743</td>
<td>9,420</td>
</tr>
</tbody>
</table>
The percentage changes in production values from EU 15 1995 to EU 27 2010, mainly show reasonable growth in each product subgroup but at various rates. The weighted average for the sector as a whole indicates an overall growth of 59.2% but certain product subgroups have performed particularly well – ‘Machinery for Liquefying Air and Gases’ (growth rate of 239%) – whilst others such as ‘Fire Extinguishers’ have contracted (-12.2%). For the ‘Metal Tube and Pipes’, ‘Metal Tube and Pipes Fittings’ and ‘Safety Valves’ markets data are not available for 1995, but it is expected that this product group would have performed well given the performance of other comparable sectors.

As one would expect, the rate of growth experienced across the product subgroups is highly sector specific and their performance is largely shaped by the conditions of their immediate marketplace.

Over the same period, the EU 27 economy grew by 32.1% (the EU 15 to EU 27 economy grew by 37.4%) at constant 2005 prices. With a weighted average growth of 56.9%, the sector has performed particularly well. Qualitative research has revealed that the areas of the European pressure equipment sector that are performing relatively well have witnessed increased levels of specialisation with an increasing concentration on high value activities. It is likely that this process has contributed to the development of the leading product subgroups.

However, a range of other factors need to be considered when considering the increases in production value. A key issue is the rising cost of raw materials, such as steel, and energy costs which have increased significantly. Some of these costs have been passed on in the form of higher prices and it may be that for some product subgroups the increases in production value are partly driven by increases in production costs rather than increases in the number of items sold.

At the same time, some of the increase in value represents an increase in quality, again reflected in a higher price. In addition, in certain cases, efficiencies will have been gained as a result of the development of innovative processes and products including those that use materials more efficiently.

For certain sectors, the data also illustrate a point raised during the course of the interview programme, that in recent years certain product subgroups have been experiencing delocalisation to third country markets, so that a significant proportion of pressure equipment production in these sub-sectors now takes place outside of the EU. This is evident in subgroups with low relative growth or in some cases, negative growth. One example of this trend is indicated by the ‘Steam or Sandblasting Machines’ market. The constant 2005 prices figures suggest that this market has now contracted in terms of production value.

Figure: 5.1

---

61 PRODCOM CODE Data Are Not Available for the following Member States
28292230 EU-15 2010 - AT, BE, IE, SE
Again, however, it should be recalled that it is difficult to determine the extent to which trends in the data directly relate to products that are actually covered by the PED. However, in contrast to the views expressed on the PED sector in the interview programme, there are some quite positive trends in economic output across a number of product subgroups. For example, for ‘Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases’, production increased significantly from 1995 to 2010 and has reached a value of €5,393m\(^62\)\(^63\).

**Figure: 5.2\(^64\)**

The production value data also indicate that manufacturing remains concentrated in the EU 15. Whilst the PRODCOM data does not offer exact precision when commenting specifically on the pressure equipment industry, it appears that a significant number of competitive advantages remain for manufacturing items in the ‘old Member States’ in comparison with the CEECs.

**Development of the Internal Market (Intra-EU trade)**

\(^62\) Please note that \(m\) refers to millions of Euros

\(^63\) As already mentioned in the methodological limitations section, it is difficult to determine with accuracy the proportion of the product group market that contains pressure equipment that fall under the regulation of the PED. It is likely that the market value for Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases’ would need adjusting to account of this aspect.

\(^64\) PRODCOM CODE Data Are Not Available for the following Member States

<table>
<thead>
<tr>
<th>Code</th>
<th>Data Are Not Available for the following Member States</th>
</tr>
</thead>
<tbody>
<tr>
<td>25291110</td>
<td>EU 15 2010 - BE, SE, UK</td>
</tr>
<tr>
<td>25291120</td>
<td>EU 15 2010 - BE, GR, SE</td>
</tr>
<tr>
<td>25291130</td>
<td>EU 15 2010 - SE</td>
</tr>
<tr>
<td>25291170</td>
<td>EU 15 2010 - AT, BE, IE, NL, UK</td>
</tr>
</tbody>
</table>
With a view to gauging how the Internal Market has developed, intra-EU export and import data have been examined for each of the product subgroups. The intra-EU export and import data provide figures on the annual value (EUR) of cross-border trade within the EU. Again, data are derived from PRODCOM for 1995 and 2010. Similarly, the data for 1995 are based on figures for the EU 15, whereas data for 2010 correspond with the EU 27 (EU level data have been selected for comparison given the previously mentioned issues with Member State level data).

A baseline from 1995 is presented below to compare the situation before the introduction of the PED to the situation in 2010. The GDP Deflator (index based on 2005) was used to take inflation into account. Given that there are discrepancies when calculating the overall value of intra-EU trade, data using intra-EU exports were employed for characterising the trade developments.

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65 The figures for intra-EU exports tend to be greater than the figures for intra-EU imports and are thought to be more representative of actual trade flows.
### Table 5.3: Development of the Internal Market (€m Intra-EU Exports) in Current and Constant 2005 Prices

<table>
<thead>
<tr>
<th>Product Category and Product Subgroup</th>
<th>€m Intra-EU Exports</th>
<th>Real Growth % between 1995 and 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Current Prices</td>
<td>Constant 2005 prices</td>
</tr>
<tr>
<td></td>
<td>EU 15 1995</td>
<td>EU 27 2010</td>
</tr>
<tr>
<td><strong>Vessels</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases</td>
<td>425</td>
<td>992</td>
</tr>
<tr>
<td><strong>Piping</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Tubes and Pipes</td>
<td>Data are not available</td>
<td></td>
</tr>
<tr>
<td>Metal Tube and Pipe Fittings</td>
<td>Data are not available</td>
<td></td>
</tr>
<tr>
<td>Plastic Tubes and Pipes with a Minimum Burst Pressure of 27.6 Mpa</td>
<td>134</td>
<td>146</td>
</tr>
<tr>
<td><strong>Safety Accessories</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety Valves</td>
<td>Data are not available</td>
<td></td>
</tr>
<tr>
<td>Pressure Measuring and Monitoring Instruments</td>
<td>133</td>
<td>1,020</td>
</tr>
<tr>
<td><strong>Pressure Accessories</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valves</td>
<td>2,314</td>
<td>6,792</td>
</tr>
<tr>
<td><strong>Industrial Assemblies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reciprocating Displacement Compressors</td>
<td>104</td>
<td>494</td>
</tr>
<tr>
<td>Machinery for Liquefying Air and Gases</td>
<td>188</td>
<td>273</td>
</tr>
<tr>
<td>Steam and Sandblasting Machines</td>
<td>245</td>
<td>443</td>
</tr>
<tr>
<td>Condensors for Steam or Other Vapour Power Units</td>
<td>60</td>
<td>31</td>
</tr>
<tr>
<td>Heat Exchange Units</td>
<td>464</td>
<td>1,477</td>
</tr>
<tr>
<td>Fire Extinguishers</td>
<td>76</td>
<td>177</td>
</tr>
<tr>
<td><strong>Boilers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boilers</td>
<td>505</td>
<td>1,848</td>
</tr>
</tbody>
</table>

**WEIGHTED AVERAGE** 123.2
Over the period 1995 to 2010, the sector as a whole experienced growth in intra-EU exports by a weighted average of 123.2%. The ‘Pressure Monitoring and Measuring Instruments’ sector performed exceptionally well and increased by 470%. However, two of the product subgroups contracted in terms of export value including the ‘Condensers for Steam and Other Vapour Power Units’ sector (-60.5%). This is mainly explained by changes in technology and an increase in imports from outside the EU.

Intra-EU trade in pressure equipment products over the period grew much more rapidly than overall production, suggesting that the Internal Market legislation in this area at least had a facilitating role. During the interview programme it was noted that the biggest increases in intra-EU trade were in products with a higher value and technical complexity.

Development of the Internal Market (Intra-EU Trade – Product Subgroup Bar Charts)

Greater detail is provided on the composition of intra-EU trade in following bar charts based on Member State level PRODCOM data at current prices for 2010. Given the wide variation in the level of trade between the Member States, it is not possible to clearly represent those countries with minimal activity and these have been omitted. Further detail of trade in product subgroups is provided in Annex (2) where the full picture is given. The following highlights the major patterns.

Figure 5.3

2010 Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases
Intra-EU Import and Export Value (Current Prices)

Figure 5.4
Evaluation of the Pressure Equipment Directive

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Figure 5.5

2010 Metal Tubes and Pipes
Intra-EU Export and Import Value (Current Prices)

Export Value
Import Value

Figure 5.6

2010 Heat Exchangers
Intra-EU Import and Export Value (Current Prices)

Export Value
Import Value

Figure 5.6

2010 Valves
Intra-EU Import and Export Value (Current Prices)

Export Value
Import Value
The Member States that are most active exporters and importers within the Internal Market stand out clearly in these data. Generally speaking, Italy and Germany appear to be leading the trade between Member States. In relation to ‘Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases’, Italy exported products to the value of €571m and Germany €371m. In relation to ‘Metal Tubes and Pipes’ Italy exported products to the value of €2,987m and Germany €2,986m. Although Germany and Italy lead the way for the majority of product groups, other EU 15 Member States are have some activity but at comparatively low levels and / or to varying extents across the different product subgroups. For example, Sweden is particularly active on the ‘Heat Exchangers’ market (€326m exports), France on the ‘Valves Market’ (€1,000m exports) the UK on the ‘Safety or Relief Valve’ market (€100m exports) and the Netherlands on the ‘Pressure Monitoring and Measuring Instrument Market’ (€215m exports). Within some product subgroups, the EU 12 are also reasonably active, particularly, the Czech Republic and Poland. With regard to ‘Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases’ the Czech Republic exported products to the value of €158m in 2010 and Poland €121m.

*International and Internal Market Competitiveness (Extra and Intra EU Trade)*
In order to assess the performance of the European pressure equipment industry in a global context, reference has been made to extra-EU trade data from the COMEXT database. Data has been extracted for 1995, 2000, 2005 and 2010. The table indicates the data for extra-EU exports over the period in constant prices and provides a figure for real growth as between 1995 and 2010.
## Relevance – Quantitative Assessment

### Table 5.4: Development of €m Extra-EU Exports in Constant 2005 Prices

<table>
<thead>
<tr>
<th>Product Category and Product Subgroup</th>
<th>€m Extra-EU Exports</th>
<th>Real Growth % Between 1995 and 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EU 15 1995</td>
<td>EU 27 2000</td>
</tr>
<tr>
<td><strong>Vessels</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases</td>
<td>600</td>
<td>496</td>
</tr>
<tr>
<td><strong>Piping</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Tubes and Pipes</td>
<td>1,344</td>
<td>1,357</td>
</tr>
<tr>
<td>Metal Tube and Pipe Fittings</td>
<td>1,008</td>
<td>1,050</td>
</tr>
<tr>
<td><strong>Safety Accessories</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety Valves</td>
<td>192</td>
<td>230</td>
</tr>
<tr>
<td>Pressure Measuring and Monitoring Instruments</td>
<td>79</td>
<td>138</td>
</tr>
<tr>
<td><strong>Pressure Accessories</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valves</td>
<td>4,578</td>
<td>5,345</td>
</tr>
<tr>
<td><strong>Industrial Assemblies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample of Industrial Assemblies</td>
<td>1,191</td>
<td>1,267</td>
</tr>
<tr>
<td>Heat Exchange Units</td>
<td>578</td>
<td>708</td>
</tr>
<tr>
<td>Fire Extinguishers</td>
<td>95</td>
<td>94</td>
</tr>
<tr>
<td><strong>Boilers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boilers</td>
<td>1,180</td>
<td>1,109</td>
</tr>
</tbody>
</table>

**WEIGHTED AVERAGE** 105%

In terms of value in 2010, the most significant products in EU trade with the rest of the world are ‘Valves’. These are also the most significant for intra-EU trade. Interestingly, all product subgroups have experienced growth over the period (the weighted average is 105%) which suggests ongoing opportunities for global exports. The data indicate that ‘Pressure Measuring and Monitoring Instruments’ are performing particularly well in both extra- and intra-EU markets.
To put this growth in the general context of world trade patterns, the World Trade Organisation’s index\textsuperscript{66} for merchandise exports (in value terms) shows an increase from 49 in 1995 to 145 in 2010, which is a rise of 196%. It appears then that the pressure equipment sector is performing reasonably well, but below the rate of world trade growth in general.

A similar exercise was conducted to determine the performance of extra-EU imports (with data from the COMEXT). The data are for 1995, 2000, 2005 and 2010. The table provides the data for extra-EU imports over the period in constant prices and gives a figure for real growth between 1995 and 2010.

\textsuperscript{66} International Trade Statistics 2011 (World Trade Organisation)
Table 5.5: Development of €m Extra-EU Imports in Constant 2005 Prices

<table>
<thead>
<tr>
<th>Product Category and Product Subgroup</th>
<th>€m Extra -EU Imports Constant 2005 prices</th>
<th>Real Growth % Between 1995 and 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EU 15 1995</td>
<td>EU 27 2000</td>
</tr>
<tr>
<td>Vessels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases</td>
<td>228</td>
<td>135</td>
</tr>
<tr>
<td>Piping</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal Tubes and Pipes</td>
<td>348</td>
<td>321</td>
</tr>
<tr>
<td>Metal Tube and Pipe Fittings</td>
<td>496</td>
<td>454</td>
</tr>
<tr>
<td>Safety Accessories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety Valves</td>
<td>97</td>
<td>149</td>
</tr>
<tr>
<td>Pressure Measuring and Monitoring Instruments</td>
<td>111</td>
<td>310</td>
</tr>
<tr>
<td>Pressure Accessories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Valves</td>
<td>1,757</td>
<td>2,751</td>
</tr>
<tr>
<td>Industrial Assemblies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample of Industrial Assemblies</td>
<td>322</td>
<td>340</td>
</tr>
<tr>
<td>Heat Exchange Units</td>
<td>137</td>
<td>226</td>
</tr>
<tr>
<td>Fire Extinguishers</td>
<td>24</td>
<td>38</td>
</tr>
<tr>
<td>Boilers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boilers</td>
<td>221</td>
<td>232</td>
</tr>
<tr>
<td><strong>WEIGHTED AVERAGE</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When comparing intra-EU exports and imports, it’s clear that the total value of exports across the selected products groups significantly outweighs imports. In 2010 the total value of exports equated to €22239m whereas the value for imports was €8500m. In terms of the rate of growth, however, the weighted average for imports over the period 1995 to 2010 was 127.1% whereas that for exports was 105%. Clearly, the EU’s trading strength, though still substantial, is beginning to decline. Again the situation varies across sub-products and the exports of two of the product subgroups actually contracted (‘Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases’ and Pressure ‘Measuring and Monitoring Instruments’).
A comparison of intra-EU trade with extra-EU trade has been made using data from the COMEXT database (please note that there is some variation between the intra-EU trade data from the COMEXT and PRODCOM databases for similar product subgroups). A sample of the data are presented as graphs below and the full set is presented in Annex 2.

**Figure: 5.9**

![Graph](image1)

**Figure: 5.10**

![Graph](image2)

**Figure: 5.11**

![Graph](image3)
Although each product subgroup has its own characteristics, the data appear to show a number of common features. In terms of intra-EU trade, the period from 1995 to 2010 tends to show increases on the whole. For example, intra-EU exports of ‘Metal Tube and Pipes’ increased from approx. €2,250m to €3,500m at constant 2005 prices and ‘Boilers’ from approx. €1,600m to €3,800m. However, although growth continues throughout the entire period, the rate appears to slow for some product subgroups during the 2005 to 2010 period, presumably influenced by the economic crises.

At the beginning of the period, extra-EU exports were considerably below the level compared of intra-EU exports, but it is interesting that this difference has tended to reduce over time and in the case of metal containers and containers for liquids and gas, extra-EU exports now exceed the value of trade flows within the EU. Furthermore there is a distinct quickening of the pace of this trade growth. Typically, activity was relatively stable until 2000 and afterwards extra-EU exports have had much higher growth rates. The 2005 to 2010 period also appears to be less affected by the economic crises and the rate of growth in some cases such as the ‘Valves’ market, which is more intense in this period than in the former period.

Imports from outside the EU represent a much lower share of the market when compared with intra-EU trade and extra-EU exports. However, in many areas there are modest increases in the rate
of growth but in the 2005 to 2010 period the rate increases quite significantly for some product subgroups.

Reflecting overall on these findings, at first glance, the pressure equipment sector in Europe appears to be well-positioned. In recent years, extra-EU exports have increased with decent rates of growth that reflect the increasing range of opportunities for European engineering firms in third country markets. In addition, the annual value of extra-EU exports is much greater than the value of extra-EU imports which, even allowing for a tendency for imports to be understated, suggests that European industry has retained its competitive edge. However, whilst the rate of growth for extra-EU exports is set to strengthen, there are signs that the rate of growth for extra-EU imports will also follow the same pattern. This may explain the perceptions of many of the stakeholders interviewed, who perceive a worsening situation.

Destination of Extra-EU Exports

Throwing further light on extra-EU trade, the data on the principal partners of the EU is of interest. The COMEXT database shows the share (EUR) of extra-EU exports for 2010 by selected trading partners and the tables below show trade with the US, Japan, South Korea, Brazil, the Russian Federation, India, China, South Africa and the Rest of the World. The data behind the pie charts are provided in Annex (2).
The data reveals that the US and China are the EU’s main markets for pressure equipment exports, but that in general trade is with a large number of partners spread right around the world. The ‘Rest of the World’ tends to account for at least 50% of EU exports in all categories. Furthermore, there are significant variations in the share of exports going to the main trade partners, depending on the particular product subgroup. Overall, this suggests a mature global market with a wide range of trading opportunities for EU exporters.

**Origin of Extra-EU Imports**

A somewhat different picture emerges in relation to the source of imports into the EU. The following pie charts show the results of a similar exercise with data on the origin of extra-EU imports. The data behind the pie charts are again provided in Annex (2).
In the case of imports, with the exception of boilers, producers are concentrated in a relatively narrow range of countries. China and the US tend to be the main origin of extra-EU imports though again their relative importance varies across the product subgroups. The US is the main supplier of ‘Safety or Relief Valves’ and ‘Pressure Regulators and Controllers’, while China is the main supplier of ...
‘Valve’s. The extent of the remaining trading partners’ relevance differs according to the sector concerned. For example, India and South Africa produce a significant share of ‘Metal Tube and Pipes’ imports but are much less important in other areas. These figures also suggest the main source of competition for European products.

International Competitiveness (Market Comparisons with Other World Regions)

To further position the findings within an international context, data has been collected from a number of commercial and industry sources that compare the European pressure equipment sector with other world regions. The first group provide data on annual sales figures or revenue forecasts or sectoral market value or in non-monetary terms such as in sales in tons or annual capacity additions in Mega Watts (MW). These figures are based on data that are collected at the level of the manufacturer and these are then used to develop overall figures for the recent past, the current context and forecasts for the future medium term.

Figure: 5.25 World Pressure Sensors and Transmitters Market (Frost and Sullivan, 2009) 67

Figure: 5.26 Industrial Valves (Global Industry Analysts, 2010)68

67 Report purchased from MarketResearch.Com
68 Report purchased from MarketResearch.com
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Figure: 5.27 Heat Exchangers (Global Industry Analysts)\(^69\)

![Heat Exchangers graph](image)

Figure: 5.28 Chemical and Pharmaceutical Plant Construction Industry – Various Country Level Reports (World Market Intelligence, 2010)\(^70\)

![Chemical and Pharmaceutical Plant Construction Industry graph](image)

Figure: 5.29 Steel Pipes and Tubes (Global Industry Analysts, 2011)\(^71\)

![Steel Pipes and Tubes graph](image)

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\(^{69}\) Report purchased from Market Research.Com  
\(^{70}\) Report purchased from Market Research.Com
The data presents some interesting findings. Within a number of product subgroups Europe is either the leading regional market, in terms of annual sales or market revenue, (‘Heat Exchangers’ and ‘Industrial Valves’) or is closely following the lead market (‘Pressure Sensors and Transmitters’). In monetary terms, the future medium term for Europe appears relatively secure even when considering the projected growth trends in Asia. However, there is a stark contrast between China and Europe in terms of the market value of the ‘Chemical and Pharmaceutical Plant Construction Industry’ in particular in regard to the projected growth trends. China is poised for rapid growth in this area which potentially indicates that the development of complex industrial assemblies for other sectors may follow similar a pattern. Whilst it’s clear that such trends present opportunities for extra-EU exporters, the level of investment will evidently strengthen the manufacturing of pressure equipment within China to significant degree.

The remaining data (Figure 5.28 and 5.29) present findings in terms of annual sales in tons (‘Steel Pressure Tubing’) and capacity additions in Mega Watts (‘Boilers’). It is interesting to note that in both cases the non-monetary data positions Asia in a much more favourable situation than Europe and the US. With regard to ‘Steel Pressure Tubing’, the Asian market is set to experience rapid growth whereas the European and US market appear relatively stable. The comparatively favourable conditions for accessing steel in Asia compared to Europe are likely to have supported this trend. The rate of growth for the ‘Boilers’ market is not as great but again there is a clear gap between Asia and the other regions. It may be the case that when using non-monetary variables to compare world regions for other product subgroups, Asia is in a much stronger position than when indicated in monetary terms.

The second group of data below presents findings based on econometric models that have been developed to provide estimates for the value of world trade or latent demand.

Figure: 5.31 2011 World Outlook for Ferrous Metal Pressure Vessels and Tanks of More than 61cm
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Outside Diameter and 0.14 Cubic Meters Capacity (ICON Group International, 2012)\textsuperscript{74}

![Graph: 2011 Ferrous Metal Pressure Vessels and Tanks of More Than 61 cm Outside Diameter and 0.14 Cubic Metres Capacity Latent Demand €](image)

Figure: 5.32 2011 World Outlook for Custom Fabricated and Field Erected Ferrous Metal Pressure Vessels for Refineries, Chemical Plants and Paper Mills (Icon Group International, 2010)\textsuperscript{75}

![Graph: 2011 Custom Fabricated and Field Erected Ferrous Metal Pressure Vessels and Tanks for Refineries, Chemical Plants and Paper Mills Latent Demand €](image)

Figure: 5.33 The World Market for Safety or Relief Vales: A 2011 Global Trade Perspective (ICON Group International, 2010)\textsuperscript{76}

\textsuperscript{74} Report purchased from MarketResearch.Com.
\textsuperscript{75} Report purchased from MarketResearch.Com
Similarly, the monetary data tends to position Europe ahead of the other world regions. In terms of latent demand, the data shows that the market in Europe and the Russian Federation is slightly

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77 Report purchased from MarketResearch.Com
78 Report purchased from Market Research.Com
bigger than the market in Asia and the Middle East for ‘Ferrous Metal Pressure Vessels and Tanks’. In terms of world trade in ‘Fire Extinguishers’, ‘Safety Valves’ and ‘Pressure Regulators and Monostats’, Europe appears to be the strongest world region but it should be noted that the findings are composed of data for both intra and extra-EU trade. Nonetheless, it seems probable that Europe will remain in a strong position if only extra-EU trade were taken into account.

However, Asia and the Middle East are the leading regions in terms of latent demand for ‘Custom Fabricated and Field Erected Metal Pressure Vessels and Tanks for Refineries, Chemical Plants and Paper Mills’. In addition, the findings show very high levels of investment in complex industrial assemblies in Asia which again suggests that the drivers for developing the manufacturing industry within the region are particularly strong.

The final group of data have been provided by industry sources, namely the Italian engineering association ANIMA (Federation of the Italian Associations of Mechanical and Engineering Industries).

In a recent study\(^7\), the Italian pressure equipment sector was examined and compared against other leading economies. Despite facing tough international competition, the Italian industry was found to continue to be particularly strong. In 2009, across 321 machinery and metal products, Italy was one of the top three leading global exporters and attained a total value of €50,200m in exports.

Table: 5.6 - 2009 Index of competitive excellence in international trade: The position of Italian machinery and metal products.

<table>
<thead>
<tr>
<th>Italy’s position among exporting countries: machinery equipment and metal products</th>
<th>Number of products according to the Harmonised System 1996 (UN Comtrade database)</th>
<th>Total value of Italian exports (€m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases where Italy is the number one global exporter</td>
<td>87</td>
<td>20,700</td>
</tr>
<tr>
<td>Number of cases where Italy is the number two global exporter</td>
<td>121</td>
<td>15,800</td>
</tr>
<tr>
<td>Number of cases where Italy is the number three global exporter</td>
<td>113</td>
<td>13,800</td>
</tr>
<tr>
<td>Total number of cases where Italy is within the top 3 global exporters</td>
<td>321</td>
<td>50,200</td>
</tr>
</tbody>
</table>

With the use of disaggregated data, a number of product subgroups were examined in detail. For example, the strength of Italian industry in the ‘Heat Exchangers’ market was underlined. During the 2005 to 2009 period, Italy had been consistently ranked as the world’s number two exporter and had almost doubled the value of its exports. Interestingly, Germany held the number one position over the duration and China had moved from 17\(^{th}\) to 8\(^{th}\) place. Similar trends could also be discerned for the market for ‘Tanks and Cisterns of Iron and Steel with a Capacity Exceeding 300L’.

\(^7\) UCC (2011) Il Libro Bianco della Caldareria
Table: 5.7 – World ranking in exports of heat exchangers (UN Comtrade database)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>Export Value (€m)</th>
<th>Rank</th>
<th>Country</th>
<th>Export Value (€m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Germany</td>
<td>1,083</td>
<td>6</td>
<td>Japan</td>
<td>363</td>
</tr>
<tr>
<td>2</td>
<td>Italy</td>
<td>801</td>
<td>7</td>
<td>France</td>
<td>329</td>
</tr>
<tr>
<td>3</td>
<td>US</td>
<td>483</td>
<td>8</td>
<td>China</td>
<td>193</td>
</tr>
<tr>
<td>4</td>
<td>South Korea</td>
<td>471</td>
<td>9</td>
<td>Holland</td>
<td>159</td>
</tr>
<tr>
<td>5</td>
<td>Sweden</td>
<td>380</td>
<td>10</td>
<td>Czech Republic</td>
<td>159</td>
</tr>
</tbody>
</table>

However, in certain areas, although Italy remains a leading player, its position has weakened. In relation to ‘Containers of Iron or Steel for Compressed or Liquefied Gas’, Italy’s position had slipped from 2nd to 3rd place (it should be recognised that this particular statistical code may cover both transportable and stationary pressure equipment). Interestingly, China had taken the number two spot. Similar trends could also be discerned in the ‘Water Tube Boilers’ and the ‘Large Size Boilers for Power Production’ markets.

Table: 5.8 – World ranking in exports of containers of iron or steel for compressed or liquefied gas (UN Comtrade database)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>Export Value (€m)</th>
<th>Rank</th>
<th>Country</th>
<th>Export Value (€m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Germany</td>
<td>213.9</td>
<td>6</td>
<td>Czech Republic</td>
<td>122.8</td>
</tr>
<tr>
<td>2</td>
<td>China</td>
<td>212.3</td>
<td>7</td>
<td>UK</td>
<td>87.0</td>
</tr>
<tr>
<td>3</td>
<td>Italy</td>
<td>204.7</td>
<td>8</td>
<td>France</td>
<td>85.6</td>
</tr>
<tr>
<td>4</td>
<td>US</td>
<td>166.8</td>
<td>9</td>
<td>Turkey</td>
<td>84.5</td>
</tr>
<tr>
<td>5</td>
<td>South Korea</td>
<td>150.1</td>
<td>10</td>
<td>Portugal</td>
<td>74.7</td>
</tr>
</tbody>
</table>

In conclusion, the study showed that the Italian pressure equipment sector was a key wealth creator for the country. Its level of international competitiveness was reflected in its position as a leading exporter. This position had been attained through years of ongoing investment, research, innovation, improvement of manufacturing methods, product specialisation and implementation of solid company strategies. However, as already stated in the methodology to this section, it should be recognised that extra-EU exports are likely not to be built according to the PED. Therefore the findings of the Italian industry association study refer to the pressure equipment industry as a whole and not simply to the PED market.

Moreover, the increasingly competitive global market was recognised along with early signs of Italy losing market share in certain product subgroups. These trends appear to parallel the findings raised by the evaluation with Europe clearly being an important player internationally but facing increasing competition from other leading markets.

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Main Findings and Conclusions

- Given that ‘Pressure Equipment’ is not recognised as a distinct industry within the EU’s system for data collection, it has only been possible to directly assess the trends within parts of the industry. However, by analysing product subgroups it has been possible to develop a partial picture of the products covered by the PED, although particularly at the level of
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certain products, it is difficult to distinguish between those that are used in circumstances governed by the Directive and those that fall outside of its provisions. The findings may also not be reliable given the views from stakeholders on the size of the markets based on data retrieved from EU statistical databases.

- As far as can be judged, the value of output, has shown significant growth (59%) at constant prices since before the introduction of the Directive (over the period 1995 to 2010). However, one needs to consider rising energy and materials costs over the period that will have contributed to the increase in production costs. At the same time, there has been an increasing focus on developing quality products and those that use less materials.

- Likewise, the integration of the Internal Market appears to have developed at a particularly strong rate with a weighted average growth of 123% in intra-EU exports at constant 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.

- The extent to which the PED has directly contributed to this outcome is difficult to determine. It is recognised that regulatory factors are much lower drivers of growth than other economic factors that have a greater effect on stimulating or dampening demand. However, given that the rate of growth for intra-EU trade is higher than production, it is likely that the PED has played a facilitating role.

- The production value data show that EU enlargement has not resulted in the relocation of industry to the CEECs to the extent that may have been envisaged at the time of enlargement.

- In terms of Europe’s international competitiveness, extra-EU exports have increased rapidly in recent years and are of much greater monetary value than extra-EU imports.

- Similarly, when assessing data that directly compares world regions, Europe appears to be the most developed production centre in monetary terms given its concentration of high value production. The projections for the medium term for a number of European markets suggest that the future is relatively promising. However, other considerations such as viewing the size of the market in tons suggest that the Asian market is developing rapidly.

- Whilst the issue has not been assessed in detail, investment in complex industrial assemblies appears to be developing rapidly in the Asian market. This will provide a strong driver for growth going forward.

- The interview programme has indicated that in certain product subgroup markets European industry is perceived to be in relative decline in comparison to other world regions. However, although this may suggest that the data needs to be treated with caution, the results of this study and other recent research suggests that although global competition is increasing and in some areas this is posing a serious threat, the pressure equipment industry continues to hold its own and has an important role in the economy in some Member States.

- Despite the pessimistic outlook of some stakeholders, the data confirm that for certain Member State (such as Germany and Italy) the pressure equipment industry is internationally

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80 UCC (2011) Il Libro Bianco della Caldareria
strong across a range of products subgroups and in other Member States a smaller range of product subgroups are performing relatively well. Global competition is increasing, as the extra-EU import data suggests, but it appears that the European pressure equipment industry remains an internationally strong sector that will benefit from an expanding range of opportunities in the future medium term.
6. Effectiveness

6.1 Introduction

The following section will explore the effectiveness of the PED. The aim in considering effectiveness is to determine in what ways a particular Directive is achieving its operational, specific and global objectives, in terms of outputs, results and longer term outcomes. With these criteria in mind, a number of questions have been formulated to explore the performance of the PED against its key aims, examine how well these aims were being executed through the specified mechanisms of the Directive and to assess the types of impact the implementation was having on the industry.

Following this logic, stakeholders have been asked to comment on whether the PED had contributed to the development of an effectively and efficiently operating Internal Market and whether the classification of pressure equipment according to the fluid that it contains and stored energy had been appropriate and adequate. In addition, questions were asked in relation to the success of the New Approach framework for the pressure equipment sector, the performance of the systems for market surveillance and whether the delocalisation of production and the import of products from third country markets had posed any challenges for the PED framework. Finally, the discussions turned to identifying whether European firms had faced problems in placing products on the market in a Member State other than where the products were originally manufactured and whether any barriers existed that hindered the effective application of the Directive and how such barriers could be overcome.

6.2 The Development of an Effectively Operating Internal Market

The main thrust of the interview responses in relation to the question examining the extent to which the PED had supported the development of an effectively operating Internal Market corresponded with the previous answers under the theme of relevance in connection with the improved consistency of the regulatory framework that the PED has helped to put in place. For the most part, stakeholders were positive and commented that an improved regulatory consistency had led to a more effective marketplace in Europe.

A fundamental aspect of this is the greater ease with which manufacturers can now place products on the market in another Member State. Compared with the prior system of national legislation, the introduction of a common regulatory framework under the PED has led to the widespread understanding across stakeholders groups of the steps necessary for ensuring the free circulation of pressure equipment. On the whole, this has led to a greatly reduced use by public authorities and NBs of national rules for determining the marketing of products across borders. The outcome of this process has been the enhancing of intra-EU trade and an improved business environment for manufacturers. As a result, one of the core objectives of the PED, the removal of barriers to trade and improving the effectiveness of the Internal Market, has to a significant extent been realised.

During the course of the evaluation, a short survey questionnaire was supplied to industry association leaders to be disseminated amongst firms across Europe. Please see Annex (3) for further details. The survey elicited 96 responses from designers, material suppliers, manufacturers, installers and users of pressure equipment. Although limited in the number of responses, the survey provides an indication that the majority of industry (51%) consider that the PED is more effective than the previous system of national regulation (with 24% giving a neutral response). Similarly, a second survey of other PED stakeholders such as national authorities and NBs (please see Annex 4), indicated that 60% consider that the Directive is more effective than the previous system of national regulation (17% gave a neutral response).
Effectiveness

Table 6.1 Is the PED more effective than the previous system of national regulation?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly agree</td>
<td>13</td>
<td>13.5</td>
</tr>
<tr>
<td>Agree</td>
<td>36</td>
<td>37.5</td>
</tr>
<tr>
<td>Neutral</td>
<td>23</td>
<td>24.0</td>
</tr>
<tr>
<td>Disagree</td>
<td>17</td>
<td>17.7</td>
</tr>
<tr>
<td>Strongly disagree</td>
<td>3</td>
<td>3.1</td>
</tr>
<tr>
<td>Don't know/no response</td>
<td>4</td>
<td>4.2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>96</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: PED Business Survey (Annex 3)

The survey responses from stakeholders tend to confirm that the Directive has provided a more effective regulatory framework than the previous system of national regulation. However, the significant minority that either disagreed or provided a neutral answer would probably emphasise the barriers that continue to hinder the effective application of the Directive.

6.3 Barriers to the Effective Application of the Directive

Whilst on the whole the PED has introduced a more effective regulatory framework than the previous system of national regulation, stakeholders have confirmed that there are a range of barriers that limit its successful implementation. However, before these barriers are explored in more detail, it should be said that the evaluation has revealed that generally speaking the issues identified are not regarded as serious impediments to the functioning of the Directive. Whilst in some cases the issues identified have serious implications, they often represent shortcomings within particular areas of the Directive or New Approach framework. As a result, the barriers need to be put into perspective and should not be considered as constituting a widespread failure with the Directive.

The business survey reflects this outlook. When asked to score a number of potential barriers on a scale of 0 (the barrier does not exist) to 5 (very strong barrier), businesses tended to score the barrier between 0 to 3. Similar findings can be identified in the stakeholder survey (please see Annex 4). This suggests that businesses tend to consider the barriers linked to the implementation of the PED as minimal to moderate.

Table 6.2 What, if any, are the barriers to an effective application of the PED? Please can you prioritise the potential barriers below from 0 (the barrier does not exist) to 5 (very strong barrier).


**Effectiveness**

<table>
<thead>
<tr>
<th>(In)consistent:</th>
<th>0-the barrier does not exist</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5-very strong barrier</th>
<th>No opinion</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nº</td>
<td>%</td>
<td>Nº</td>
<td>%</td>
<td>Nº</td>
<td>%</td>
<td>Nº</td>
<td>%</td>
</tr>
<tr>
<td>Enforcement of the rules by government authorities</td>
<td>17</td>
<td>17.7</td>
<td>20</td>
<td>20.8</td>
<td>17</td>
<td>17.7</td>
<td>13</td>
<td>13.5</td>
</tr>
<tr>
<td>Interpretation of the Directive and requirements by Notified Bodies</td>
<td>11</td>
<td>11.5</td>
<td>17</td>
<td>17.7</td>
<td>18</td>
<td>18.8</td>
<td>16</td>
<td>16.7</td>
</tr>
<tr>
<td>Application of the EU guidelines</td>
<td>15</td>
<td>15.6</td>
<td>20</td>
<td>20.8</td>
<td>24</td>
<td>25.0</td>
<td>12</td>
<td>12.5</td>
</tr>
<tr>
<td>National level guidelines</td>
<td>16</td>
<td>16.7</td>
<td>19</td>
<td>19.8</td>
<td>22</td>
<td>22.9</td>
<td>16</td>
<td>16.7</td>
</tr>
<tr>
<td>National in-service inspection regimes</td>
<td>12</td>
<td>12.5</td>
<td>14</td>
<td>14.6</td>
<td>21</td>
<td>21.9</td>
<td>15</td>
<td>15.6</td>
</tr>
<tr>
<td>Interaction with the Transportable Pressure Equipment Directive</td>
<td>32</td>
<td>33.3</td>
<td>14</td>
<td>14.6</td>
<td>12</td>
<td>12.5</td>
<td>8</td>
<td>8.3</td>
</tr>
<tr>
<td>Interaction with the Simple Pressure Vessels Directive</td>
<td>34</td>
<td>35.4</td>
<td>18</td>
<td>18.8</td>
<td>13</td>
<td>13.5</td>
<td>6</td>
<td>6.3</td>
</tr>
<tr>
<td>Interaction with the Machinery Directive</td>
<td>28</td>
<td>29.2</td>
<td>25</td>
<td>26.0</td>
<td>20</td>
<td>20.8</td>
<td>7</td>
<td>7.3</td>
</tr>
</tbody>
</table>

Source: PED business survey (Annex 3)

The areas where the problems were seen to be greatest were in the interpretation of the Directive, the related area of the application of the PED Guidelines and in the interaction with national in-service inspection regimes. The interaction with other Directives was seen as representing a comparatively lower barrier.

The remainder of the section explores the issues mentioned in the above table as well as other barriers raised during the course of the interview programme (the barriers relating to interaction with other Directives are explored in the relevance section).

**6.4 The Effects of the All Inclusive Scope of the PED**

The all inclusive scope of the Directive was an immediate issue raised by a number of stakeholders. Although the PED has created a consistent vision for the operation of the Internal Market, its equal treatment of all pressure equipment based on the notion of the removal of hazards according to the products intended use has led, it is claimed, to onerous, unclear or complex requirements for some manufacturers. In addition, it seems that the all inclusive scope has led to regulatory creep in some product areas and strengthened regulatory requirements in some Member States.

One aspect is that given that the market is made up of consumer goods (serial items) and industrial products (serial, catalogue and custom made items) the impact of the regulatory requirements differ depending on the nature of the product, manufacturing process and the extent of involvement by users in the process. For example, manufacturers may be well placed for understanding the intended use of products that have been designed according to user specifications. However, manufacturers can find it difficult to determine what the eventual use of the product may be when developing for example catalogue products designed according to their own specifications. The application of the PED and selection of the appropriate conformity assessment modules may therefore be less certain.

According to one NB, users should be more involved in contributing to the conformity assessment procedures. This is because manufacturers are sometimes not in a position to understand how the
Effectiveness

product will be used and users may not provide sufficient data to support the hazard analysis process. The Directive was seen as placing significant responsibility on manufacturers in terms of guaranteeing the safety of their products but does not require users to support the conformity assessment process to an equivalent extent.

Similarly, manufacturers may not be in a position to develop the required supporting documentation such as the instructions to users (including maintenance aspects) to the appropriate level of detail given that the use of products differs greatly within different types of business and consumer environment. It is often the case that the instructions that manufacturers are obliged to prepare require dialogue with the user.

The scope of the Directive had been seen by some NBs as resulting in a particularly complex range of requirements that manufacturers have to deal with given the range of issues and products that the PED covers. Technical interpretation of the Directive was occasionally thought to be difficult. However, there were no clear alternative approaches proposed that the Directive could adopt. Any alternatives discussed were seen as unfeasible.

The scope of the Directive has also been said to have led to regulatory creep by covering products that perhaps may not have been considered when the PED was originally formulated. One example given was a particular type of heat exchanger used in the tyre manufacturing industry. This now falls under the scope of the Directive but some stakeholders believe that it was never originally envisaged to do so. In addition, certain products now fall under considerably more stringent regulation. These include liquid nitrogen and oxygen vaporisers. The associated regulatory costs for manufacturing these items have been said to have increased significantly and it is claimed that this has made the products uncompetitive to produce in Western Europe.

Furthermore, a number of firms that tended to service user installations in Northern and Western Europe mentioned that the introduction of the PED had not realised improved regulatory conditions. Given that the conformity assessment systems in many of these countries were already to a high standard, the transition to the PED had not really led to any significant changes apart from introducing more stringent requirements (for example in the UK). However, it was recognised that the PED had led to the upgrading of standards and organisational capacities in other parts of Europe that previously had very different regulatory traditions.

In response to these aspects, industry association leaders, although recognising that their suggestion was politically unfeasible, mentioned that an alternative form of regulation, namely product specific regulation, would further enhance the effectiveness and efficiency of the Internal Market. By having EU regulation designed specifically for certain products, it would be possible to better consider the needs of manufacturers and the context in which the product is being used. The areas of the PED / ‘one size fits all’ regulation which are perceived as burdensome could then be reduced in relation to each type of product.

However, this approach to policy making would clearly be highly resource intensive and would produce numerous pieces of regulation considering the range of products that fall under the scope of the PED. In addition, a range of stakeholders thought that by establishing a series of ESRs that pressure equipment are required to meet and by leaving the technical details to the role of standards, the PED’s framework facilitates the realisation of its key objectives (namely to strengthen the Internal Market and maintain high safety standards). Other alternatives to this approach were perceived as less relevant considering the results that had been achieved by the PED.
6.5 The Classification of Pressure Equipment

A key regulatory feature of the PED is the classification of pressure equipment according to the fluid that it contains and stored energy. Pressure equipment is categorised according to an ascending level of risk with the most hazardous categories being linked to the more stringent conformity assessment modules. Stakeholders were asked to comment on the appropriateness of this approach and to identify any shortcomings.

Overall, the approach was found to be satisfactory and the most sensible method to adopt. The tables provided in the Directive were considered as transparent and easy to use and the different conformity assessment modules linked to the various categories were said to provide manufacturers with some flexibility. A number of NBs made the case that it had increased safety levels and rationalised the inspection process. It was also found to be one of the keys for removing the barriers to trade given that national authorities and NBs need to accept and apply its core principles.

In addition, countries which were not familiar with similar systems until the introduction of the PED had for the most part been able to accommodate and apply the requirements. However, for some countries such as the UK, certain types of pressure equipment such as piping that was once categorised as Category I has subsequently been placed within higher Categories under the PED. This has meant that the costs for manufacturing such items in previously less stringent countries are now much greater. However, this has not affected more traditionally stringent countries such as Germany.

Some stakeholders mentioned that manufacturers may take advantage of the framework by manufacturing equipment just below the threshold of the following upper Category in order to avoid certain conformity assessment modules. However, such manufacturing approaches cannot be avoided if the specified parameters have already been given.

Only a small number of difficult cases in applying the framework were raised. For some cases, the manufacturer of the pressure equipment has difficulty in classifying the fluid, as required by the Directive. This arises for example in the pharmaceutical sector where the user retains the proprietary data about the fluids to be used in the pressure equipment.

Where required compliance with the PED is carried out by the manufacturer of the pressure equipment (in certain cases users may have the capacity to perform this role), he has therefore to make certain assumptions, usually in dialogue with the user, but in cases where no agreement is reached the manufacturer has to presume that the fluid is ‘hazardous’ and the pressure equipment classified accordingly within Fluid Group 1. It may be the case that more stringent conformity assessment modules have had to be applied unnecessarily and costs increased.

It was mentioned that small firms may have particular difficulties in dealing with the framework, simply because procedures are relatively complex for products where there is the greatest hazard. However, it was generally felt that all pressure equipment had to be assessed based on common rules and aligned to common safety categories regardless of the size of the manufacturer.

In addition, manufacturers and standardisation experts have expressed concerns regarding the upcoming alignment of the Directive with the CLP. Depending on the options chosen (in terms of the hazard classes and categories) for alignment to the CLP, the classification of a specific substance might change from group 1 or group 2 of the PED or vice versa. The intention with the alignment is to stay as close as possible to the current classification (Article 9 Based on the Dangerous Substances Directive). However, for a limited number of substances, the classification will change
because of the requirements of the underlying classification system of the CLP. The impact of these changes is subject to a specific Impact Assessment study.

6.6 An Overall Observation Regarding the Effectiveness of the New Approach Framework in Fulfilling the Objectives of the PED

Before the issues and actors that support the functioning of the New Approach framework under the PED are explored in detail, it would be useful to keep in mind an overall observation. Whilst the New Approach has supported the PED in largely meeting its objectives of supporting the free movement of pressure equipment while maintaining high safety standards, there are identifiable weaknesses in terms of the way key stakeholders hold each other to account or in the way various actors can fulfill their duties to the extent that the objectives of the PED are entirely fulfilled.

As an indicative example, pressure equipment are expensive items and market surveillance authorities may not have the resources to purchase equipment for testing on a sufficient scale. Moreover, comments were made about difficulties encountered by national authorities when attempting to exercise their powers. A national authority may successfully identify a non-conforming product and subsequently remove the item from its national market. However, procedures are not in place to ensure that the manufacturer of such items puts beyond use the non-conforming products in its ownership. It may be the case that the same manufacturer attempts to place the same batch of products on the market in another Member State. Similarly, a national authority may identify a non-conforming product and positions itself for removing the product from the market. However, the firm in question may threaten legal action as a result of potential reputational damages. Whilst the authority may have the resources to verify whether or not a product conforms to the regulations, it may not have the resources to pursue legal cases. In addition, the withdrawal of certificates by a Member State authority from a Notified Body with a view to suspending provision of services (in line with Article 12 of the PED) has rarely occurred.

Similarly, a number of stakeholders thought that occasionally the relationship between NBs and manufacturers may be suspect. Given that NBs have a commercial interest in providing conformity assessment services to the pressure equipment sector, the extent to which NBs may hold clients to account on certain safety requirements may deviate from the specific requirements of the PED. Likewise, the withdrawal of certificates by NBs from manufacturers with a view to withdrawing approval of design and production processes has rarely occurred. If such instances have occurred, they are often not the subject of debate between NBs as this would indicate a gap in the market that another NB may wish to fill.

Related issues are explored in more detail in the sections below.

6.7 The New Approach and the Performance of Notified Bodies (NBs)

In line with the specifications of the New Approach, NBs play a crucial role in overseeing the conformity assessment of pressure equipment. By approving such items, NBs enable manufacturers to fix the CE marking to their manufactured goods. The CE marking then acts as an indicator to market surveillance authorities and to users that the conformity assessed products have been designed according to the appropriate Directive and are safe for commercial or consumer use. NBs therefore play a fundamental role in providing consistency in the delivery of quality and safety procedures and for enabling the functioning of markets across borders.

The Impact of NBs on the Functioning of the Internal Market
Evaluation of the Pressure Equipment Directive  

Effectiveness

The main perception of stakeholders is that, as intended, NBs have been instrumental in overseeing the largely smooth functioning of the conformity assessment process and for positioning manufacturers for their goal of product approval. In many cases, NBs were perceived to be offering quality services in line with the needs of the Directive.

It is recognised that these efforts have consequently supported the consistent development of the Internal Market and have contributed to its effective functioning. As such, the movement of goods across borders has been strengthened given that NBs have generally accepted the results of conformity assessment procedures that take place in a Member State other than where they are located.

A key advantage of this is that the former monopoly position of equivalent authorities under the previous system of national legislation has been dissolved. It has been replaced by a more consistent set of EU-wide procedures and decision-making outcomes as well as greater choice in conformity assessment service providers for manufacturers.

Barriers to the Consistent Performance of NBs

However, the immediate reaction from industry is that whilst there are advantages compared to the previous system, inconsistencies are also highly apparent. The main issue is that the management of the conformity assessments process is markedly different between the Member States in some areas and also between NBs. Consequently, the approach taken by NBs in one Member State to a particular product may differ from the approach taken by NBs in another Member State for the same item. Similar differences are apparent between NBs within the same Member State but generally these are less pronounced.

Because of emphasis on different parts of the Directive or modules, the processes that manufacturers across Europe have to go through to ensure that similar products can be placed on the market can lead to varying outcomes. This may be in terms of the proven safety standards that the product conforms to and the associated costs. For example, it was mentioned that in Northern Europe, carbon steel impact testing is often regarded as essential for particular types of product. However, elsewhere, NBs only apply the test if it is specifically stated in the design codes. Similar comments were made about pneumatic testing. The concept of hazard analysis and the constituting elements of a hazard analysis were also said to vary across Europe. It was further

81 There may be inconsistencies in understanding the environmental context in which pressure equipment is intended to be used across the Internal Market. Pressure equipment approved in Southern Europe may be relatively safe for operation in a warm climate. However, if the pressure equipment was sold for use in northern Scandinavia, then consideration of the operation of the product in freezing temperatures may not have been fully considered.

82 When bidding for work, it was noted that some NBs would state that they would offer an agreed number of unexpected visits or that this was a requirement as part of the user’s tender specifications. For some, this goes against the principle of ‘unexpected visits’.

83 One NB noted that one of their clients tested the extent to which the materials they had purchased related to the properties outlined in their corresponding material certificates. It was found that 40% of the purchased materials did not correspond with the material certificates. The NB concluded that there is a strong statistical probability of non-conforming materials being used in the production of pressure equipment.

84 It was found that a batch of products that had been Post Weld Heat Treated and approved by a NB in one Member State were later removed from the market in another Member State given that the products did not conform to the ESRs;

85 It has been noted that sometimes the conformity assessment paperwork and the standards they refer to do not correspond with the related product.
asserted that the approach to the application or sequencing of the modules may vary between countries. This leads to the use of different regulatory procedures and also different costs for similar products. Some countries may even avoid a small number of the modules altogether, although there was no firm evidence provided to support this allegation. In addition, a number of firms are said to use assessment techniques that aren’t totally permissible under the PED, but are subsequently approved by NBs. These can include cryogenic or cool stretching.

Overall, some stakeholders commented that similar products appear to have been proven to conform to the Directive through different types of techniques and approaches. As a result, in many cases, there may be ‘shades of grey’ in terms of the extent to which equipment that has been placed on the market corresponds with the ESRs.

In addition, the capacity of NBs to offer appropriate services has been said to differ and this has led to a variation in the quality of the implementation of the conformity assessment procedures. Typically, there are perceived differences in the scale and quality of the skill-sets across the NBs. Some stakeholders mentioned that this was particularly the case for companies that are relatively small and it was believed that it would be largely impossible for them to offer the range of services that are expected under the PED. They may be able to comfortably deliver a small number of the testing procedures but not across all of the PED testing range in the same way as a large organisation. This tendency was considered to be most acute in countries that have multiple firms offering conformity assessment services and less so if the Member State had put measures in place to restrict the market to just a few players.

Related to this, are the competitive pressures that operate within the NB market. From the perspective of some stakeholders, less established or less well-known operators have to compete aggressively with large and more reputable organisations. By offering cheaper services, less well known organisations gain entry into segments of the market that are more sensitive to regulatory costs. But in the eyes of certain firms, a proportion of the NBs that offer low cost services do not critically assess their clients’ products to the same extent as the ‘expensive NBs’.

However, given that the above finding is based on qualitative research alone, one would have to critically assess and compare the conformity assessment documentation from a sample of NBs to determine if the allegations are really well-founded. In addition, ‘expensive NBs’ should not always be perceived as those offering the most appropriate services. Manufacturers sometimes base the selection of NBs on other issues such as the extent to which they can successfully market their approved products rather than on the quality of testing procedures. Similarly, larger NBs were said to be subject to considerable competitive pressures and may not always offer services to the same high standards.

Furthermore, attracting appropriately qualified staff appears to be a problem affecting most NBs, even those regarded as well resourced. One NB recommended that a European qualification relating to PED conformity assessment may help to address the matter.

Existing Scientific Research on the Quality of Conformity Assessment Procedures Overseen by PED Notified Bodies

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86 It should be noted that a Member State may designate a NB for only part of the conformity assessment procedures under the PED.
During the course of the evaluation, an existing piece of research, produced by a recognised NB\(^{87}\) in 2009 was submitted for consideration. This study highlights some of the problems within the NB (Netherlands and Belgium) market by referring to the outcomes of analysis of conformity assessment documentation and corresponding materials and pressure equipment. These include administrative shortcomings (e.g. anomalies in the contents and form of declarations of conformity and material certificates etc.) and technical problems (e.g. materials not attaining the prescribed material characteristics, undetected deficiencies in material welding or joints etc.). For example it was noted that:

- 30% of 3.1 material certificates (from a sample of over 200) in the Netherlands were issued erroneously (3.1 material certificates are drafted by the material manufacturer and confirm that the material correspond with the order and requirements);
- ‘Foul play’ had occurred with the issuing of incorrect 3.2 certificates (3.2 certificates are drafted jointly by the manufacturer and NB and confirm that the material correspond with the order and requirements);
- A small number of European but a larger number of Asian NBs had falsely approved the procedures of materials suppliers;
- Material suppliers had fraudulently certified materials (the Belgium Welding Institute found that the brittle breaking behaviour of 50 to 60% of flanges that were based on SA 105 materials did not fully or completely correspond to the certificates issued to them);
- Non-destructive testing and non-destructive analysis had been incorrectly conducted by inspectors and engineers;
- Acceptance of non-conforming design practices by NBs was identified such as the use of erroneous non-allowable stresses or design input data, the use of configurations not accepted by the standard and lack of assessments of the extent to which the constructed pressure equipment deviates from the specifications of the original design.

The findings of the research appear to support the view that the competitive pressures in the NB market have led to the emergence of poor practices. They may also be grounds for saying that varying standards in the testing procedures and organisational skill-sets of NBs have given rise to unacceptable procedures and certification. The evidence from two countries does not of course immediately support an assumption that a similar situation applies in other Member States, but it does suggest that a similar technical examination of the practices within the NB market elsewhere should be undertaken.

**Problems Identified with the Role of Accreditation Bodies and Holding NBs to Account**

Several stakeholders pointed out that a number of accreditation bodies do not exercise their powers in line with the needs of the PED NB market. For example, for some, it was not credible that an accreditation body could accredit a small NB with limited organisational capacity to offer the entire range of PED services demanded under the Directive.

Moreover, the steps that potential NBs have to go through in order to be appointed differ markedly across Europe. In some countries, such as Sweden, accreditation bodies require NBs to fulfil the conditions of recognised standards whereas the requirements and the associated costs for NBs be

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\(^{87}\) Vinçotte (2009) Safety Surveillance Approach During the Installation
appointed in other countries are perceived to be much lower. In addition, currently, accreditation systems are not a mandatory feature of the Directive.

Furthermore, the subsequent checks and levels of scrutiny placed on NBs after they have been appointed were perceived to be weak. Rigorous systems of evaluation to assess the performance of NBs in detail were not believed to be widespread. NBs were therefore regarded as operating freely on the market with no effective authority holding them to account.

In addition, some manufacturers noted poor levels of service from NBs in terms of poor examination approaches and the length of time (sometimes over 18 months) it takes to receive the approval certificates. The potential pressure that manufacturers could place on NBs to improve their services was often seen as limited.

**The New Legislative Framework (NLF) and its Vision to Strengthen the Conformity Assessment Process**

The proposal to align the PED with the NLF will provide an opportunity to strengthen the legislative requirements for selecting, monitoring and assessing the performance of NBs. It is recommended that these requirements are elaborated in full in the context of a newly aligned Directive. The NLF aims to ensure that the appropriate conformity assessment procedures in relation to the product concerned are selected by NBs and are delivered to a consistently high level of quality across Europe. NBs should be accredited on a mandatory basis in line with appropriate criteria (the evaluators recommend that it would be beneficial to have harmonised accreditation criteria) and should be continually monitored by accreditation bodies. Member States are responsible for ensuring that accreditation bodies are appropriately staffed in order to ensure that they can determine the ongoing performance of NBs. It is expected that accreditation bodies should exercise their powers of suspending or withdrawing accreditation certificates from NBs when necessary. If foul play has been detected, court cases could be taken forward against NBs. The introduction of these and other features of the NLF into an aligned PED should provide a stronger legal basis for the oversight of the NB market.

**6.8 The New Approach and the Performance of Market Surveillance Authorities**

The opinions presented on market surveillance authorities regarding their overall impact on the functioning of the Internal Market mainly ranged from slightly less than fair to unsatisfactory. All of the interviewees tended to agree that whilst certain authorities may be performing their activities to a reasonable level, generally there are significant weaknesses in the system. As a result, the overall system for market surveillance was mostly characterised as deficient in its role of identifying and removing nonconforming products from the market.

**Variation in the Performance of Market Surveillance Authorities**

The interview programme indicated that certain authorities are particularly active and relatively well resourced and have experience of removing nonconforming products from the market based on the legal avenues provided by the PED. However, there was a perception that the relative performance, capacity, staffing levels and activeness of market surveillance authorities differ across the Member States. It appears to be the case that those authorities with more limited resources, staffing levels, capacity or willingness to proactively address the issue of the circulation of non-conforming are not fulfilling their role in line with the needs of the Directive.

A related issue is that there are a number of different perceptions of how a market surveillance authority should fulfil its remit. For example, some market surveillance authorities are more risk
averse than others and may target certain products from certain European and non-European countries based on historical findings and instincts. Other authorities may require more evidence before making such judgements and will only respond to information received from stakeholders. However, it may be that those operating reactively are located in well regulated countries and can generally rely upon NBs and insurance firms to support the enforcement of the PED. But this may not be the case in other countries.

**Barriers to the Successful Performance of Market Surveillance Authorities**

A further general impression is that market surveillance authorities face resource constraints particularly in countries where the pressure equipment sector is less developed. This obviously has an immediate impact on the extent and frequency that products can be purchased from the market for testing and also affects the type selected (i.e. cheap consumer products as opposed to expensive industrial items). The authorities with limited resources may concentrate on the consumer market only and to a certain extent rely upon the role of NBs and insurers to oversee the enforcement of the PED in relation to the industrial market.

In addition, a further barrier to the successful functioning of the system appears to be the lack of sharing of information on non-conforming products and the development of EU-wide positions towards them. It was claimed that, after warnings have been issued regarding potentially non-compliant products, the reaction from counterpart market surveillance authorities is sometimes unsatisfactory and rather slow. Occasionally, market surveillance authorities mentioned that the response from other countries is even muted and questions have been raised as to why other authorities have not found similar problems in their home market in relation to the same or similar products.

A further problem that faces market surveillance authorities is in identifying suitably qualified recruits. In addition to the fact that there is a shortage of engineers on the marketplace, public authorities may not be able to offer the same level of salary to potential recruits who are expected to have detailed knowledge of a large range of standards, manufacturing processes and pressure equipment. Such individuals may therefore find more attractive positions in the private sector. However, in a minority of countries such as Germany, finding recruits did not appear to be a major problem but rather hinged upon the willingness of decision-makers to invest in new personnel.

One suggestion that emerged to make the market surveillance system more effective (and efficient) is to allocate responsibilities for different types of products to different countries based on their expertise and resources. This would replace the current situation where different Member State authorities are monitoring the same products. Obviously, this proposal would require significant investment of time and resources in order to make it both feasible and operational.

**The Perception of Industry of the Performance of the System for Market Surveillance**

The uneven performance of market surveillance authorities frustrated a number of firms (and industry associations\(^8\)) that have invested in the compliance process. They considered that the circulation of non-conforming products on the market placed them at a competitive disadvantage and that action should be taken by the EU to remedy the situation.

\(^8\) The industry association ORGALIME have produced a position paper “Towards Comprehensive and Efficient Market Surveillance” that suggests action that Member States should take in order to reinforce the system for market surveillance: [http://www.orgalime.org/Pdf/NAMS.%2020091005.pdf](http://www.orgalime.org/Pdf/NAMS.%2020091005.pdf)
Another issue was the perception of the way in which rules are enforced by relevant bodies. A number of firms argued that in some countries there are stringent requirements placed on them by authorities (and insurers) and heavy fines and costs for non-compliance. However, the same firms mentioned that authorities in other countries are not as tough at enforcing the rules which meant that their competitors may invest less in guaranteeing the same levels of safety in products and processes.

In addition, some firms were unaware of the market surveillance function altogether and incorrectly thought that the questions on market surveillance related to the procedures performed by NBs. After this impression had been corrected, the interviewees were surprised that they had been given no information on the nature and role of these bodies.

The Vision of the New Legislative Framework (NLF) to Strengthen the Market Surveillance System and Other Recommendations

The proposal to align the PED with the NLF will provide an opportunity to strengthen the legal basis for the market surveillance system for pressure equipment. It is recommended that the aspects on market surveillance within the NLF are carefully elaborated during the alignment with the PED in order to address some of the identified weaknesses within the current system. This includes ensuring that effective measures by Member States are taken in terms of providing appropriate oversight of the Internal Market, streamlining the safeguard procedure, delivery of training activities with the cooperation of the EC to national authorities, ensuring that the public are aware of the existence and role of market authorities and how they may be contacted, ensuring that appropriate coordination and sharing of information takes place between authorities, obliging Member States to provide sufficient resources in relation to the tasks at hand, ensuring that products are checked on an adequate scale and ensuring that appropriate measures are taken in relation to non-conforming products.

In addition, although certain web based tools are currently in place to support the market surveillance process, it was mentioned that they are currently underused by some Member States. This includes RAPEX89 (which covers consumer products) and ICSMS90 (which covers industrial products and RAPEX updates). Although ICSMS is in the process of being rolled out with a view to including all Member States, national authorities could be encouraged to make greater use out of these platforms.

6.9 The Impact of the Delocalisation of Production on the Internal Market for Pressure Equipment

The impact of the delocalisation of production on the effective performance of the Internal Market was a key issue raised during the course of the discussions. The full implications of this development are far from clear but generally it was considered that in certain areas the trend has raised a number of serious issues for the successful implementation of the Directive.

European Industry’s Perception of the Quality of Pressure Equipment Produced in Low Cost Centres

For new entrants to the market, a steep learning curve has to be overcome before their manufacturing processes are perfectly aligned to the PED. One concern is that this is a challenging

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89 RAPEX is an EU web-based rapid alert system that facilitates the rapid exchange of information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers.

90 Information and Communication System for Market Surveillance provides product information and other relevant information such as safeguard clause updates to market surveillance authorities via the Internet.
proposition particularly in countries that do not have a long tradition or strong capacity in engineering. Additionally, given that some stakeholders consider that manufacturers located outside Europe are not sufficiently informed of their legal obligations under the Directive, the potential for non-conforming products to be placed on the Internal Market has apparently increased significantly.

This finding appears to be particularly true in relation to low cost pressure equipment that has been produced without significant user oversight. A number of examples were given of manufacturers based in low cost centres, who had produced inexpensive items that, when tested, did not fully conform to the requirements of the Directive. For example, certain valves that were produced in China and integrated into complex assemblies in Finland were found to contain a number of deficiencies and were removed from the market.

A further issue is that given that production of certain products have now mostly been relocated outside Europe, in some cases manufacturers and users consider that they have no choice but to purchase pressure equipment that have been poorly manufactured and do not fully meet the requirements of the Directive. Similarly, the quality of certain materials that are produced in third country markets and are necessary for the manufacturing of pressure equipment in the EU was also found to be unsatisfactory. Given the poor specifications used for certain imported materials, it was difficult to see how they could be used for pressure equipment designed according to EN standards.

However, another group of stakeholders commented that if a user or procurer of pressure equipment is heavily involved in specifying the requirements for the manufacturing and quality processes, then firms based in low cost centres can be guided towards meeting their obligations under the PED. For example, European chemical firms that had overseen the building of installations in China had guided the process according to their own design specifications that apparently were more onerous than those set out in the PED. Similarly, positive examples were given for large firms that have shifted their production units outside of Europe but had retained strong managerial control over their manufacturing and quality processes.

The results from the PED business survey indicate the differences of opinion on whether pressure equipment manufactured outside Europe is of a high quality. It is interesting to note that in relation to a separate question, roughly 40% of the respondents to the PED business survey confirmed that they had branches located outside Europe. However, only 25% agreed with the statement below.

**Table 6.3 In general, do you consider that pressure equipment manufactured outside the EU is of a high quality?**

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly agree</td>
<td>2</td>
<td>2.1</td>
</tr>
<tr>
<td>Agree</td>
<td>22</td>
<td>22.9</td>
</tr>
<tr>
<td>Neutral</td>
<td>37</td>
<td>38.5</td>
</tr>
<tr>
<td>Disagree</td>
<td>17</td>
<td>17.7</td>
</tr>
<tr>
<td>Strongly disagree</td>
<td>1</td>
<td>1.0</td>
</tr>
<tr>
<td>Don’t know/no response</td>
<td>17</td>
<td>17.7</td>
</tr>
</tbody>
</table>

Source: PED Business Survey (Annex 3)
Several stakeholders questioned the capacity of certain subsidiaries of European NBs (that were based in low cost centres) to fully enforce the requirements of the conformity assessment process. Although NB European head offices are responsible for overseeing the work of their subsidiaries, numerous sources mentioned that the skill-sets of subsidiaries tend to be much weaker than those of their EU-based counterparts, including sometimes subsidiaries of reputable organisations. Consequently, the application of key aspects of the PED requirements for conformity assessment were sometimes said to be insufficient.

Related to this, European NBs may not have the resources to properly manage their subsidiaries in low cost centres. There were comments that the competitive pressures of the NB market had resulted in European head offices having limited time and funds for delivering sufficient managerial and training activities for their subsidiary organisations.

In addition, the competitive pressures for conformity assessment services in low cost centres were also thought to be particularly intense. This might have led to cases of foul play (as indicated in the previously mentioned study\(^\text{91}\) where subsidiaries of NBs have knowingly approved pressure equipment according to substandard conformity assessment procedures in order to retain and expand their client base\(^\text{92}\).

However, it should be recognised that European firms who had strong oversight of their overseas manufacturing units were much less critical on this particular issue. Generally speaking, they considered that some of the major providers of conformity assessment services outside Europe where equally as effective as their European counterparts. It could be suggested that the extent of involvement by European firms, users and procurers in supporting the conformity assessment process outside of the EU is a key factor in determining the performance of this process.

**The Impact of the Delocalisation of Production on Market Surveillance**

A number of stakeholders considered that the impact of the delocalisation of production had not been fully responded to by market surveillance authorities. If there is a potential for a high volume of non-conforming products to enter the Internal Market, the measures and resources currently in place would appear to be insufficient to address the issue in full. The market surveillance system was therefore considered to be stretched and under increasing pressure.

However, there were comments (in line with statements to be found in the NLF) that some market surveillance and customs authorities have enhanced their efforts to assess products originating from low cost centres. In particular, authorities have coordinated activities to stop non-compliant products from entering the Internal Market by checking the contents of shipment containers.

At the same time, it was also pointed out that whilst this is a satisfactory approach for some products, there are limitations to the assessment of complex pressure equipment. This is because market surveillance of pressure equipment requires the use of detailed testing and examination techniques in order to determine whether the product is compliant or not. Obviously, this requires investment in specific scientific tools and methods rather than simply using checklists to check for the CE marking etc.

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\(^{91}\) Vinçotte (2009) Safety Surveillance Approach During the Installation

\(^{92}\) One NB commented that during unexpected visits at the production units of firms based in low cost centres, managers of the firm may state that the equipment is not destined for Europe and therefore the PED does not apply. However, although it is difficult prove, in such instances other evidence collected at the production unit suggests that the equipment is destined for Europe.
The Future Role of the PED and the New Legislative Framework (NLF)

Clearly, in today’s world the PED is performing a series of functions that are additional to those originally envisaged. The regulations are responsible for governing a range of manufacturing activities and bodies outside of the EU with a view to ensuring the safety and protection of European industries and citizens. At a later stage when the EC considers that the Directive is fit for revision, inclusion of an additional global objective could be considered to reflect this function and to make it clear that it remains properly focused on the trends shaping the modern pressure equipment industry.

In addition, the NLF has emphasised the importance of NBs overseeing the work of their subsidiary organisations in order to safeguard safety standards. Subsidiaries are required to fulfil their remit to the same high standards as their European counterparts. As part of their monitoring duties, accreditation bodies should assess whether the work of subsidiaries is in line with the requirements of the relevant Directive. Market surveillance authorities should also cooperate much more closely on related matters (and in the development and coordination of appropriate programmes) with their counterparts in Europe. Efforts to strengthen good relations and share knowledge would support this process given that national market surveillance authorities lack legal authority to perform market surveillance activities outside of their own countries. Given the pressures placed on the PED by the delocalisation of production, it is recommended that key aspects of the NLF are carefully elaborated and aligned with the Directive.

Table 6.4:

<table>
<thead>
<tr>
<th>Identified weaknesses in the conformity assessment process;</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Uneven application of the conformity assessment modules by NBs for similar products;</td>
</tr>
<tr>
<td>• Variance in the capacity and knowledge of NBs and their subsidiaries;</td>
</tr>
<tr>
<td>• Competitive pressures in the NBs market that may affect the full enforcement of the modules;</td>
</tr>
<tr>
<td>• Poor oversight of subsidiaries of NBs by European head offices;</td>
</tr>
<tr>
<td>• Differing standards in accrediting and monitoring NBs by accreditation bodies;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Identified weakness in the systems for market surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Limited resources to address the task of examining complex pressure equipment;</td>
</tr>
<tr>
<td>• Limited coordination between and responsiveness of (some) national authorities towards the problem of non-conforming products (the safeguard procedure has been used on roughly 5 occasions);</td>
</tr>
<tr>
<td>• The number of online market surveillance product notifications through systems such as RAPEX</td>
</tr>
</tbody>
</table>
(consumer items) and ICSMS (industrial items) are surprisingly low and seem to originate only from a small number of Member States;

The perceived scale of the problem is reflected in the identification of problems in tested sample of pressure equipment.

**Examples of the problems include:**

- A proportion of materials do not correspond with the properties outlined by their material certificates;
- Particular Material Appraisals (PMA) may not meet the expectations of the ESRs;
- Pressure equipment may not correspond with the test results outlined in conformity assessment documentation;
- Approved pressure equipment may not be able to withstand weather conditions in different parts of Europe;
- Non-conforming products consistently emerging from certain countries / manufacturers located inside and outside the EU;

### 6.9 Problems in Placing Products on the Market in a Member State Other than Where it was Originally Produced

The interview programme revealed that the frequency and number of problems in placing products on the market in a Member State other than where it was originally produced had significantly decreased since the introduction of the PED. This has been due to the largely common recognition of the rules of the Directive by NBs and authorities which has facilitated the removal of barriers in the Internal Market.

However, a significant minority of firms confirmed that some problems in this area continue to exist. These viewpoints are also reflected in the results of the PED business survey with 26% confirming that they knew of instances of this kind.

**Table 6.5: Are you aware of any problems that manufacturers have experienced in placing pressure equipment on the market in another EU Member State other than the one where it was produced?**

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>25</td>
<td>26.0</td>
</tr>
<tr>
<td>No</td>
<td>70</td>
<td>72.9</td>
</tr>
<tr>
<td>No response</td>
<td>1</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>96</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

Source: PED Business Survey (Annex 3)

Based on the interview findings, national in-service inspection legislation was the main cause of problems. This type of legislation consists of various legal requirements, assessments and tests conducted either during the installation of pressure equipment (involving the granting of permits to operate) or at subsequent intervals after it has been put into service. In some countries, this can govern the design of pressure equipment and the selection of standards (often former national ones) by manufacturers.

For example, in Germany, if the former national standards and codes have not been selected for the design of pressure equipment, then the subsequent in-service inspection intervals are set at a much
higher frequency. One firm mentioned that the commercial case for selecting standards and codes other than the former German ones was non-existent given the greater regulatory costs. Another firm mentioned that this approach discriminates against the use of EN standards given the preferential treatment of German standards.

Similar comments were made about France, Italy and the Netherlands. Given these findings, it may be the case that in-service inspection regimes in a number of other countries may affect the placing on the market of pressure equipment and have resulted in a number of problems for manufacturers.

In order to manage the requirements of national in-service inspection legislation, some firms cooperate in-advance with local authorities with a view to alerting them of their forthcoming commercial activities and to ensure that they design their products according to the correct specifications. Often they will only request the conformity assessment services of an NB that is located in the same country as the client so that they can demonstrate that the in-service inspection requirements have been met. This has been said to impose additional costs for entering certain Member State markets.

Nevertheless, other national in-service inspection regimes were said to be comparatively ‘light’ and more flexible than the regimes of more stringent countries and were consequently more suited to the needs of industry.

The response from firms on this issue reflects the need for further examination of the matter. National in-service inspection regimes were said to be highly complex and required detailed research in order to map out their main features and implications for the functioning of the Internal Market. Detailed analysis of the legal requirements and practices of certain national in-service regimes may reveal that they run counter to the logic of the PED and functioning of the Internal Market. If such research is undertaken and discriminatory and other similar practices are identified, proposals should be put forward on how to address such issues (one possibility could be the requirement for the equal treatment of EN and other standards in line with the New Approach philosophy by national in-service legislation within a revised PED).

However, it should be recognised that it would be difficult to harmonise national in-service inspection requirements through EU legislation as there is a limited legal base in the EU Treaty to formulate ‘non-Internal Market’ initiatives of this kind. In addition, if it was determined politically feasible to harmonise in-service inspection regimes, industry should recognise that European-level policy making often results in regulatory outputs based on consensus between the Member States rather than simply the introduction of ‘lighter’ regimes.

6.10 Enforcement and Uptake of the PED Guidelines and National Guidelines

Since the introduction of the PED, a number of instances have occurred where stakeholders have requested clarifications from the EC related to the technical interpretation of the Directive. In response, the PED is supported by a stakeholder group (Working Party Guidelines) that formulates non-statutory guidelines in order to establish a consistent vision of what is expected from authorities, NBs and industry. The use of similar procedures has been initiated under other comparable Directives.

The PED Guidelines provide answers to specific questions (to date roughly 200 questions have been responded to) and are made available to the public. It should be noted that the PED Guidelines confirm or clarify issues or provide possible solutions that are acceptable with a view to meeting the ESRs but do not go beyond the requirements of the PED.
In wider cooperation with NBs and market surveillance authorities, the PED Guidelines are further disseminated and discussed in order to ensure broad uptake and a consistently governed marketplace. For the most part, stakeholders mentioned that the PED Guidelines are generally accepted as the most accurate interpretation of the Directive and are enforced accordingly.

However, because the PED Guidelines have a non-statutory basis, stakeholders are not legally obliged to accept and implement them. As a result, a small number of comments were made that the PED Guidelines are consistently applied by some NBs but not others. This was said to send out confusing signals to manufacturers. In some cases, this had led to apparently costly outcomes for firms that had followed the PED Guidelines during the manufacturing of pressure equipment but had later engaged with NBs in other Member States that had disagreed with some of them.

PED Guidelines - Recommendations

The PED Guidelines play an important role given that they can define certain areas of the Directive in detail but at the same time allow the PED to maintain the flexibility of a traditional New Approach Directive (e.g. particularly in relation to scope and ESR related issues). The PED Guidelines therefore help to elaborate how the Directive should be applied in specific contexts. As such, if the Directive is revised in the future, the PED Guidelines would continue to play an important role in supporting the implementation of the requirements. Encouraging their uptake through relevant NB discussion groups would be one way of ensuring that the most suitable interpretation of the Directive is broadly disseminated.

However, an assessment of the PED Guidelines could take place in order to considering whether a small number could be integrated into a revised PED. Only the most appropriate PED Guidelines should be selected for consideration with a view to providing a more consistent and legally reliable framework for the implementation of the Directive. In addition, it is interesting to note that the French government has issued a Decree that legally requires stakeholders to adhere to the PED Guidelines. Other Member States may wish to follow this practice.

National Guidelines

National authorities have also produced summary guides to help national stakeholders understand the PED. Whilst these may be fine as introductory tools, some of them are not deemed to be satisfactory for interpreting the actual PED and PED Guidelines in full. A very small number of stakeholders consider that mistakes have been made by NBs that use their nationally produced documents as the main basis for implementing the PED requirements. It should be made clear that such items have no authority and that the PED itself (and PED Guidelines) are the main sources of information for implementing the legislation correctly.

6.11 Aspects of the Directive that were Critically Assessed by Stakeholders

Stakeholders scrutinised various aspects of the Directive and suggestions were put forward to revise such areas either individually or during a full revision. The evaluators consider that a full revision of the Directive is not required at this stage given that a number of the key aspects of the Directive appear to be performing relatively well. However, at the point when the Commission decides to undertake a revision, it is recommended that the below points are assessed.

The Scope of the Directive

An area that may warrant reconsideration is the current scope of the Directive particularly in relation to the product exclusion for offshore pressure equipment mainly used in the oil and energy industries. These products are currently regulated through national laws by a small number of
Evaluation of the Pressure Equipment Directive

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Member States. Given the perceived increased levels of risk of accidents and pollution in this area, an extension of the Directive may provide the industry with stronger and more appropriate safety measures. This issue is currently under investigation through an Impact Assessment and if the findings are positive the Directive may be extended to cover this product group. *The Concept of Assemblies*

One aspect of the Directive that has been said to be difficult to interpret is the concept of assemblies. For some, the definition in the PED is rather vague and has led to confusion on how the Directive should be applied (for example in relation to highly complex industrial installations used in the power or petrochemical industries). In some countries, NBs are particularly rigorous in ensuring that all the items of pressure equipment within an assembly have been CE marked whilst others less so.

In addition, confusion has arisen when an assembly is composed of pressure equipment from multiple manufacturers. This is in terms of whether ultimate responsibility lies with the organisation that has built the assembly or the multiple producers that have manufactured the component items of pressure equipment. However, other comments have been made that there is a poor understanding by certain manufacturers and NBs on this issue rather than there being a problem in terms of clarity with the Directive. From this perspective, the concept of assemblies does not require reform. In fact, comments were made that some manufacturers and NBs were ignoring existing PED Guidelines that have provided clarifications on the matter. It might be the case that stakeholders who don’t fully follow the rules may wish to operate under ‘lighter’ regulatory requirements.

It needs to be established if the concept should be reviewed to see if a clearer definition of the notion of assemblies would provide a more consistent application of the Directive particularly in relation to where the ultimate responsibility for an assembly lies. *The Requirements for Pressure Accessories*

Some manufacturers thought that the PED’s references to pressure accessories are unclear. When the Directive was first introduced, industry considered that the Directive applied to all pressure accessories. However, after examination of the wording, it was found that a large proportion would no longer be covered. This was supplemented with a guideline that apparently removed 70% of pressure accessories from the PED’s scope. This proportion of the pressure accessories are now manufactured according to the ‘sound engineering practices’ of the Member State where the manufacturer is based.

However, parts of the industry are confused on the position and continue to manufacture pressure accessories according to PED requirements. In addition, some manufacturers consider that to bring consistency to the industry, it may be reasonable to amend the wording in order fully cover pressure accessories. A small number of national authorities have mentioned that pressure accessories should be built according to the PED in order to enhance the safety of pressure equipment. Detailed examination of the issue may lead to the finding that safety aspects and market surveillance activities would be enhanced if the wording was amended. However, it should be noted that this would lead to an extension of EU regulation on industry. *Sound Engineering Practices*

A small number of market surveillance officials mentioned that they had problems examining products that are categorised below Category I and are designed according to the ‘sound engineering practices’ of the Member State where the manufacturer is based. In particular, they...
thought that this concept was difficult to deal with given that the sound engineering practices of another Member State is not well known. However, extending the scope of the PED to include conformity assessment of all items that fall into this category would have a major impact given the large number of products involved.

The PED’s Quantitative Requirements

The Directive contains a number of quantitative requirements in Annex I (7). They provide specific allowable stresses for a range of testing practices, demonstrating material characteristics and benchmarking the acceptable levels of material ductility. Again, inconsistencies between Member States have arisen with regard to the interpretation of these requirements which have left material suppliers in different parts of Europe producing materials to different specifications in order to fulfil the requirements of the PED.

Another concern is their relevance for the modern pressure equipment industry and their interaction with the development of new materials and the technically innovative properties of EN standards. One advantage of using EN standards is that materials can be safely developed according to other quantitative parameters. As a result, material suppliers that wish to place their materials on the market in Member States that stringently interpret the Directive may not be able to apply EN standards to their full potential. Revising the quantitative requirements would enable manufacturers to develop their technically innovative approaches for developing materials. In addition, it was stated that other comparable Directives do not contain quantitative requirements and were more flexible in their approach.

However, given that there isn’t a legal requirement under the New Approach framework for designing materials according to EN standards, material suppliers are free to use other standards and codes for developing materials in order to meet the ESRs. As such, some officials consider that the quantitative requirements are essential for providing minimum safety guarantees particularly for materials based on standards and codes that do not have the same properties as EN standards. It was also pointed out that there are a number of insufficient materials on the market and the quantitative requirements of the PED provide a measure of safety in this regard because those materials do not meet the ESRs and can hence not be used for manufacturing pressure equipment in compliance with the PED.

A number of stakeholders requested reforms in this area largely based on the premise that specific quantitative requirements are outmoded, unnecessary and act as barriers to innovation. At the same time, the PED should continue to provide a sufficient level of safety. If the Commission identifies that there is a need to review this aspect, then the safety implications of removing the requirements need to be fully examined. Declaration of Conformity

The PED requires firms to issue declarations of conformity in relation to their manufactured goods when requested by authorities. Declarations of conformity provide a range of detailed information on the conformity assessment procedures that have been followed, type and design certificates provided by the NB and other pieces of information that indicate how the pressure equipment meets the ESRs.

Officials commented that declarations of conformity are effective documents that contain meaningful information. In their opinion, market surveillance procedures particularly on-the-spot
checks would be enhanced if manufacturers were obliged to automatically supply the documents given that checking the CE marking alone does not provide significant background information on how the pressure equipment meets the ESRs. If the Commission were to review this aspect, it would need to be recognised that industry may be less enthusiastic about having to automatically supply the documents.

**Stakeholder Responses to the Article for User Inspectorates and the Outcome of the Previous Evaluation on User Inspectorates**

Although only a small number of UIs were interviewed, the performance of this feature of the Directive was found to be effective. Overall, UIs had met their intended goal of enabling users of pressure equipment to assemble and put into service complex assemblies in line with the relevant modules that are overseen by internal but independent second party bodies. This had provided the advantage of enabling a unit internal to the firm to gain detailed knowledge of the equipment being used, maintain appropriate safety levels and be excluded from the requirement of using NBs to perform the conformity assessment procedures in question. Similar views were echoed by other stakeholders.

However, during the course of the interviews the view was expressed that UIs are sometimes overlooked during the production of New Approach documentation (such as EA-2/1794) given that this is often designed only with third parties in mind and not second parties. This makes the requirements difficult to apply for UIs. Reviewing this particular issue and considering the specific role of UIs within similar future documents may help to improve the effective operation of these bodies.

During the initial formulation of the PED, there were some concerns that pressure equipment approved by UIs may present a higher risk than items approved by NBs. As such, the PED requires that the Commission monitors their performance and a recent evaluation was undertaken to this effect95. The conclusion of the evaluation was that no safety issues could be identified with the operation of UIs and that they were functioning in line with their intended purpose. However, the evaluation further concluded that UIs would not be made a mandatory aspect of the PED given that the related benefits were not significant enough in view of the administrative reform costs.

If UIs were made mandatory, it would enable users of pressure equipment in all Member States to benefit from their positive impacts. The limited number of Member States that have not yet adopted this feature may wish to consider the results of the evaluation and the former review.

**6.12 Organisations Falsely Claiming to be NBs**

Although an issue which is not directly related to the PED, another problematic observation is the identification of organisations falsely claiming to be NBs and offering fake PED conformity assessment and product approval services and certificates. It was mentioned that such operators had committed fraudulent activities both inside and outside Europe and that the scale of this problem was difficult to determine.

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UK officials mentioned that the Department of Business, Innovation and Skills had issued a warning on the matter and requested feedback from stakeholders if potentially falsely operating organisations had been identified\(^{96}\). However, the monitoring of this problem was likely to be less active in third countries.

Clearly, this horizontal issue is a key threat to the successful functioning of New Approach framework, it raises safety issues for the users of non-conforming pressure equipment and distorts fair competition between NBs. National authorities may wish to develop procedures to identify and restrict the operation of such organisations. The results could be shared in the ADCO group and if possible communicated on the ICSMS system.

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**Main Findings and Conclusions**

- To a significant extent, one of the core objectives of the Directive, the removal of barriers to trade and improving the effectiveness of the Internal Market, has been realised. Compared with the previous system of national regulation, the PED has had a positive impact overall on the pressure equipment industry;

- 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;

- The all inclusive scope of the PED and its focus of the removal of hazards according to the products intended use has, according to some stakeholders, caused negative impacts. These include a high level of legal responsibility being placed on manufacturers, the introduction of over-stringent regulation for certain product groups and regulatory creep to potentially unforeseen areas of the market. However, politically feasible and equally effective alternatives to the PED do not appear to be available;

- The classification of pressure equipment according to the fluid that it contains and stored energy is regarded as the most sensible system to adopt. It has added transparency and consistency to the conformity assessment process which has benefited the functioning of the Internal Market.

- The actors that operate under the New Approach framework are sometimes not able to hold each other to account or fulfil their duties to the extent that the objectives of the PED are entirely fulfilled. This raises issue for the safe placing on the market of pressure equipment.

- The management of the conformity assessment process differs markedly between the Member States and between NBs in terms of the type and quality of the applied techniques.

- There appears to be limited oversight of the NB market and a lack of accountability by accreditation bodies in their duty to ensure that a consistently high level of quality services

\(^{96}\) Department for Business, Innovation and Skills (2010) Warning about organisations falsely claiming to be notified bodies.
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are delivered across Europe;

- The extent of, and approach to, market surveillance varies across Europe. There appears to be a lack of strong coordination between all the Member States and officials are sometimes concerned about the response on key issues from their counterparts in other parts of Europe. The lack of resources and finding suitably qualified personnel is problematic given the demands of examining complex pressure equipment. External stakeholders commented that overall the system is underperforming;

- The delocalisation of production to low cost centres presents a number of heightened challenges for the system of market surveillance (in terms of the likelihood of non-conforming products to enter the Internal Market) and the conformity assessment process (in terms of the quality of services delivered by the subsidiaries of European NBs). The framework in place to address the perceived scale of these challenges appears to be insufficient;

- The introduction of the PED has significantly reduced the likelihood that firms will face problems in placing products on the market in a Member State other than where the products were produced. However, a significant minority of firms have commented that some problems remain and are mainly derived from the enforcement of national in-service inspection legislation. The worst of these findings reveal that potentially discriminatory practices for selecting EN and other standards (other than former national standards and codes) are in operation;

- The PED Guidelines have provided clarification in specific areas of implementation of the Directive and are generally accepted and enforced by stakeholders. However, given that they have a non-statutory basis, they may not be applied by all stakeholders. This has led to inconsistent interpretation and implementation of the Directive. It is interesting to note the French government has passed a Decree to legally commit all stakeholders to adhere to the PED Guidelines.

- Guidelines produced by national authorities have been incorrectly understood as the correct interpretation of the Directive and PED Guidelines by a limited number of NBs. This has led to inconsistent interpretation and implementation of the Directive;

- The PED contains a number of product exclusions one of which is for products used in the offshore industry (e.g. oil and energy). These products are currently regulated through national laws by a small number of Member States. However, the environmental and safety risks that the offshore industry faces appear to be increasing including in relation to pressure hazards;

- The concept of assemblies has been said to be poorly defined but others believe that the notion has simply been poorly interpreted by some stakeholders. This has led to inconsistent interpretation and implementation of the Directive;

- Some stakeholders consider that the PED’s definition of pressure accessories has failed to cover this market consistently. As a result, certain items that contain pressure accessories are not entirely conformity assessed to the requirements of the PED;

- A number of national authorities have had difficulties in assessing products according to the
sound engineering practices of the Member State where it was produced;

- A number of stakeholders consider that the specific quantitative requirements that feature in the Directive run counter to the technically innovative potential of EN standards for materials and in some cases should be erased from the Directive. However, some officials consider that they provide safety guarantees for materials that are mainly produced to ‘non-EN standards’ and should be retained;

- The Directive requires manufacturers to provide declarations of conformity only when requested by authorities. As a result, effective on the spot checks of pressure equipment by market surveillance and customs officials are difficult to perform as it sometimes proves difficult to obtain the declaration of conformity in a short time frame;

- The evaluation (and a previous review) found that User Inspectorates are performing as intended and have provided a number of beneficial impacts for the users of pressure equipment. However, currently they are not a mandatory feature of the Directive;

- Unfortunately, some organisations are falsely claiming to be NBs and are providing fake approval certificates to manufacturers. This is clearly a threat to the New Approach framework, to the safety of the users of pressure equipment and distorts fair competition in the NB market;
7. Efficiency

7.1 Introduction

In this Chapter the PED will be assessed against the criterion of efficiency. This aspect of the evaluation framework broadly assesses how efficiently the processes and procedures of a Directive operate, how the Directive is being managed and assesses the impacts of any regulatory burdens on stakeholders. It also examines how efficiently the intended results are being realised in view of the Directives objectives and optimal performance targets.

With this in mind, a range of topics have been assessed including procedures and aspects of the PED that are regarded as particularly efficient or inefficient in terms of the resources mobilised, the extent of the administrative burdens placed on stakeholders, how successful the development of harmonised European standards have been and their take-up by industry, and the extent to which the intended results of the PED have been realised.

7.2 Procedures that Aim to Support the Efficient Functioning and Application of the Directive

There have been a number of comments by stakeholders on the comparative efficiency of certain procedures that support the operation of the PED. They particularly related to the procedures for the European Approval of Materials, Particular Material Appraisal, the PED Guidelines that are produced under Working Party Guidelines and the Safeguard Procedure.

**European Approval of Materials (EAM)**

One of the advantages of the ‘European’ approach to pressure equipment safety is that it is based on scientific principles and is believed to be relatively open to innovation and technological development, especially in relation to the use of new materials. During the formulation of the Directive, it was recognised that a procedure was necessary approve new materials and that this should take account of the fact that industry may have limited knowledge of new materials entering the marketplace. A procedure outside the normal standardisation processes was seen to be the most relevant and efficient way of dealing with this issue. This is known as the European Approval of Materials and is established by Article 11 of the Directive.

The EAM enables firms to submit new materials to NBs referred to in Art. 12 of the PED. The EAM applications are then submitted for approval at EU-level, a process in which there is participation by national stakeholders. If there are no formal objections, the reference to the EAM is published in the OJ and it provides presumption of conformity to the PED. However, there were no specified mechanisms in the Directive for the implementation of the EAM which has led to the development of ‘Guiding Principles’. These are currently under revision in light of recent difficulties.

Generally speaking, many stakeholders don’t have a full understanding of the EAM process and the EAM was deemed by some standardisation specialists to be relatively cumbersome and outmoded.

Comments were made that the EAM mechanism has not proven to be successful. During the initial years of implementation of the PED, there were numerous EAM applications but most of these were objected to formally by one of more Member States and they were never published in the OJ. Consequently, the current list of accepted EAM applications is very limited. In addition, the EAM process was said not to be informed by robust technical expertise, is wasteful of stakeholder time and resources, operates on principles that are contrary to standardisation objectives and the procedure is too onerous for a single NB to deal with.
The standardisation experts maintain that CEN procedures handle similar processes with greater levels of efficiency. An alternative route for the PED has therefore been suggested. CEN procedures could be used to produce a Technical Specification (as opposed to a standard) by a focused range of stakeholders to specify the technical framework for the new material. The aim would be to facilitate the rapid transfer of new research and innovations into the marketplace and to increase their visibility and uptake. After, the technical document would develop into a full standard as further experience with the new material is gained.

If the procedure were to be reviewed in the future, its role in efficiently supporting the approval of new materials should be assessed. If found to be inefficient, the discussions could assess the suitability of replacing the procedure with another process. The discussions would have to take into account the views of stakeholders that may support the EAM procedure in light of the fact that it provides mechanisms for preventing uncertain materials from being approved. However, it will be important to recognise that alternative procedures may have a stronger impact on the development of the pressure equipment sector.

**Particular Material Appraisal (PMA)**

If a material has not been referenced by an EN standard or approved by the EAM procedure, a manufacturer can provide a ‘description of the solutions adopted to meet the ESRs’ within a Particular Material Appraisal (PMA). This will allow the material to be used for the development of pressure equipment. In relation to Category III and IV pressure equipment, a NB is required to assess the PMA. Given that the PMA relates to demonstrating that the material characteristics are suitable for the intended application, it is a crucial element for proving the safety of the equipment. The PED is not specific on the technical information required to develop a satisfactory PMA. However, given the range of pressure equipment regulated under the Directive, it would be very difficult to have a single template document that would cover all types, and often there needs to be room for flexibility when demonstrating how a material meets the ESRs.

However, random checks undertaken by market surveillance authorities have demonstrated that whilst some PMAs conform to the Directive, others vary in their quality and level of detail including when a NB has been directly involved in overseeing the process. For example, sometimes PMAs were not sufficiently detailed to demonstrate compliance of the material with the ESRs. In a small number of cases, the PMA was not available on request and this provides a clear indication of non-compliance.

If manufacturers do not have the complete information related to the performance of the material, they may be tempted to take a creative approach to developing the PMA which may not be legally correct. In addition, the equipment manufacturer may be genuinely ignorant or have a poor understanding of the purpose of the PMA. It may also be the case that the manufacturer recognises that the material does not meet the ESRs and prefers not to demonstrate this within the PMA. There appear, therefore, to be a number of ways in which the procedure can go wrong.

These problems appear to have intensified as a result of the trend towards delocalisation of some production to low cost centres. New entrants to the market and subsidiaries of NBs may not have a full understanding of the expectations placed on them when producing a PMA. This has added additional pressures to the system for market surveillance.
PED Guidelines and other supporting documents\textsuperscript{97} that outline the requirements for PMAs are available to manufacturers and NBs. Currently, the Working Party Materials and Working Party Guidelines are in the process of seeing if the situation can be improved by providing better guidance. It is recommended that guidance of this nature is developed and that the finalised guidance is appropriately communicated to the relevant stakeholders.

**PED Guideline Procedures and Documents**

As already mentioned, through the work of expert groups (Working Group Pressure, Working Party Guidelines), non-statutory PED Guidelines have been developed in order to provide the correct interpretations of specific aspects of the Directive and encourage its consistent enforcement by stakeholders.

However, certain aspects of the process for developing PED Guidelines are considered to be inefficient. The time it takes to resolve issues and issue guidance is sometimes thought to be too long. In some cases, discussion involves issues in the Directive that have already been clarified or where the PED is already clear.

In addition, over 200 PED Guidelines have now been made, which means that the document is lengthy and certain parts of industry have commented that it is not straightforward to use. Concerns have therefore been raised about the document’s ‘questions and answers’ format. In some cases, the quality of certain PED Guidelines has also been questioned.

To improve the efficiency of the procedure, a reform to the process could take place to see if the operation of Working Party Guidelines could be enhanced. One suggestion could be selecting issues for discussion that are known to be of significant importance only in order to limit the proliferation of unnecessary questions. Clarifications that emerge that do not require additional information could be responded to directly without the need for debate and extension of the document. Industry should understand that is their responsibility to interpret and apply the PED Guidelines rather than submitting additional questions particularly in areas where existing guidance is already available. The PED Guidelines themselves could be revised and consolidated into a clearer format. This would enable the key issues addressed by the guidance to be highlighted, strengthened and set out more systematically.

**The Limited Use of the Safeguard Clause**

The safeguard clause can be invoked by market surveillance authorities in order to initiate the removal of non-conforming products from the market. If a market surveillance authority identifies a non-conforming product and non-conformity is confirmed by the EC, the other Member States are informed of the finding and are requested to adopt similar responses to ensure the enforcement of the Directive.

However, the safeguard procedure has been utilised on less than five occasions. This has led to a number of observations from officials that the almost negligible use of the safeguard procedure means that the system is largely disregarded and operates at far from its full potential. It was also noted that the use of the safeguard procedure does not reflect the perceived scale of non-conforming pressure equipment that has been put into circulation on the Internal Market.

Whilst this is not regarded as a valid excuse, authorities have commented that the safeguard procedure is an inefficient process and occasionally they may choose to remove the product from their own national market rather than attempting to support an EU-wide response.

In response to this poor record, the Commission could try to renew efforts through ADCO meetings (see below) to re-establish the effective use of the safeguard clause.

7.3 PED Conformity Assessment and Market Surveillance Meetings

The enforcement of the Directive is further supported through the work and meetings of conformity assessment and market surveillance bodies. However, there have been doubts expressed about their efficiency in supporting the implementation of the Directive.

Conformity Assessment Bodies Forum (CABF)

The Conformity Assessment Bodies Forum (CABF) aims to disseminate best practice between NBs, facilitate discussions and support the process for the development of the PED Guidelines. The CABF therefore plays a critical role in encouraging NBs to implement the Directive consistently.

The two hundred NBs that provide PED conformity assessment services are all invited to attend the meetings. Nevertheless, despite the open invitation, only around forty NBs regularly attend. This can be partially explained by the fact that some countries send only a limited number of representatives and have a national mirror group to share the information.

However, the low number of attendees and the lack of national mirror groups in some Member States was highlighted by those who are active participants. Concerns have been raised given that for some Member States there is not a single NB participating in the meetings. This has led to the observation that the NBs from Member States that do not attend the meetings and don’t have national mirror groups tend not to implement all of the PED Guidelines in full or take on board CABF recommendations and suggested best practices. It was noticeable that a clear knowledge and competency gap had emerged between attendees and non-attendees. This has led to the emergence of an inner core of NBs that are more technically coherent than their counterparts in the wider group.

Furthermore, there were some issues raised with some of the NBs that attend the meetings. In response, whilst the management of the CABF has been regarded as satisfactory, it was noted that the body was missing a strong self-regulation function. Currently, there may be absence of reaching common positions or monitoring the performance of attendees in enforcing the agreed interpretation of the PED and PED Guidelines.

The dissemination of information through the CABF is critical for the consistent implementation of the conformity assessment modules. Given the identified weaknesses in this area, it is recommended that NBs should be obliged to attend either EU or (establish) effective national mirror group meetings. This requirement could be made clear in the relevant accreditation documentation and the extent of attendance could be monitored by the national notifying authorities and accreditation bodies as part of their enhanced role anticipated under the alignment to the NLF. Alternatively, as in some Member States, NBs are obliged to attend the meeting and authorities make their notification conditional to participation.

As part of the evaluation, numerous attempts were made to interview representatives from NBs from certain Member States that do not have any representatives that attend the CABF meetings. However, this was offer was declined.
**Efficiency**

*Market Surveillance Cooperation Group (ADCO)*

The Market Surveillance Cooperation Group (ADCO) provides the opportunity for national authorities to discuss market surveillance issues. The main aim of ADCO is to exchange information and other practices with the intention that this leads to the consistent enforcement of the Directive. The highlighting of national findings during the meetings aims to limit the circulation of non-compliant products on the European market.

The viewpoint of some national authorities was that ADCO is a crucial means for sharing information between authorities. Another official mentioned that over time ADCO has become a stronger forum for discussions with counterparts from other parts of the EU. ADCO was also seen as benefitting from having access to detailed information on the performance of EN standards and knowledge on certain actions for example in the area of fire extinguishers.

Other authorities who perhaps were not as well resourced as their counterparts thought that more resources could be invested at the European level in order to strengthen the operation of the market surveillance system. This would involve the Commission playing a facilitating role in coordinating the strengthening of efforts between Member States.

**7.4 Administrative and Reporting Burdens on Industry**

Administrative and reporting activities are key features of any regulatory regime. However, as expected, the PED’s all inclusive scope and coverage of numerous sectors had resulted in the perception that administrative burdens are unevenly distributed across the sector.

*The Perspective from Industry that have Applied EN Standards*

Certain manufacturing sectors that conduct intra-EU trading activities pointed to a number of advantages under the PED compared to the previous system of national regulation. By using a single set of conformity assessment rules and EN standards that provide presumption of conformity with the ESRs of the Directive, the PED process was perceived as more efficient than the previous system of national regulation. This has resulted in less onerous regulatory requirements and cost savings for this group of manufacturers when the PED is compared with the former national system.

*The Perspective from Industry that Continue to Use Other Standards and Codes*

In addition, some manufacturers of certain pressure accessories (that are designed to other standards and codes) in countries with formerly ‘lighter’ regulatory regimes believed that whilst the PED has created additional paperwork and consumes more time, the process is not that much different from the previous national system and is relatively straightforward to manage.

Other firms thought otherwise. It was suggested that the conformity assessment system encourages non-value added processes, outcomes and costs particularly for firms that have to deal with or manufacture products according to standards other than EN standards. For example, firms that imported products from outside Europe that were not designed according EN standards were said to benefit little from the process particularly for items that they purchase on a frequent basis or at regular intervals. In such cases, it was said that NBs are required to perform repeatedly the same tests on the same products with the same results emerging for the firm. The PED was said to be a system that did not learn from itself’.

However, it should be recognised that regulatory systems in other world regions require that pressure equipment are designed according to their own national legislation. To enter certain third country markets, the national standard must be used and alternatives to that approach are not
provided. Alternatively, under the PED, foreign manufacturers are free to design pressure equipment according to EN standards, if they wish to gain presumption of conformity with the Directive, or other standards and codes that are required to demonstrate that they meet the ESRs. Compared to other international trading regimes, the PED provides relatively open conditions.

Similarly, officials pointed out that the PED provides strong safety measures for guaranteeing the safety of pressure equipment. For this reason, it was not clear why the Directive should be considered as burdensome.

The Perspective from the Sections of Industry that were not previously regulated by Comprehensive Pressure Equipment Regulations

Representatives from other sectors were even more critical of the Directive. This included sectors that previously did not fall under comprehensive pressure equipment regulations but because of the all inclusive scope of the PED were now required to conform to the requirements of the Directive.

For example, contractors in countries such as the Netherlands that install and maintain heat pumps, refrigeration and air conditioning equipment have experienced serious difficulties in implementing the Directive in full. This is compounded by the fact that they are often SMEs and consequently find the requirements rather costly and difficult to manage. Moreover, as well as finding aspects of the PED inapplicable, for example in relation to the control of vessels and valves, the requirement that every new installation should be assessed by NBs has been found to be onerous.

Industry associations have supplied training to the sector in order to improve SMEs’ skills in calculations and methods to categorise pressure equipment amongst other things. However, despite these efforts, the sector is demanding separate regulation outside the framework of the PED that would take into account the specific needs of their industry.

However, pressure equipment stakeholders may consider that by providing separate regulation for one sector may lead to similar demands from elsewhere and result in a less coherent and efficient framework for regulating pressure equipment.

PED Business Survey

The PED business survey indicates the mixed views of respondents on the regulatory impact of the PED.

Table 7.1: To what extent does the PED incur administrative burdens and costs for businesses?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very high</td>
<td>3</td>
<td>3.1</td>
</tr>
<tr>
<td>High</td>
<td>32</td>
<td>33.3</td>
</tr>
<tr>
<td>Neutral</td>
<td>32</td>
<td>33.3</td>
</tr>
<tr>
<td>Low</td>
<td>20</td>
<td>20.8</td>
</tr>
<tr>
<td>Very low</td>
<td>3</td>
<td>3.1</td>
</tr>
<tr>
<td>Don’t know/no response</td>
<td>6</td>
<td>6.3</td>
</tr>
<tr>
<td>Total</td>
<td>96</td>
<td>100.0</td>
</tr>
</tbody>
</table>

99 The specific viewpoint on the PED of this sector is indicated in detail in the PED Installation Industry Survey (Annex 5).
Whilst the majority believe that the PED creates a neutral, low or very low burden, over one third consider that the PED is highly or very highly burdensome for their industry. If the PED is reviewed in the future it may be useful to examine the extent of its perceived regulatory burdens but it appears that to date the majority of industry can successfully manage the process.

7.5 The Development and Uptake of EN Standards

This section will set out the instrumental role that CEN has played in developing EN standards. It will then consider how efficiently they have been issued and the extent of the contribution made by Member States and other bodies in encouraging their dissemination. The extent of the uptake of EN Standards by industry will then be considered along with stakeholder perceptions of their relative performance.

The Role of CEN in the Development of EN Standards

The development of EN standards through CEN has been an instrumental objective of the PED. Over the years, the European standardisation body, CEN has produced a significant number of standards and related documents relating to a vast range of product groups with the aim of providing presumption of conformity with the Directive.

However, this has been a challenging process as far as the PED is concerned. During the initial stages, there were doubts from some quarters that the procedure would actually function in practice given the different engineering traditions and outlooks across Europe. As a result, a significant investment of time and resources was required in order to build relationships between national experts, develop processes and reach agreements on technical content.

Despite these challenges, a robust ‘standards toolbox’ has emerged that broadly covers a particularly complex and varied sector. In addition, in certain quarters, EN standards are regarded as providing economic and technically innovative advantages that means that they compare well with other standards and codes. The most significant standards are also supported by efficiently managed help desks that operate in cooperation with CEN. These outcomes can be seen as key achievements for the sector.

Nonetheless, these accomplishments have not been without their problems. The development of EN standards has been a lengthy and occasionally inefficient process. During the initial introduction of the PED, a large number of EN standards were still in the developmental phase. Some were issued during the initial stages but later had to be revised in order to cover the product group that they related to with an appropriate level of quality and detail (an example is the coverage of specific materials). Further work is still required to enhance the existing EN standards and to develop new ones, but it was suggested that the Technical Committees (TCs) have not been highly efficient at tackling these issues (these outcomes may partly explain why EN standards have not been taken up by industry to the extent that may have been anticipated which is explored in more detail below).

The main reason provided to explain why CEN processes are not as efficient as they could be was that much of the work is undertaken by volunteers, with no financial support now that the basic standards have been developed (funds from the EU’s Framework Programme were invested in research activities at one stage but have now ended). As a result there are often poor levels of attendance in the Technical Committees, particularly from some parts of industry and to a much greater extent from NBs and public authorities. In addition, experts in the field who could potentially contribute to the process may be tempted to support the national standardisation processes where attractive daily fee rates are provided. This should be perceived as a key risk for the future of the EN standardisation process.
It’s apparent that CEN faces resources constraints that impact on the efficient development of relevant standards. There is a case for encouraging greater support from a broader range of national bodies, NBs and other stakeholders, since this would increase attendance and the speed and quality with which EN standards are produced. Efforts should also be made to improve the existing standards in circulation. It is noted that the EC has recently allocated a limited budget (roughly €0.2m) for public awareness activities related to EN standards but this could be extended in the future.

**Results of the CEN Survey on the Uptake of EN Standards by Industry**

Despite the number of EN standards produced and their perceived relative economic and technical advantages, their uptake by European industry has so far only been partial. Whilst for certain products within certain countries there has been a relatively positive uptake, for example the boiler market within Germany and the piping industry within France, there remains large and significant segments of the pressure equipment sector that have not efficiently adopted EN standards (such as the vessels sector).

This finding was recently illustrated in a survey by CEN relating to the uptake of EN standards. The answers were provided largely by manufacturers of pipes and vessels and for these respondents found that the use of EN standards over the past two years is either stable (in relation to vessels) or very gradually growing (in relation to piping). However, the response to the survey was relatively limited (57 in total) and therefore the results are not conclusive\(^ {100}\). Perhaps one could conclude that the use of EN standards is established in certain areas, is at least stable and may be increasing slowly.

**The Efficiency of Member States and Other Actors in Developing Framework Conditions for the Uptake of Standards**

A key issue in explaining why EN standards have not been taken up to the extent that might have been envisaged relates to the performance of Member States in providing the framework conditions to support the process.

Despite the fact that EN standards were intended to legally replace former national standards, a number of Member State standardisation bodies have continued the process of supporting their own national standards and codes. In some countries, standardisation bodies have continued to publish their existing standards but under a different technical format. In addition, European private bodies have not been obliged under the PED to cease the sale of the codes that they issue. This has meant that firms have continued to have access to the former national standards and codes that they were already familiar with and their subsequent updates.

To a certain extent, the continuing issuing of former national standards and codes reflects some of the initial shortcomings in the introduction of EN standards. Because EU standards were not widely available when the Directive came into force, some of the momentum generated by its introduction was lost. Although this has been subsequently partially addressed by CEN, there were and continue to be gaps in terms of the technical issues that EN standards cover. In many instances, the former national standards and codes address these gaps. The national standardisation bodies considered that because of the perceived shortcomings (and potentially risks) with EN standards their own role in supporting national industry should be maintained.

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\(^ {100}\) CEN (2011) Survey on the Use of Standards in the Pressure Equipment Sector
Moreover, given that national firms were not immediately familiar with the EN documentation, national standardisation bodies did not appreciate that additional burdens may be imposed on industry through adjustment costs. They also did not wish to erase national practices that had been regarded by key figures as functioning perfectly well.

Furthermore, a number of Member State authorities and related national organisation such as NBs that represent a significant proportion of the industry may be regarded as only being moderately supportive of the introduction of EN standards. As a result, they have not helped to drive their uptake to the extent that supporters of EN standards would wish. The concerns and issues mentioned above may contribute to an explanation for this approach.

To encourage a faster and improved uptake of EN Standards, some Member States could have moved away from the former national standards in recent years (particularly given that some of the most important EN standards have been improved and reissued). In addition, given that standardisation processes continue to operate in a number of Member States, expertise and resources have been fragmented to the detriment of developing EN standards.

However, Member States, especially those that did not have strong pressure equipment standardisation traditions, have responded to the perceived technical and economic advantages of EN standards and promoted their use. They have created strong framework conditions for their wide-spread uptake by their own national industry. One such example is Finland and the initiatives adopted to promote the vessels standard EN 13445:

<table>
<thead>
<tr>
<th>The Successful Introduction of EN 13445 to Finland</th>
</tr>
</thead>
<tbody>
<tr>
<td>The successful introduction of EN 13445 to Finland has been attributable to a number of key decisions by leading bodies including:</td>
</tr>
<tr>
<td>• Recognition of the importance of having presumption of conformity with the ESRs;</td>
</tr>
<tr>
<td>• A strong interest in applying innovative techniques;</td>
</tr>
<tr>
<td>• The Finnish standardisation body SFS ceased the publication of former national standards and concentrated on EN standards;</td>
</tr>
<tr>
<td>• The Finnish authority for pressure equipment ‘Tukes’ recommends the use of EN standards;</td>
</tr>
<tr>
<td>• Leading Finnish NBs actively support the use of EN standards;</td>
</tr>
<tr>
<td>• This has encouraged leading Finnish vessel manufacturers such as Rautaruukki Halikko Works to adopt EN 13445.</td>
</tr>
</tbody>
</table>

Given the widespread uptake of EN standards in Finland, it appears that a combination of Member State framework conditions and willingness to promote EN standards are required if their widespread uptake by industry is to be encouraged. The coherence of this approach and its results illustrate what can be achieved and deserve to be replicated across the Member States. Efforts could be also made to engage with national standardisation bodies to learn if EN standards have reached the stage where they sufficiently cover the manufacturing processes of national industry. Member State standardisation bodies also need to be reminded of their legal obligation to cease publishing former national standards. The use of EN standards within public procurement documents could be promoted.

**The Evaluation Findings on the Uptake of EN Standards by Industry**

Efficiency

Clearly industry has played a key role in determining the extent of the uptake of EN standards. In certain areas of the market, there appears to be a broad uptake of some of the standards. The boilers sector in Germany has already been indicated. The positive case for using EN standards in certain areas of the market appears to have been accepted. But in others, such as the vessels sector, the rate of uptake continues to be sluggish. This uneven picture across a number of different sectors was confirmed in the PED business survey:

Table 7.2: What proportion of the pressure equipment that you produce / use has been manufactured according to EN standards?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20%</td>
<td>29</td>
<td>30.2</td>
</tr>
<tr>
<td>21-40%</td>
<td>12</td>
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<td>33.3</td>
</tr>
<tr>
<td>No response</td>
<td>1</td>
<td>1.0</td>
</tr>
<tr>
<td>Total</td>
<td>96</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Source: PED Business Survey (Annex 3)

However, whilst the survey results indicate that parts of the industry may not be receptive of EN standards, there are very initial signs that this may be changing. For example, in the Netherlands, over the last 5 years, the use of EN 13480 for the piping sector has reached 50% of the market and although not yet as pronounced the use of EN 13445 is also growing. Young engineers were also said to be more familiar with and open to EN standards and in the future will more naturally make use of them and increase their uptake. In addition, there are initial signs that major users of pressure equipment will adopt EN 13445 for use in their future business models.

Implementation of EN 13445 at BASF

A presentation recently delivered by BASF (a major user of pressure equipment) underscored their emerging recognition of EN 13445. At the point of the standard’s introduction, BASF did not consider EN 13445 to be a credible alternative to former national codes. This was because of its late completion, an ongoing need for debate in certain areas and the expectation that extra expenditure would be incurred as a result of a general lack of experience of working with the standard. In addition, former national codes were recognised as having well-rounded manufacturing and operation concepts, well-established routines for manufacturers, users, NBs and authorities, and consequently facilitated the successful marketing of products.

However, BASF now recognise EN 13445 as user friendly after it is has been presented recently in a consolidated version that has been technically and editorially revised. From the perspective of BASF, the advantages of using EN 13445 include:

- Development of cost-effective solutions achieved across its European-wide application;
- Presumption of conformity with the ESRs;

BASF (2011) EN 13445: Potential Benefits for Plant Users?
Evaluation of the Pressure Equipment Directive

Section

Efficiency

- A coherent code process for process equipment construction and plant engineering;
- Easy assembly of pressure equipment into existing infrastructures;
- Strengthened export potential for manufacturers.

As a result of their increasing recognition of EN standards, since July 2011, BASF have made their technical inquiries to manufacturers on the basis that either AD 2000 or EN 13445 could be used. However, going forward, although there will be an appropriate transition phase, it is intended that technical enquiries will eventually be conducted exclusively on the basis of EN 13445. The future vision for BASF procurement requirements in the medium term is that EN 13455 will completely replace AD 2000 (DE), BS PD 5500 (UK) and Codap 2005 (FR).

Explanations for the Slow Uptake of EN standards by Industry

A basic reason for the slow up-take in some areas is that, although EN standards enable presumption of conformity with the ESRs, their application is not mandatory as long as manufacturers provide the appropriate evidence and pass the necessary tests to demonstrate that their design solutions and equipment are compliant with the ESRs. This, of course, is the case with similar New Approach Directives.

A barrier that SMEs tend to face is that EN standards are not available in every EU language. Given their technical nature, EN standards are therefore difficult to adopt. Solving this problem would require an investment in the translation of a small number of key and high quality EN standards, but it is not clear how these funds could be provided. Another barrier is that to understand a single EN standard it may be required to understand other complementing standards but currently they are not sold in appropriate bundles. In addition, the standards are not hyperlinked which makes them difficult to navigate.

It should be recognised there are other very important factors that have prevented the uptake of EN standards inside and outside the EU. Other world regions have their own national engineering traditions and there is often not a particularly strong business case for adapting manufacturing processes to the PED to specifically cater for the European market, especially since using EN standards are not a legal requirement. Furthermore, the world market is dominated by longstanding ASME VIII and other codes and to ensure efficient geographical coverage, firms market their products based on the most commonly known and accepted standards.

A key issue when considering this aspect is the role of the user. Users have been accustomed to installing pressure equipment designed to particular methodologies for decades and have been assured of their functionality. Transition to a new set of standards may not appear immediately sensible and manufacturers have accordingly followed the expectations of their clients. Some of these are adopting European standards, as is illustrated by the case cited above, but the US industry has a strong global reach and will continue to use the ASEM VIII code, so the user’s requirements are likely to be differentiated regionally. Overall, the issue of poor uptake is as much a demand side as a supply side problem.

Industry’s Perception of the Costs of Adopting EN Standards

EN standards have been designed to offer a particular engineering approach. Rather than adopting high safety factors that imply thick vessel walls, EN standards have aimed to reduce safety factors and produce equipment that is precision engineered according to its intended use. Consequently, pressure equipment built to EN standards have thinner material walls, can make use of advanced materials, and according to research on the matter are comparatively cost and resource efficient.
However, whilst segments of the market are convinced of the commercial benefits of this approach others are far from persuaded. Additional costs that are linked to the use of standards also need to be taken into account by manufacturers and users.

For example, EN standards incur greater costs in design and testing. In order to prove that they are fit for purpose, EN designed products require rigorous assessment, since the prescribed safety factors are not offered in the standards. High-end engineering skills and greater expenditure on design and testing are therefore demanded. Firms that wish to use EN standards therefore need to invest in the overhaul of their existing systems and processes. Certain parts of industry consider that these factors off-set any cost advantages gained as a result of increased resource efficiencies.

Secondly, integration of EN designed equipment into existing installations can present additional costs for users over the life-cycle of the assembly. Installations built to other standards are linked to their own maintenance codes and combining equipment that is designed to different design philosophies adds to the maintenance complexities. The overall cost impact needs to be considered by users for major assemblies as well as the initial purchase price of equipment. Given that many existing complex assemblies are designed to other standards, the business case for using EN standards in the minds of some users is not established.

Consequently, the perceived commercial benefits of EN standards are far from accepted by broad segments of the sector. The survey conducted for the evaluation asked if businesses thought that the use of EN standards resulted in comparatively cost effective equipment. Although it should be acknowledged that the sample was small considering the size of the market, over a half of respondents thought that this was not the case and over a quarter did not know.

Table 7.3 Do you consider that using EN standards for designing pressure equipment leads to overall lower production costs in comparison to other standards?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>19</td>
<td>19.8</td>
</tr>
<tr>
<td>No</td>
<td>51</td>
<td>53.1</td>
</tr>
<tr>
<td>Don’t know/no response</td>
<td>26</td>
<td>27.1</td>
</tr>
<tr>
<td>Total</td>
<td>96</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Source: PED Business Survey (Annex 3)

The uptake of EN standards in certain areas of the market may therefore be limited by the perception that EN standards are not more cost effective than other alternative standards. This is despite the fact that EU funded research\(^{103}\) has suggested otherwise. It is likely that the transition costs to EN standards and the existence of current complex installations based on other standards has influenced this outcome.

\(^{103}\) TUV Austria & CEC Italy. (2004) Comparative Study on Pressure Equipment Standards
the EAM process are currently under revision.

**Efficiency**

- Despite the availability of PED Guidelines and supporting documents, checks undertaken by market surveillance authorities have revealed that a proportion of Particular Material Appraisals (PMA) fail to demonstrate material characteristics in line with the ESRs.

- Some parts of industry believe that the ‘questions and answers’ format of PED Guidelines is not as user-friendly as it might be, given that there are now 200 questions addressed.

- The safeguard clause (that provides market surveillance authorities with the means to take action against non-conforming product, 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 perceived volume of non-conforming products on the market.

- The Conformity Assessment Bodies Forum (CABF) plays a critical role in encouraging NBs to provide consistent implementation of the Directive. However, only a small proportion of the PED NBs attend the meetings. This has led to the emergence of an inner core that is technically more coherent and knowledgeable than their counterparts. In addition, the management of the CABF lacks a strong self-regulation approach in terms of the oversight of the NBs to meet their regulatory obligations.

- The regulatory impact on industry is predictably uneven given the all inclusive scope and broad product group coverage of the Directive. Firms that develop products according to EN standards and receive presumption of conformity with the PED have experienced reductions in regulatory burdens. A proportion of other firms that do not design equipment according to EN standards believe that the administrative requirements of the PED are relatively satisfactory to manage. However, other firms believe that PED is burdensome. This includes firms that do not design equipment according to EN standards and sectors that were not previously regulated by comprehensive pressure equipment requirements. Despite these findings, officials believe that the regulation provides a sufficient framework for guaranteeing that pressure equipment is built according to high safety standards.

- CEN has played a key role in developing a significant number of EN standards that provide economic and technical advantages when compared with other standards and codes. A significant amount of time and resources has been invested in the standardisation process in order to achieve this outcome. This should be perceived as a key achievement for the Directive.

- However, some stakeholders believe that the standardisation process has been inefficient. For example, during the initial introduction of the PED, a large number of EN standards were still in the developmental phase. Some were issued during the initial stages but later had to be revised in order to cover the product group that they related to with an appropriate level of quality and detail.

- The inefficiencies in the standardisation process can be explained by the fact that much of the work is undertaken by volunteers and that the process lacks sufficient support from a broad range of stakeholders.

- Despite the number of EN standards produced and their perceived relative economic and technical advantages, their uptake by European industry has so far been only partial. Whilst for certain products and in certain countries there has been a relatively positive uptake,
Efficiency

there remain large and significant segments of the pressure equipment sector that have not adopted EN standards.

- A key issue in explaining why EN standards have not been taken up to the extent that might have been envisaged relates to the performance of Member States in providing the framework conditions to support the process. Whereas some Member States have been proactive in supporting the uptake of EN standards, others have continued to support former national standards.

- One of the reasons for the uneven uptake of EN standards is the mixed perception of industry regarding the extent of their beneficial impacts (such as the reduction in material costs). Whilst segments of the market are convinced of the commercial benefits others are far from persuaded.
8. Utility, Sustainability and European Value Added

8.1 Introduction
The final set of criteria against which to evaluate the Directive are utility, sustainability and European value added. Collectively, these aim to determine the extent to which a Directive has really responded to the initial needs and problems of the target beneficiaries and European citizens, the extent to which positive changes attributable to the Directive may be expected to continue to have their effect and whether EU level interventions have brought benefits over and above those that would have occurred through Member States acting on their own.

This section is based on the analysis of areas where identifiable benefits are being delivered to the sector for both manufacturers and users, whether the changes brought about by the Directive will continue to have an effect, what measures might be introduced to sustain the competitiveness of industry and whether the Directive has provided any European value added.

8.2 Utility of the Directive
This section will explore the utility of the Directive and the types of benefits that have resulted for manufacturers and users.

The Regulatory Format, Approach and Objectives of the Directive
It’s clear that the regulatory format, approach and objectives of the Directive have been formulated on the basis of a good understanding of the initial needs and problems of the target beneficiaries. The trade barriers that manufacturers faced prior to the introduction of the PED required an all encompassing framework in order facilitate the free movement of pressure equipment across the EU. At the same time, the Directive has provided stringent ESRs with a view to maintaining high safety standards and in some areas improving the manufacture and installation of pressure equipment.

Central to this has been the requirement that pressure equipment must be designed and manufactured according to its intended use. This has placed a great deal of responsibility on manufacturers to ensure that their manufactured items correspond to the needs of the use phase of the product in line with established safety expectations. The classification of pressure equipment (according to fluid that it contains and the stored energy) has supported this process to a significant extent given its clear framework for determining the risks that the pressure equipment poses and the subsequent route to conformity assessment. By following these procedures, NBs and national authorities have been provided with a common methodology for determining the placing on the market of pressure equipment.

In addition, the approach of the Directive has left the technical requirements for meeting the ESRs to be established by standards, in recognition of the existing Member States engineering and standardisation traditions. CEN has played a key role in developing standards with economic and technically innovative advantages to meet the ESRs and provide presumption of conformity with the Directive.

The objectives, regulatory format and approach of the Directive have to a significant extent led to harmonisation of the Internal Market for pressure equipment. A number of sources confirmed that national authorities and NBs located across the EU perform their anticipated functions satisfactorily within the same regulatory framework. Manufacturers understand that national markets can be entered by following the same requirements and conformity assessment processes for each. The ultimate impact is the facilitation of increasingly effective and efficient trade flows between Member
States. The findings of the quantitative analysis suggest that the PED has contributed to the improved performance of the Internal Market.

**The Identifiable Benefits for Manufacturers**

The benefits that had been derived from the introduction of the PED were made clear by manufacturers given their experience of conducting business under the prior system of national regulation. As opposed to the former conditions, in today's market pressure equipment can be conformity assessed according to a single set of requirements and uniformly marketed across all Member States. Similarly, manufacturers that are based outside Europe can target the EU as a whole rather than adopting a country by country strategy. The scale and scope of the market has been enhanced for pressure equipment designed according to the PED.

CEN has played a key role in advancing standards that provide economic and technically innovative advantages. Manufacturers that had adopted EN standards commented on the beneficial effects, arising from the presumption of conformity and cost savings for materials. However, it can be seen from responses to the PED business survey that the wider market has the opinion that EN standards are not better in terms of cost advantages when compared with other standards. This feedback included responses from firms that see the transition to EN standards as costly (given that higher engineering standards are demanded for their application) and the fact that existing user installations are composed of items of pressure equipment that are designed to other standards and codes (users need to consider lifecycle maintenance costs and not simply the initial price of the equipment). We may conclude from the differing opinions that those who see cost advantages in adopting EN standards have largely done so, whereas those who have not adopted EN standards see technical and cost obstacles to their adoption.

**The Identifiable Benefits for Users**

With regard to the users of pressure equipment, there is less awareness of the differences between the current and the previous systems and it is less easy to identify benefits. It may be the case that large users benefit from efficiencies realised from having the same conformity assessment procedures across their installations in Europe but this point was not mentioned during the course of the interviews. However, a recent presentation by BASF referred to previously, noted that the presumption of conformity with products designed according to EN standards does bring benefits and in order to take advantage of these benefits, the company would specify the use of EN standards in future procurement documentation.

This evaluation and previous research\(^{104}\) have revealed that users that have established User Inspectorates have benefited from this innovative legislative feature. For those Member States that have taken advantage of this optional feature of the Directive, rather than relying upon NBs to conformity assess the installation of complex assemblies, users can establish specific units that are internal to the firm in order to undertake this function. The results of both sets of research indicate that UIs are performing as intended and have provided users with greater flexibility and also have helped users accumulate specific knowledge and expertise. One User Inspectorate mentioned that given the experience they have gained in this area, it would be difficult to see how a NB could perform the same role to the same level of quality.

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NBs had noted that competition was intensifying in the EU as a result of the PED. This was reflected in the increased number of firms bidding for contracts in a Member State other than where they were located. In addition, users are demanding the construction of increasingly complex pressure equipment. For example, it was mentioned that approximately €10,000m has been invested in power plant development in the Netherlands. Users are therefore benefiting from the experience and expertise of firms that are based in different parts of Europe and from the mobilisation of a wider range of resources. It may be difficult to see how such projects could be realised by national companies alone.

8.3 Sustainability

This section will assess the sustainability of the Directive in terms of the lasting changes it has brought about and perceived risks that may affect its future performance.

Lasting Changes in the Operation of the Internal Market

The PED has encouraged the introduction of a European-wide approach to the regulation of pressure equipment. This has led to fundamental changes taking place in the operation of the Internal Market. National authorities have recognised the PED’s requirements for enabling the free movement of pressure equipment that are designed to the necessary standards. The former monopolistic position of national conformity assessment bodies has been replaced by a market for conformity assessment services delivered by NBs. Manufacturers are in a stronger position to develop pressure equipment according to a recognised format with the assistance of third party bodies and develop their intra-EU trading activities. In short, the interaction between firms, authorities and NBs in different Member States has taken on a different form since the introduction of the PED.

Along with this, the capacity within specific organisations and firms on how to meet the requirements of the PED is strengthening. It was noted that in 2003 NBs in some countries were continuing to draw upon national processes when conformity assessing pressure equipment but this appears to be unthinkable in today’s market. Firms in parts of Europe that were not previously required to meet comprehensive pressure equipment requirements now employ in-house conformity assessment specialists. This has made their quality management systems more efficient and effective. Over the last decade, training services have been provided to NBs and firms across Europe on how to apply and meet the requirements of the PED. An increasing number of specialists are gaining knowledge and expertise in an area of regulation that applies to all Member States.

For some stakeholders, these two points provided confirmation that the PED was a stable and sustainable piece of regulation and it was difficult to see how the current situation would be reversed.

Risks to the Sustainability of the Directive

However, the PED suffers from uneven enforcement across Europe. This includes NBs that have different interpretations of the Directive, different levels of capacity for implementing the large range of testing requirements and different approaches to applying the conformity assessment modules. In some Member States, the market for conformity assessment is particularly extensive and intense and this appears to have encouraged inappropriate behaviour from some third party organisations that may not strictly follow the rules. Elsewhere, some Member States have provided restrictions to limit the size of the market for conformity assessment services.
The approach that manufacturers take to applying the rules also appears to vary. Non-conforming pressure equipment appears to be circulating on the market along with materials that do not correspond with their material certificates and Particular Material Appraisals. The system for market surveillance is not operating in a coordinated fashion with a view to removing non-conforming products from the market on a European-wide basis. National in-service regimes may have requirements that introduce a bias towards the selection of former national standards and infringe upon the New Approach philosophy. This is discouraging for manufacturers that have invested in conformity assessment processes that meet the requirements of the PED.

These problems appear to have intensified as a result of the delocalisation of production of some pressure equipment to low cost centres. Firms that are new entrants to the market have a steep learning curve to climb before they can comprehensively apply the Directive. However, the enforcement of the Directive outside Europe is difficult to achieve given that there are different traditions to complying with regulatory requirements and that the risks from non-compliance do not appear to be recognised.

The failures in market surveillance risk undermining the credibility of the PED and the EU’s reputation for fair competition. For the ongoing sustainability of the Directive there has to be stronger and more consistent enforcement of the rules with the aim of ensuring that the same conformity assessment standards are applied to the same products. As mentioned in the effectiveness section, the alignment of the PED to the New Legislative Framework is a fundamental step in this process. Procedures should be tightened for accreditation processes for NBs and their subsequent monitoring by accreditation bodies. This should be complemented by the suspension or withdrawal of accreditation certificates when necessary. Compulsory participation by NBs in the Conformity Assessment Bodies Forum (CABF) should improve the sharing of knowledge between NBs and expand the number of NBs that have a comprehensive understanding of the Directive and associated best practice. The system for market surveillance is key to the overall coordination framework and requires strengthening, together with the increased use of the safeguard procedure for the removal of non-conforming products from the market. It has been noted that there has been a limited number of legal proceedings on the basis of the PED against organisations undertaking dishonest or illegitimate behaviour. Given the documented failings of manufacturers and NBs in terms of meeting the PED in previous research, efforts should be made to enforce the rules of the Directive in full along with the allocation of severer penalties for serious failings.

**Strengthening of the Standardisation Procedure**

Standardisation has a key role in improving the sustainability of the Directive. NBs have mentioned that the widespread use of EN standards within complex industrial installations will reduce the cost of manufacturing pressure equipment and improve the efficient use of materials. The engineering skill-sets within firms will also be strengthened. The existing practice of using multiple standards for similar products that need to demonstrate that they meet the ESRs will be simplified if EN standards are used uniformly. However, to achieve this, significant efforts need to be made to encourage users to select EN standards. In this the Commission could play a role. Member States need to be encouraged to move away from national standardisations processes and contribute to the widespread introduction of EN standards through the development of appropriate framework conditions. Tailored public procurement requirements could contribute to this process.

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Vinçotte (2009) Safety Surveillance Approach During the Installation
ASME, one of the leading and better resourced standardisation bodies, have recognised that future markets will require technologically advanced standards to meet their needs. It has recently released a standard that academics and CEN standardisation consultants have confirmed is similar to the technically innovative approach developed by CEN for the EN standards. This provides a good indication of the quality and relevance of EN standards. However, it also confirms that wider support could be accessed from NBs, national bodies and other stakeholders in order to ensure that CEN remains at the forefront of this area.

Furthermore, it has been noted that the steps have been taken to encourage global harmonisation efforts through the development of EN ISO standards. To ensure the broader dissemination of EN standards, this approach could be strengthened given that ISO is a voluntary body and does not have a commercial focus.

8.4 European Value Added

Before the introduction of the PED, the Internal Market was suffering from the implementation of national requirements that impinged upon the free movement of goods. Pressure equipment was manufactured according to national standards in line with needs of national and monopolistic bodies. Manufacturers had limited powers to question the decisions of the authorities that governed national markets that were seen to support businesses from their own countries.

The European Value Added in terms of the justification for initial formulation of the Directive was clear. To improve the functioning of the Internal Market, a harmonised legislative framework would have the greatest impact. Given the results of the evaluation, it appears that the European Value Added of the Directive has been realised. Stakeholders recognised that the Directive has played its role in moving the pressure equipment sector towards a level playing field. This could not have been achieved through Member States acting alone or bilaterally.

Key actors in the market have aligned their practices towards conforming to a single set of regulatory requirements. The performance of the Internal Market has been strengthened as a result and has created a wider range of opportunities for economic operators located within and outside Europe. Ongoing initiatives are therefore justified in terms encouraging stronger enforcement of the rules in order to ensure that the safety requirements of the Directive are met and to facilitate the wider dissemination of EN standards with a view to shifting engineering practices towards a more technically innovative and resource efficient model.

Utility, Sustainability and European Added Value

Main Findings and Conclusions

Utility

- The regulatory objectives, format and approach of the Directive have been formulated with a strong understanding of the initial needs and problems of the target beneficiaries. To a significant extent this has led to the harmonisation of the Internal Market for pressure equipment.

- In addition, CEN has played a key role in advancing standards that provide economic and technically innovate advantages for industry. Their uptake will play a role in strengthening the skill-sets within engineering firms

- Users are benefitting from the development of experience and expertise of firms that are
based in different parts of Europe and the mobilisation of a wider range of resources. In certain Member States, it may be difficult to see how highly complex projects could be realised by national companies alone.

**Sustainability**

- The PED has encouraged the introduction of a European-wide approach to the regulation of pressure equipment. This has led to fundamental changes taking place in the operation of the Internal Market. The interaction between firms, authorities and NBs in different Member States has taken on a different form since the introduction of the PED. Along with this, the capacity within specific organisations and firms on how to meet the requirements of the PED is strengthening.

- However, the PED suffers from uneven enforcement across Europe. This includes NBs that have different interpretations of the Directive, different levels of capacity for implementing the large range of testing requirements and different approaches to applying the conformity assessment modules.

- The system for market surveillance is not operating in a coordinated fashion with a view to removing non-conforming products from the market on a European-wide basis.

- This is discouraging for manufacturers that have invested in conformity assessment processes that meet the requirements of the PED and threatens the sustainability of the PED.

- The ongoing sustainability of the Directive hinges upon stronger and consistent enforcement of the rules in order to encourage fair competition and the application of the same conformity assessment rules to the same products. As mentioned in the effectiveness section, the alignment of the PED to the New Legislative Framework is a fundamental step in this process.

- Standardisation has a key role in improving the sustainability of the Directive. NBs have mentioned that the widespread use of EN standards within complex industrial installations will reduce the cost for manufacturing pressure equipment and improve the efficient use of materials. Encouraging greater participation from stakeholders in CEN technical committees and the development of ISO EN standards will add value to the standardisation process.

**European Value Added**

- The European Value Added of the initial formulation of the Directive is clear. To improve the functioning of the Internal Market, a harmonised legislative framework would have the greatest impact. The evaluation confirms that a European Value Added has been realised from the Directive. Stakeholders recognise that the Directive has played its role in moving the pressure equipment sector towards a level playing field. This could not have been achieved through Member States acting alone or bilaterally.
9. Main Findings, Conclusions and Recommendations

9.1 Introduction

This section provides the evaluation’s main findings, conclusions and recommendations. These summarise the key issues that have been examined in the previous sections. However, unlike the main body of the report, rather than exploring the key issues under separate evaluation thematic areas - i.e. relevance, effectiveness, efficiency, utility, sustainability and European Value Added - the structure of this section is set out so that the main points are dealt with consecutively with the analysis drawing upon one or more thematic areas.

In addition, given that the section reflects on the main findings presented so far, in some areas an additional tier of analysis than what has been already presented has been included. This helps to reinforce the reasoning behind the proposed recommendations which seek to strengthen the enforcement of the PED.

Before these points are examined, the evaluators would like to point out that the PED appears to be a relatively successful Directive. To a significant extent, the Directive has accomplished its core objectives and provides a much more relevant regulatory framework for the functioning of the Internal Market than the previous system of national regulation. The main weaknesses of the PED relate to shortcomings in the New Approach framework that supports the operation of the Directive. The Commission’s strategy to align the Directive with the New Legislative Framework (NLF) is therefore welcomed given its objective of addressing the current deficiencies in the New Approach. Other supporting measures are proposed and should also be considered.

9.2 The Accomplishment of the PED’s Core Objectives

National legislation on equipment under pressure has a relatively long history going back to the 19th century. Prior to the introduction of the PED, national legislation had the role of determining the conditions under which pressure equipment could be placed on the market. This meant that firms trading across the EU had to comply with multiple regulatory regimes in order to satisfy the safety requirements of the national authorities. Research on the market noted that these activities represented a barrier to the successful functioning of the Internal Market which could only be successfully removed through an EU-level intervention.

With these obstacles in mind, the PED was designed with two key objectives. The first was to enhance the competitiveness of European industry by ensuring the free movement of stationary pressure equipment within the Internal Market. At the same time, the PED aimed to maintain the high levels of safety that Europe was already accustomed to by establishing a number of Essential Safety Requirements (ESRs) for the design and manufacturing of pressure equipment.

After 10 years of implementation, the evaluation has had the opportunity to determine the impact of the PED on the pressure equipment sector. The stakeholders interviewed - national authorities, industry associations, industry, Notified Bodies (NBs), User Inspectorates, standardisation experts and academics - generally recognised that the PED has been highly relevant for the improved functioning of the Internal Market. The introduction of the PED has led to a greatly improved and much more consistent regulatory framework for facilitating the free movement of pressure equipment.

The relevance of the PED to the Internal Market has strengthened its effective and efficient functioning. The introduction of the PED has opened up intra-EU trading opportunities since
Main Findings, Conclusions and Recommendations

Manufacturers have an improved understanding of the rules they need to follow to access other national markets. National authorities on the whole follow the regulatory framework established by the PED and to a much lower extent draw upon national requirements. Notified Bodies commented that clients are now offered a greater degree of choice in selecting products and services from firms located in a Member State other than their own.

Furthermore, the introduction of the PED has successfully combined market integration with maintaining the high levels of safety that Europe was already accustomed to. To a certain extent, this is not surprising given that the requirements established by the ESRs, classification of pressure equipment and conformity assessment procedures generally reflect the previous practices of a number of well regulated Member States. On the whole, it is unlikely that any of the infrequent pressure equipment related accidents that have occurred in Europe could be linked to a failing of the PED. If an accident had occurred it was more likely to be associated with poor maintenance of equipment or a failure to apply the regulations. However, it has not been possible to obtain data to verify these claims and the evaluators have relied on the standing of the key stakeholders providing these comments, which given the market oversight role of a number of them is thought to be reliable.

9.3 Assessment of the Economic Performance of the Industry

The evaluation sought to comment on the continuing relevance of the Directive in the context of evolving global markets and for this purpose attempted to provide information on the sector drawing on economic data available from statistical databases such as PRODCOM and COMEXT and information available in market and other reports. The pressure equipment sector encompasses a diverse product group, from consumer items such as fire extinguishers to products that collectively comprise complex industrial assemblies. From a data collection and analysis perspective, it is difficult to fully characterise the industry given that the data do not entirely correspond to all of the product groups that fall under the scope of the PED. Moreover, certain product groups (such as industrial metal pipes) contain products that are not covered by the PED and it is difficult to determine the proportion that is covered.

The approach that was taken was to determine the performance of various product groups, that are likely to include products that are manufactured in conformity with the PED. These were examined both before and after the introduction of the Directive. Moreover, in order to comment on the overall performance of the industry extra-EU exports were considered even though the majority of such products are designed according to third country specifications rather than the PED.

Certain difficulties were encountered in developing a consistent account from the data. In particular, the data suggest that the market value of some sectors such as metal vessels for liquids and gases is smaller than others such as valves, which surprised a number of the experts interviewed. No explanation of this apparent disparity was identified, other than the over-generous attribution (from the PED perspective) of certain activities to the classifications examined. This suggests that more than the usual degree of caution should be exercised in interpreting the results.

However, examination of the results do appear to show that over the 1995 to 2010 period, the sector had a weighted average output growth (production value) of 59% at constant 2005 prices. 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 particularly strong rate with a weighted average growth of 123% in intra-EU exports at constant 2005 prices over the
Main Findings, Conclusions and Recommendations

1995 to 2010 period. The data appear to validate some of the qualitative statements that indicate that the PED has contributed significantly to encouraging intra-EU trade.

Moreover, the data from the PRODCOM and COMEXT database generally reflect the trends indicated by other published research on similar product groups, which indicate that for certain Member States (such as Germany and Italy) the pressure equipment industry is internationally strong across a range of products subgroups and in other Member States a smaller range of product subgroups are performing relatively well. Global competition is certainly increasing and extra-EU imports are growing faster than extra-EU exports. However, the value of exports remains at a much higher level than imports. Despite increasing challenges, it appears that the European pressure equipment industry remains an internationally strong sector that will benefit from an expanding range of opportunities in the medium term.

Despite the quantitative findings of the evaluation and other studies, a significant proportion of the firms interviewed were less optimistic about the future. A number of firms mentioned that production in Europe had decreased significantly over the years and that there was an ongoing trend towards relocation of manufacturing units outside of Europe. Low cost centres such as Asia and elsewhere were seen as offering beneficial conditions particularly in relation to labour and material costs as a result of the ongoing increase in global competition. Given the complexity of the market, it seems that certain product subgroups may be performing less well than others but on the whole this was not reflected in the data. It appears that only a firm level study that collected data directly from industry would be able to take market trends fully into account.

9.4 The Shortage of Supply of Skilled Workers and Relevant Training Courses

The shortage of supply of skilled engineering graduates was recognised by most stakeholders. To deal with this issue, a number of firms have developed internal training and processes for recruiting graduates from outside of Europe. Similarly, it was notable that the supply of skilled manual workers such as welders was decreasing. This may in the near future have negative consequences, especially given that many European engineers in the industry are in the later stages of their careers.

In addition, the number of graduate and vocational courses that cover relevant pressure equipment topics such as the application of pressure equipment standards and conformity assessment modules are very limited. Firms and Notified Bodies often have to train staff in-house in order for them to attain the necessary skills.

9.5 The Consequences of the All Inclusive Scope of the PED

Although the PED was recognised as meeting its core objectives, there were some issues raised with the way the PED regulates the sector. The PED has an all inclusive approach in regulating the vast array of products that fall under the Directive’s classification of stationary pressure equipment. Whilst generally the Directive was seen as having the right approach to selecting pressure equipment for specific groups of conformity assessment modules, for some stakeholders it had created a number of negative consequences. For example, it was mentioned that certain types of products may be more stringently regulated under the PED than under former national legislation in some Member States and this represents an excessive burden. In addition, it is said that a small number of products such as particular type of heat exchanger used in the tyre industry that were not initially intended as targets for the PED regime have nonetheless been brought under its provisions as a result of the comprehensive nature of pressure equipment.
Main Findings, Conclusions and Recommendations

In addition, manufacturers are required to ensure the removal of hazards according to the product’s intended use. However, for the development of certain types of product, the user may not be heavily involved in the design process or provide sufficient proprietary data. Manufacturers may not be well placed to understand how a product will be eventually used and may find it difficult to design the equipment correctly for the intended use. Similarly, manufacturers may not be in a position to develop the required supporting documentation such as the instructions to users (including maintenance aspects) to the appropriate level of detail given that the use of certain products differs greatly within different types of business and consumer environment.

However, no stakeholders were able to propose a feasible alternative approach to regulating the EU market in this area. European regulations are subject to agreements between Member States and this includes those with both comparatively ‘light’ and ‘more stringent’ regulatory regimes. In addition, whilst the PED does place a great deal of legal responsibility on manufacturers, the New Approach framework provides benefits in terms of providing manufacturers with opportunities for circulating pressure equipment on the Internal Market.

9.6 The Coherent Regulatory Landscape for Pressure Equipment

The evaluation explored how the PED interacts with other pieces of European regulation for pressure equipment and pressure equipment within certain types of machinery. Generally speaking, whilst some concerns were raised, the PED was found to operate in a coherent regulatory landscape with only a small number of areas of overlap with other pieces of legislation.

Simple Pressure Vessels Directive

To begin with, the interaction with the Simple Pressure Vessels Directive (SPVD) was believed to be clear with two distinct product groups being regulated by the respective Directives. However, one issue mentioned by a small number of stakeholders was that from time to time manufacturers may incorrectly apply the SPVD in the development of equipment that should be regulated under the PED. Whilst this is a concern, the evaluators see the correct application and enforcement of the existing regulation as the solution rather than suggesting any legislative adjustments.

However, a further aspect relates to whether the SPVD and PED could be merged with a view to encouraging a simplified regulatory framework for pressure equipment. This issue has already been explored in a previous review which concluded that the Directives should remain as separate pieces of legislation given that the requirements for manufacturing simple pressure vessels are comparatively ‘light’ under the SPVD and that manufacturers should be offered the choice in selecting their preferred regulatory route.

The response from industry associations during the course of the evaluation was that the findings of the review still remain valid. Extending the scope of the PED to include simple pressure vessels would not be beneficial for manufacturers that prefer the regulatory conditions established by the SPVD. However, this was not the view of a number of national authorities and standardisation experts. They generally regard the SPVD as an additional burden for their administrations, given that it provides regulation for a small proportion of the pressure equipment market. It would be more efficient from an administrative point of view to regulate the stationary pressure equipment

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and simple pressure vessels sector under a single piece of regulation. A merger of the Directives was proposed by this group.

Transportable Pressure Equipment Directive

The interaction between the PED and the Transportable Pressure Equipment Directive (TPED), was also examined. However, before this issue is explored it should be recognised that the TPED was introduced to meet the requirements of the Agreement for the International Carriage of Dangerous Goods (ADR)\textsuperscript{107} which falls under the remit of the UN. The approach taken by the ADR differs greatly with the New Approach given that the ISO standards for transportable pressure requirement are prescribed in the regulations. In addition, the ISO standards for transportable pressure equipment contain a range of safety criteria, thresholds and tests that when considered as a whole do not correspond entirely with the safety measures in comparable PED standards. As a result, many of the key stakeholders recognise that it is not technically feasible to merge the two Directives.

However, there were some issues raised in relation to areas of overlap between the TPED and PED. Whilst these represent a small number of cases they include products such as gas cylinders and stationary assemblies that include transportable cylinders. In a number of cases, a manufacturer may not fully know how a product will be eventually used and may not be in a position to apply the correct Directive. At the same time, manufacturers may recognise that they produce products that may be used as either transportable or stationary pressure equipment but may select one regulatory route only given that it is less cost effective to develop similar products according to different sets of procedures. Encouraging the correct enforcement of existing legislation would appear to be the best way forward to address this particular issue.

However, there are also products such as cylinders for breathing apparatus where there is a lack of clarity regarding which Directive is the legally correct one to apply. This issue is currently subject to debate in the Working Group Pressure (WGP). In addition, there is also the prospect of new products that may fall into a grey area between the two Directives such as fuel cells. Machinery Directive

The Machinery Directive (MD) contains regulation for pressure equipment that is used in machines. For Category I pressure equipment or below, manufacturers are in a position to apply the MD only in order to remove the hazards related to pressure. For Category II pressure equipment or above, manufacturers must ensure compliance with the PED, in parallel to MD and other directives that may apply.

The coexistence of the two Directives was believed to be reasonably clear with manufacturers generally understanding how to correctly apply the Directives. However, one area of concern raised by some pressure equipment industry associations was that Category I pressure equipment in machines may sometimes not meet safety expectations for this type of equipment. There was a suggestion that more stringent regulation of Category I pressure equipment in machinery should be introduced. However, experts in the MD field believed that there was little evidence of the need for this and that the MD is sufficient for removing any potential safety hazards in machines. The evaluators suggest that further action in this area is not required.

\textsuperscript{107} \url{http://www.unece.org/trans/danger/publi/adr/adr2011/11contentse.html}
Another issue mentioned was that the PED conformity assessment modules for Category II pressure equipment or above in machinery may be incorrectly applied in some cases. Questions regarding the safety of such equipment were raised. The response to this matter would be to encourage stronger enforcement of existing legislation rather than to recommend any substantive changes to the rules.

9.7 The Impact of In-service Inspection Legislation on the Function of the Internal Market

The introduction of the PED has significantly reduced the likelihood that firms will face problems in placing products on the market in a Member State other than where the products were produced. However, a significant minority of firms commented that some barriers that hamper the smooth functioning of the Internal Market remain particularly in relation to national in-service inspection legislation.

National in-service legislation provides a range of requirements for the on-going maintenance and testing of pressure equipment and other related areas after it has been placed on the market. National in-service legislation diverges across the Member States but in some countries the legislation affects the design and manufacturing of pressure equipment. For example, in Germany, national in-service inspection requirements provide for a lower number of inspections if pressure equipment is designed according to former national standards. If other standards are selected, the frequency of inspections is much higher.

Manufacturers argued that the legislative practices in Germany and other Member States discriminated against the selection of certain standards or other design and production approaches. In effect, they were seen as providing an additional set of requirements over and above the PED which need to be appropriately addressed in order to efficiently enter these markets.

9.8 Weaknesses in the New Approach framework

Although positive findings were identified particularly when compared with the previous system of national regulation, a number of barriers that continue to hinder the performance of the Directive were highlighted. Even though in some specific cases these have serious implications, they should not be considered as constituting a widespread failure with the Directive given that a large proportion of pressure equipment adheres to the necessary requirements.

One area of concern relates to the performance of the New Approach framework in guaranteeing the safety performance of pressure equipment in line with the Essential Safety Requirements of the PED. Before the various issues related to this aspect are explored, it should be mentioned that when looking at these issues collectively an important observation can be made. Namely, that 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 uneven enforcement of the Directive and PED Guidelines, and resulted in the circulation of non-conforming pressure equipment on the Internal Market.

Issues Related to Market Surveillance Authorities

As an indicative example, from an EU-wide perspective, the removal from the market of non-conforming products by national market surveillance authorities occurs infrequently. The safeguard
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Clause (under Article 8 of the Directive) which facilitates the removal of products from the market on an EU-wide basis has only been used on a handful of occasions.

In some cases, this may be explained by the fact that Member State resources to test products on a sufficient scale may be limited given that industrial pressure equipment includes expensive items. Customs authorities that cooperate with market surveillance authorities may prioritise the examination of other products such as toys. On the spot checks of pressure equipment are sometimes insufficient to detect whether the items meet the ESRs, since more detailed testing is required. It may be the case that there are staffing issues in terms of finding suitably qualified officials who can competently perform such activities or it may be the case that authorities in some Member States do not generally prioritise these types of activities.

According to a number of national authorities, coordination between officials across Europe in terms of sufficiently sharing information or developing joint strategies 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. The external perception of the Market Surveillance Cooperation Group (ADCO) is that national authorities need to find ways to cooperate more closely within this forum in order to remove non-conforming products from the market on a much larger scale.

Moreover, comments were made about the difficulties encountered by national authorities when attempting to exercise their powers. It has been mentioned that a national authority may successfully identify a non-conforming product and subsequently remove the item from its national market. However, procedures are not in place to ensure that the manufacturer of such items puts beyond use the non-conforming products in its ownership. It may be the case that the same manufacturer attempts to place the same batch of products on the market in another Member State. Similarly, a national authority may identify a non-conforming product and position itself to remove the product from the market. However, the firm in question may threaten legal action because of potential reputational damages. Whilst the authority may have the resources to verify whether or not a product conforms to the regulations, it may not have the resources to pursue legal cases. Furthermore, it was surprising to some that to date not a single manufacturer of non-conforming products with serious safety failings has been convicted through legal processes.

Similarly, in some Member States, where there are a large number of NBs, oversight of the market by the authorities may be limited. In other Member States, the market may be restricted to a handful of NBs and oversight was said to be comparatively strong. In addition, the withdrawal of certificates by a Member State authority from a Notified Body with a view to suspending provision of services (in line with Article 12 of the PED) has rarely occurred.

Although not linked to the New Approach framework as such, unfortunately, some organisations are falsely claiming to be NBs and are providing fake approval certificates to manufacturers. Whilst some authorities had developed measures to monitor and address the issue, it was felt that the problem had not been fully responded to and the mechanisms for co-operation in this area are weak.

Issues related to Notified Bodies

In a similar vein, in some cases, a number of stakeholders thought that the relationship between NBs and manufacturers may be worrying. Given that NBs have a commercial interest in providing conformity assessment services to the pressure equipment sector, the extent to which NBs may...
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hold clients to account on certain safety requirements may be restricted and deviate from the specific requirements of the PED. Likewise, the withdrawal of certificates by NBs from manufacturers with a view to withdrawing approval of design and production processes has rarely occurred. If such instances have occurred, they are often not the subject of debate between NBs as this would indicate a gap in the market that another NB may wish to fill.

Related issues include inconsistency in the management of the conformity assessment processes between NBs located in different Member States and between NBs located in the same Member State. Scientific evidence has been presented that has confirmed the existence of non-conforming products that have been conformity assessed by NBs. Whilst the evidence only relates to a limited number of Member States, it is possible that similar problems would be identified elsewhere.

The Conformity Assessment Bodies Forum (CABF) plays a critical role in encouraging NBs to implement the Directive consistently. However, only a small proportion of the PED NBs attend the meetings. This has led to the emergence of an inner core that is technically more coherent and knowledgeable than their counterparts.

9.9 The Impact of the Delocalisation of Production on the New Approach Framework

A further issue that appears to be testing the New Approach framework is the trend towards the delocalisation of production to low cost centres. Before this issue is explored, it needs to be pointed out that there was confirmation from stakeholders that a proportion of pressure equipment manufactured in low costs centres does conform to PED requirements. This is particularly true when there is strong user involvement in the manufacturing process or when reputable firms ensure that the conformity assessment processes are properly carried out.

However, comments were made that the delocalisation of production to low costs centres presents a number of heightened challenges for the PED. One issue is the capacity of subsidiaries of European NBs to oversee the conformity assessment process properly. Whilst the head offices of NBs are responsible for the performance of their branches outside Europe, it was suggested that the skill-sets of subsidiaries were weaker than their counterparts in the EU. In addition, the competitive pressures for conformity assessment services in low cost centres were also considered to be particularly intense and subsidiaries may apply substandard conformity assessment procedures in order to retain and expand their client base.

Likewise, the European system for market surveillance was thought of some stakeholders to be insufficiently robust to respond to the challenges of pressure equipment imported from low cost centres. The resources and level of coordination was considered to be inadequate in relation to the potential of a high volume of non-conforming products to enter the Internal Market.

It was also suggested that in the future, the PED will be regulating production processes in third countries in relation to the manufacturing of products destined for the European Internal Market. Therefore the PED and supporting processes may have to take greater account of this aspect in order to sustain sufficient regulatory oversight of the market.

9.10 The Role of the PED Guidelines in Supporting the Enforcement of the PED

The PED Guidelines that provide responses to questions from stakeholders through the Working Party Guidelines (WPG) have played a useful role in supporting the clarification of key aspects of the Directive particularly when applied in certain contexts. Generally speaking, although they have non-statutory basis, they are generally accepted as the correct interpretation of the Directive by a
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significant proportion of stakeholders. However, given that there isn’t an EU legal obligation to adopt the interpretation outlined by the PED Guidelines, in some cases there is inconsistency between NBs and other stakeholders in the way the provisions of the Directive are interpreted and enforced. Interestingly, in France, a national Decree obliges relevant bodies to adopt the PED Guidelines but this is not the case elsewhere.

Moreover, the document that contains the PED Guidelines is not as effective as it might be, given that there are now 200 questions addressed. Suggestions have come forward about restructuring the document so as to highlight the key areas of relevance for stakeholders and make the document easier to navigate. This might help the WPG to deal with the many unnecessary questions that have already been addressed by the existing PED Guidelines.

9.11 Suggestions from Stakeholders on Specific Aspects of the Directive

A number of suggestions were made by stakeholders on specific aspects of the Directive. Either additional PED Guidelines should be provided, the revision of items should be undertaken individually, or adaptations should be made during a full revision of the Directive. However, whilst improvements to the Directive could be made, it is felt that given the solid performance of the Directive at this stage there is no urgent need for further changes to take place.

Offshore pressure equipment

One aspect relates to the current product exclusion of pressure equipment used by the offshore industry. Concerns were raised that the industry faces increased safety and environmental risks and could usefully be brought within the scope of the PED. This issue will be shortly subject to an impact assessment.

The concept of assemblies

Some manufacturers and NBs commented that the concept of assemblies is poorly defined and requires revision. One issue relates to the level of responsibility an installer or manufacturer of a complex assembly needs to assume in order to guarantee that an assembly meets the requirements of the PED. A small number of NBs and manufacturers stated that if a complex assembly is composed of pressure equipment that has been manufactured by various manufacturers and has been CE marked, the Directive is not clear as to whether the manufacturer needs to take responsibility for the whole assembly or the part of the assembly that they have specifically developed. Other stakeholders believe that the Directive and PED Guidelines are very clear and that the manufacturer needs to take responsibility for the entire assembly. This position has been repeatedly confirmed by the Commission and in the relevant expert groups.

Pressure Accessories

According to some manufacturers and national authorities, the definition of pressure accessories has been poorly worded and requires revision. It is believed that the Directive was intended to regulate the entire pressure accessories market, but a guideline has been developed that confirmed that only pressure accessories that contain pressure bearing housings should fall under conformity assessment procedures. A large proportion of the pressure accessories market that do not have such features are regulated according to the sound engineering practices of the Member State where they are produced. Some stakeholders believe that safety standards could be raised in this area. However, the views of industry need to be considered if this area is reformed given that it would represent an extension of EU regulation on a broad product group.
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Quantitative Requirements

The Directive contains a number of quantitative requirements in Annex I (7). They provide specific allowable stresses for a range of testing practices, demonstrating material characteristics and benchmarking the acceptable levels of material ductility.

This includes for example the safety requirement about the bending rupture energy of a material measured on an ISO V Test Piece. A number of stakeholders including industry associations, manufacturers, standardisation experts and academics regarded this particular requirement as undermining the innovative potential of the EN standards. Materials designed according to EN standards can attain equivalent levels of safety but may not meet the specific requirement referred to. Their preference was to remove this aspect from the Directive. However, a number of officials commented that removing this aspect does not take into account the fact that manufacturers may develop materials with insufficient properties. The quantitative requirements provide a measure of safety in this regard.

Declaration of Conformity

The PED requires manufacturer or this authorised representative to provide declarations of conformity in relation to their manufactured goods when requested by the authorities. Declarations of conformity provide a range of detailed information on the conformity assessment procedures that have been followed, the type and design certificates provided by the NB and other pieces of information that indicate how the pressure equipment meets the ESRs.

Officials commented that given the length of time it sometimes takes to receive declarations of conformity, on the spot checks would be facilitated if manufacturers were obliged to supply the documents automatically, alongside their manufactured goods. This would appear to be a relevant suggestion for enhancing market surveillance procedures. However, industry may be less enthusiastic about having to supply the documents as a matter of course.

User Inspectorates

UIs are independent bodies that are part of a user company or group and have the remit of performing conformity assessment activities (specifically modules A1, C1, F and G). By performing this role, they enable firms to take advantage of their in-house technical know-how and avoid using NBs, and are particularly advantageous for users of highly complex pressure equipment (such as major installations and plants). The evaluation (and a previous review) found that User Inspectorates are performing as intended and have provided a number of benefits for the users of pressure equipment. However, currently they are not a mandatory feature of the Directive and a small proportion of Member States have opted out of transposing this particular feature. It may be beneficial for all Member States to adopt this feature.

European Approval of Materials

One of the procedures for approving new materials under the Directive relates to the European Approval of Materials (EAM). The EAM enables firms to submit new materials to NBs referred to in Art. 12 of the PED. The EAM applications are then submitted for approval at an EU-level, a process in which there is participation by national stakeholders. If there are no formal objections, the reference to the EAM is published in the OJ and it provides presumption of conformity to the PED. However, there were no specified mechanisms in the Directive for the implementation of the EAM.
which has led to the development of ‘Guiding Principles’. These are currently under revision in light of recent difficulties.

Comments were made that the EAM mechanism has not proven to be successful and requires revision. During the initial years of implementation of the PED, there were numerous EAM applications but most of these were objected to formally by one of more Member States and they were never published in the OJ. Consequently, the current list of accepted EAM applications is very limited.

**Particular Material Appraisal (PMA)**

If a material has not been referenced by an EN standard or approved by the EAM procedure, a manufacturer can provide a ‘description of the solutions adopted to meet the ESRs’ related to the materials within a PMA. This will allow the material to be used for the development of pressure equipment. In relation to Category III and IV pressure equipment, a NB is required to assess the PMA. Given that the PMA relates to demonstrating that material characteristics are suitable for the intended application, it is a crucial element for proving the safety of the equipment.

The PED is not specific on the technical information required to develop a satisfactory PMA. However, given the range of pressure equipment regulated under the Directive, it would be very difficult to have a single template document that would cover all types, and often there needs to be room for flexibility when demonstrating how a material meets the ESRs.

However, random checks undertaken by market surveillance authorities have demonstrated that whilst some PMAs conform to the Directive, others vary in their quality and level of detail including when a NB has been directly involved in overseeing the process. For example, sometimes PMAs were not sufficiently detailed to demonstrate compliance of the material with the ESRs. In a small number of cases, the PMA was not available on request and this provides a clear indication of non-compliance.

**PED Guidelines and other supporting documents**\(^\text{108}\) that outline the requirements for PMAs are available to manufacturers and NBs. Currently, the Working Party Materials and Working Party Guidelines are in the process of seeing if the situation can be improved by providing better guidance.

**Sound Engineering Practices**

A small number of market surveillance officials mentioned that they had problems examining products that are categorised below Category I and are designed according to the ‘sound engineering practices’ of the Member State where the manufacturer is based. In particular, they thought that this concept was difficult to deal with given that the sound engineering practices of another Member State may not always be well known. However, extending the scope of the PED to include conformity assessment of all items that fall into this category would have a major impact given the large number of products involved.

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The PED’s regulatory impact on industry is predictably uneven given the all inclusive scope and broad product group coverage of the Directive. As expected, firms that develop products according to EN standards and have presumption of conformity with the PED have experienced reductions in regulatory burdens and have benefited the most. A proportion of other firms that do not design equipment according to EN standards believe that the administrative requirements of the PED are relatively satisfactory to manage. However, a significant minority of firms believe that PED is burdensome. This includes firms that do not design equipment according to EN standards and sectors that were not previously regulated by comprehensive pressure equipment requirements.

Some officials have commented that whilst a proportion of industry may perceive the PED as burdensome, the Directive plays a key role in ensuring that pressures equipment is manufactured according to high safety standards. In addition, the PED is much more open when compared with other international trading regimes that prescribe national standards through specific legislative and insurance provisions. The Directive offers manufacturers the choice of selecting EN standards that have presumption of conformity or other standards and codes that when applied must demonstrate conformity with the ESRs.

9.13 The Performance of EN Standards

CEN has played a key role in prompting the development of EN standards that provide presumption of conformity with the Directive. Research has determined that EN standards provide economic and technically innovative advantages when compared with other standards and codes, and allow manufacturers to develop precision engineered pressure equipment with thinner material walls. A significant amount of time and resources has been invested in the standardisation process and a large number of standards have now been issued. This should be recognised as a key achievement.

However, some stakeholders made a number of critical comments. For example, some stakeholders believe that the standardisation process has been inefficient. During the initial introduction of the PED, a large number of EN standards were still in the developmental phase. Some were issued during the initial stages but later had to be revised in order to cover the product group (and materials) that they related to with an appropriate level of quality and detail. Other issues were the lack of availability of key standards in certain Member State languages and the difficulties in managing the length of the documents.

Some of the inefficiencies in the standardisation process can be explained by the fact that much of the work is undertaken by volunteers and that the process lacks sufficient funding and support from relevant bodies. Often only a small number of industry or specialists participate and a wider range of relevant stakeholders such as NBs are not involved.

Despite the number of EN standards produced and their perceived relative economic and technical advantages, their uptake by European industry to date has been only 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.

A key issue in explaining why EN standards have not been taken up to the extent that might have been envisaged relates to the performance of Member States in providing the framework conditions to support the process. Whereas some Member States have been proactive in supporting the uptake of EN standards, others have continued to support former national
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standards. Similarly, NBs located in different countries are more supportive of firms adopting EN standards than others.

A further reason for the uneven uptake of EN standards is the mixed perception of industry regarding the extent of their beneficial impacts (such as the reduction in material costs). Whilst segments of the market are convinced of the commercial benefits others are far from persuaded. This may relate to the fact that EN standards require high-end engineering skills to be applied and a number of firms prefer to use less onerous standards that carry lower design costs. In addition, users of pressure equipment are more familiar with other standards and codes particularly outside Europe and manufactures may prefer to follow global market trends. In addition, given that many existing complex assemblies are not manufactured according to EN standards, users do not want to maintain their existing assemblies with new EN designed equipment. This is because the in-service inspection costs for an assembly composed of equipment built according to EN and non-EN designed equipment are believed to be higher than an assembly built according to the same set of standards. The whole life-cycle costs of the product need to be considered when selecting pressure equipment.

However, these are some signs that the uptake of EN standards is very slowly increasing. For example, certain major users of pressure equipment have begun to recognise the benefits of having presumption of conformity with the Directive and have developed processes for specifically procuring EN designed equipment. It has been suggested that, whereas initially slow progress in developing the relevant standards reduced the momentum generated by the introduction of the Directive, now that a substantial part of the required standards are in place, it is time to have a co-ordinated promotional effort. Moreover, this could be complemented by global harmonisation efforts, where the positive development of ISO EN standards indicate that more could be done.

Overall, the reservations expressed are not be seen as constituting a failure of the standardisation process, given the level of progress that has been made and the quality of the outputs achieved. However, given the strategic importance of appropriate standards, industry and other stakeholders could be encouraged to devote appropriate resources to making further progress.

9.14 Utility, Sustainability and European Value Added

The evaluation confirms that a European Value Added has been realised from the Directive. Stakeholders recognise that the Directive has played its role in moving the pressure equipment sector towards a regulatory level playing field. This could not have been achieved through Member States acting alone or bilaterally.

However, the uneven enforcement of the Directive and weakness in the New Approach framework is discouraging for manufacturers that have invested in conformity assessment processes that meet the requirements of the PED. This threatens the sustainability of the Directive. The ongoing sustainability of the Directive hinges upon stronger and consistent enforcement of the rules in order to encourage fair competition. The overall goal for conformity assessing products should be the same rules and measures being applied to the same products. As mentioned, the alignment of the PED to the New Legislative Framework is a fundamental step in this process along with the consideration of other supporting measures as outlined below.
9.15 Recommendations (Non-legislative)

- The European Commission should speed up the process for clarifying with legal certainty the scope of the PED and TPED and how the Directives should be applied to certain types of products such as cylinders for breathing apparatus. It is understood that work in this area is underway. The EC should also consider new products that may fall into a grey area between the two Directives such as fuel cells in order to provide clear orientation for manufacturers.

- Given the ongoing trend towards manufacturing pressure equipment outside of Europe, the European Commission could closely monitor trends in this area and assess the implications that this may have from a regulatory perspective for the PED.

- The European Commission may view it appropriate to assess the ongoing enforcement of the Directive and the economic performance of industry based on a number of indicators that are outlined in Annex 6.

- In cooperation with the Member States, the European Commission, could collect and centralise Member State data on the safety performance of pressure equipment. As an initial measure, data could be collected from Member State systems that store information for the purpose of supporting national in-service inspections.

- The European Commission with the support of Member States could raise the profile of the problem of engineering skill shortages and improve the marketing, quality and relevance of engineering courses with a view to supporting the pressure equipment sector (such as developing the number of courses that provide training on EN standards and conformity assessment issues). This may provide a partial response to the impending shortage in relevant skill-sets.

- 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.

- Given the identified weaknesses in the market surveillance system, Member State funded PED communication programmes could be initiated for market surveillance and customs authorities with a view to raising awareness about the identification of non-conforming pressure equipment.

- 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;

- Member States should encourage relevant national authorities to establish procedures to identify and restrict organisations falsely claiming to be NBs. The results could be shared through the ADCO group or if feasible through the ICSMS system;

- It is recommended that improved guidance for specifying the requirements for Particular Material Appraisal (PMA) is developed by Working Group Pressure and Working Party Guidelines and is appropriately communicated to the relevant stakeholders.
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- The European Commission’s procedure for developing PED Guidelines should be made more efficient. Clarifications that do not require additional information could be responded to directly without the need for debate and an extension of the document. Industry should understand that it is their responsibility to apply the existing guidance to their own circumstances rather than seek highly nuanced guidance to do so. The document itself could be revised and published in a clearer format. The key issues addressed by the PED Guidelines could be highlighted, strengthened and set out more systematically and navigation through the document facilitated. 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 should focus its efforts on developing high quality standards that are user friendly and have sufficient coverage of key areas (such as materials). A small number of key EN standards should be translated to cover the needs of industry in all Member States. EN standards could be hyperlinked and sold in appropriate bundles if knowledge of more than one standard is required for its efficient application.

- The European Commission may have a role in a renewed campaign to promote the take-up of EN standards by industry, now that many of those required are in place. An initial budget has been allocated to CEN for public awareness activities but could be extended in the future.

- In order to encourage the global harmonisation of industry, it would be preferable if the development of ‘modern standards’ were promoted and took place through the ISO route. This process could be driven by CEN with support received from the European Commission when and where relevant.

- 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.
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- 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.

9.16 Recommendations (Further Research)

- 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 ESRs 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.

9.17 Recommendations (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

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109 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.

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.

9.18 Recommendations (Legislative)

- 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 address the areas suggested below:
  - the automatic provision of declarations of conformity alongside the transport of pressure equipment in order to support the process of on-the-spot checks by customs and market surveillance authorities (however the impact of this proposed measure on industry needs to be properly assessed).
  - the definition of assemblies should be reviewed to the extent that it is unclear as to where legal responsibility currently lies (as a suggestion it may be more efficient if the notion of assembly is revised to subassembly in order to limit the responsibility of manufacturers to the parts of the assembly which they have specifically developed);
  - whilst the full impact of this suggestion needs to be properly assessed, the wording for pressure accessories could be revised in order to broadly cover the pressure accessories market and raise safety standards;
  - the specific quantitative requirements could be assessed to see if they limit the performance and application of the EN standards (e.g. bending rupture energy of a material measured. However, the safety implications of removing these requirements need to be carefully assessed before doing so. In particular when equipment is built based on standards which do not follow the PED design approach;
  - User Inspectorates could be adopted by the limited number of Member States that have not transposed this optional legislative feature. This would offer benefits to the users of pressure equipment.
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- the EAM procedure could be assessed and revised in order to develop new procedures that could more efficiently approve and support the dissemination of a greater number of new materials;
- a very small number of highly relevant PED Guidelines could be included in the Directive if it is believed that it will encourage improved implementation of the PED;
- based on the outcome of an impact assessment, the PED’s scope could be extended to include offshore product groups that suffer from pressure hazards.
- the concept of Sound Engineering Practices could be examined to see if it is sensible and viable to review this area with a view to increasing the safety of pressure equipment.
- to take into account the regulatory challenges presented by the delocalisation of industry, an additional objective could be inserted in the Directive to reflect its role of regulating products produced in third countries that are intended for the Internal Market.
ANNEX 1 – Bibliography

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Global Industry Analysts (2011) Steel Pipes and Tubes\(^{115}\)


ICON Group International (2012) World Outlook for Ferrous Metal Pressure Vessels and Tanks of More than 61cm Outside Diameter and 0.14 Cubic Meters Capacity\(^{116}\)

Icon Group International (2010) World Outlook for Custom Fabricated and Field Erected Ferrous Metal Pressure Vessels for Refineries, Chemical Plants and Paper Mills\(^{117}\)


International Trade Statistics 2011 (World Trade Organisation)


TUV Austria & CEC Italy. (2004) Comparative Study on Pressure Equipment Standards

\(^{111}\) Report purchased from MarketResearch.Com
\(^{112}\) Report purchased from Market Research.Com
\(^{113}\) Report purchased from Market Research.Com
\(^{114}\) Report purchased from MarketResearch.Com
\(^{115}\) Report purchased from MarketResearch.Com
\(^{116}\) Report purchased from MarketResearch.Com
\(^{117}\) Report purchased from MarketResearch.Com
\(^{118}\) Report purchased from MarketResearch.Com
\(^{119}\) Report purchased from MarketResearch.Com
\(^{120}\) Report purchased from Market Research.Com
Annex 1

UCC (2011) Il Libro Bianco della Caldaria


**Data Sources**

COMEXT is an EU database that provides statistics on intra and extra EU trade according to different types of nomenclature. It can be accessed through the Eurostat website: http://epp.eurostat.ec.europa.eu/newxtweb/

PRODCOM is an EU database that provides statistics on roughly 4500 different types of manufactured goods. It can be accessed through the Eurostat website: http://epp.eurostat.ec.europa.eu/portal/page/portal/prodcom/introduction

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121 Report purchased from Market Research.Com
ANNEX 2 – Quantitative Analysis

The below table indicates the problems in the availability of the data for the EU 15 2010. For the EU 15 2010 an aggregate needs to be developed from Member State level data. However, in many cases data are missing. This makes it difficult to compare data between different time periods for certain product subgroups e.g. ‘Condensers for Steam and other Vapour Power Units’. Please see section 5.3 and 5.4 which outlines the methodological approach and shortcomings to the quantitative analysis. One needs to be cautious when assessing the results.

Table: A1 Comparison of EU 15 1995 data with data for the EU 15 2010 and EU 27 2010 (PRODCOM)

<table>
<thead>
<tr>
<th>Product Category and Product Subgroup</th>
<th>£m Production Value</th>
<th>Real Growth % EU 15 1995 and EU 15 2010</th>
<th>Real Growth % EU 15 1995 and EU 27 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Current Prices</td>
<td>Constant 2005 prices</td>
<td></td>
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<tr>
<td>VESSELS</td>
<td></td>
<td></td>
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<tr>
<td>Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases</td>
<td>2,374</td>
<td>4,980</td>
<td>5,720</td>
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<td>PIPING</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Metal Tubes and Pipes</td>
<td>Data are not available</td>
<td>10,486</td>
<td>13,997</td>
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<tr>
<td>Metal Tube and Pipe Fittings</td>
<td>Data are not available</td>
<td>257</td>
<td>703</td>
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<tr>
<td>Plastic Tubes and Pipes with a Minimum Burst Pressure of 27.6 Mpa</td>
<td>803</td>
<td>1,255</td>
<td>1,372</td>
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<tr>
<td>SAFETY ACCESSORIES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety Valves</td>
<td>Data are not available</td>
<td>576</td>
<td>611</td>
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<tr>
<td>Pressure Measuring and Monitoring Instruments</td>
<td>454</td>
<td>1,073</td>
<td>1,224</td>
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<tr>
<td>Valves</td>
<td>6,501</td>
<td>11,255</td>
<td>13,487</td>
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<td>INDUSTRIAL ASSEMBLIES</td>
<td></td>
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### Annex 2

<table>
<thead>
<tr>
<th>Description</th>
<th>499</th>
<th>559</th>
<th>865</th>
<th>621</th>
<th>527</th>
<th>815</th>
<th>% Difference</th>
<th>% Growth</th>
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<tr>
<td>Reciprocating Displacement Compressors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-15.1</td>
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<td>243</td>
<td>2,400</td>
<td>667</td>
<td>229</td>
<td>2,263</td>
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<td>239.5</td>
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<td>Steam and Sandblasting Machines</td>
<td>613</td>
<td>738</td>
<td>787</td>
<td>764</td>
<td>696</td>
<td>742</td>
<td>-8.8</td>
<td>-2.8</td>
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<td>Condensers for Steam or Other Vapour Power Units</td>
<td>60</td>
<td>25</td>
<td>113</td>
<td>74</td>
<td>24</td>
<td>107</td>
<td>-50.2</td>
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<td>Heat Exchange Units</td>
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<td>4,578</td>
<td>5,040</td>
<td>2,167</td>
<td>431</td>
<td>4,752</td>
<td>99.2</td>
<td>119.3</td>
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**CONSUMER ASSEMBLIES**

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<th>450</th>
<th>440</th>
<th>522</th>
<th>560</th>
<th>415</th>
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<th>% Growth</th>
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<td>Fire Extinguishers</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>-25.9</td>
<td>-12.2</td>
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**BOILERS**

<table>
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<tr>
<th>Description</th>
<th>5,743</th>
<th>7,297</th>
<th>9,420</th>
<th>7,148</th>
<th>6,881</th>
<th>8,883</th>
<th>% Difference</th>
<th>% Growth</th>
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<tr>
<td>Boilers</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td>-3.72</td>
<td>24.3</td>
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</tbody>
</table>

**WEIGHTED AVERAGE %**  | 56.9  |

---

**Economic Output (Production Value – Product Subgroup Bar Charts) PRODCOM**

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151
PLEASE NOTE THAT THE CHARTS BELOW MAINLY CONTAIN DATA PRESENTED IN CONSTANT 2005 PRICES. HOWEVER IF DATA ARE NOT AVAILABLE FOR THE EU 15 1995 THE DATA ARE PRESENTED IN CURRENT PRICES (i.e. Figure 2, 3 and 5)

Figure: 1

Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases
Production Value (Constant 2005 Prices)

€ Millions

EU15 - 1995 EU15 - 2010 EU27 - 2010

Figure: 2

Metal Tubes and Pipes
EU15 and 27 Production Value (Current Prices)

€ Millions

EU15-2010 EU27-2010

Figure: 3

Figure: 4

PRODCOM CODE Data Are Not Available for the Below Members States
25291110 EU 15 2010 - BE, SE, UK
25291120 EU 15 2010 - BE, GR, SE
25291130 EU 15 2010 - SE
25291170 EU 15 2010 - AT, BE, IE, NL, UK

PRODCOM CODE Data Are Not Available for the Below Members States
24203310 EU-15 2010 - AT, BE, GR, IE, NL, PT, SE
24203340 EU-15 2010 - BE, IE, NL, SE, UK
24203370 EU-15 2010 - AT, BE, NL, PT, UK
24203410 EU-15 2010 - DE, ES, GR, IE, FR, UK
24203430 EU-15 2010 - AT, BE, GR, NL, PT
24203470 EU-15 2010 - AT, DE, ES, IE, SE
24203500 EU-15 2010 - DE, PT, SE,
Evaluation of the Pressure Equipment Directive

Annex 2

**Figure: 5**

Metal Tube and Pipe Fittings

EU 15 and 27 Production Value € (Current Prices)

![Graph showing Metal Tube and Pipe Fittings production values for EU 15 and 27 for 2010 and 2015.]

**Figure: 6**

Plastic Tubes and Pipes with a Minimum Burst Pressure of 27.6 Mpa

EU 15 and 27 Production Value € (Constant 2005 Prices)

![Graph showing Plastic Tubes and Pipes production values for EU 15 and 27 for 1995, 2010, and 2015.]

---

**Figure: 5**

**Figure: 6**

---

**PRODCOM CODE**

Data Are Not Available for the Below Members States

All codes below EU-15 1995 data are missing at aggregate and Member State level

- 24513030 EU 15 2010 - FR, GR, NL, PT, UK
- 24513050 EU 15 2010 - DE, FR, GR, NL, UK
- 24523000 EU-15 2010 - AT, BE, GR, IT, IE,

**PRODCOM CODE**

Data Are Not Available for the Below Members States

- 22212935 EU 15 1995 data -AT, IE, NL
- EU 15 2010 data - NL, IE

---
PRODCOM CODE  Data Are Not Available for the Below Members States
28141180  EU-15 1995 data are missing at Member State and aggregate level
           EU-15 2010 data - AT, BE, NL, SE

PRODCOM CODE  Data Are Not Available for the Below Members States
28141140  EU-15 2010 -BE, DE, ES,

PRODCOM CODE  Data Are Not Available for the Below Members States
28141160  EU-15 1995 data are missing at Member State and aggregate level
           EU-15 2010 - AT, NL, SE

PRODCOM CODE  Data Are Not Available for the Below Members States
28141313  EU-15 2010 -AT, NL, SE

PRODCOM CODE  Data Are Not Available for the Below Members States
28141315  EU-15 2010 -AT, BE, DE, IE

PRODCOM CODE  Data Are Not Available for the Below Members States
28141313  EU-15 2010 -PT

PRODCOM CODE  Data Are Not Available for the Below Members States
28141333  EU-15 2010 -AT, BE, SE

PRODCOM CODE  Data Are Not Available for the Below Members States
28141375  EU-15 2010 -BE

PRODCOM CODE  Data Are Not Available for the Below Members States
28141377  EU-15 2010 -DK, UK
Figure: 7

Figure: 8

Figure: 9

PRODCOM CODE: Data Are Not Available for the Below Members States
26515271 EU 15 2010 - BE, IE, NL
26515274 EU 15 1995 – data are not available for all Member States and at an aggregate level
   EU 15 2010 -BE, FR, NL, SE
26515279 EU 15 2010 - AT, NL, SE

PRODCOM CODE: Data Are Not Available for the Below Members States
28132630 EU 15 2010 - ES
28132650 EU 15 2010 - NL
28132670 EU 15 2010 - BE, ES, IT
28132690 EU-15 2010 - AT, BE, ES, NL,
Evaluation of the Pressure Equipment Directive

Annex 2

Figure: 10

**Machinery for Liquefying Air or Other Gases**

EU 15 and 27 Production Value € (Constant 2005 Prices)

- EU 15 - 1995
- EU 15 - 2010
- EU 27 - 2010

Figure: 11

**Steam or Sandblasting Machines**

Production Value € (Constant 2005 Prices)

- EU-15 1995
- EU-15 2010
- EU-27 2010

Figure: 12

**Condensers for Steam or Other Vapour Power Units**

EU 15 and 27 Production Value € (Constant 2005 Prices)

- EU 15 - 1995
- EU 15 - 2010
- EU 27 - 2010

---

PRODCOM CODE | Data Are Not Available for the Below Members States
28251150 | EU 15 2010 AT, DE, ES, IT, UK

PRODCOM CODE | Data Are Not Available for the Below Members States
28292230 | EU-15 2010 - AT, BE, IE, SE

PRODCOM CODE | Data Are Not Available for the Below Members States
25301250 | EU-15 2010 -DE, ES
Figure: 13

PRODCOM CODE | Data Are Not Available for the Below Members States
---|---
28251130 | EU-15 2010 - AT, BE, GR

Figure: 14

PRODCOM CODE | Data Are Not Available for the Below Members States
---|---
28292210 | EU-15 2010 - AT, IE, NL, PT, SE
Development of the Internal Market (Intra-EU Trade – Product Subgroup Bar Charts) PRODCOM

Figure: 15

<table>
<thead>
<tr>
<th>PRODCOM CODE</th>
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</thead>
<tbody>
<tr>
<td>25211200</td>
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</tr>
<tr>
<td>25211300</td>
<td>EU 15 2010 - IE, BE, SE</td>
</tr>
<tr>
<td>25301110</td>
<td>EU 15 2010 – BE, FR, GR, IE, NL, PT, SE, UK</td>
</tr>
<tr>
<td>25301150</td>
<td>EU 15 2010 - BE, NL, PT, SE</td>
</tr>
<tr>
<td>25301170</td>
<td>EU 15 2010 - BE, DE, FR, GR, NL, PT, SE, UK</td>
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<tr>
<td>25301230</td>
<td>EU 15 2010 - BE, FR, NL, SE</td>
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<tr>
<td>25301330</td>
<td>EU 15 2010 - BE, FR, NL, IE,</td>
</tr>
</tbody>
</table>
Annex 2

2010 Metal Reservoirs, Tanks, Vats and Containers for Liquids and Gases
Intra-EU Import and Export Value (Current Prices)

- **Figure: 16**

2010 Metal Tubes and Pipes
Intra-EU Export and Import Value (Current Prices)

- **Figure: 17**
Evaluation of the Pressure Equipment Directive

Section

Annex 2

Figure: 18

2010 Metal Tube and Pipe Fittings
Intra-EU Import and Export Value (Current Prices)

Figure: 19

2010 Plastic Tubes and Pipes with a Minimum Burst Pressure of 27.6 Mpa
Intra-EU Import and Export Value (Current Prices)
Figure: 20

Figure: 21
Evaluation of the Pressure Equipment Directive

Section

Annex 2

A2

Figure: 22

2010 Valves
Intra-EU Import and Export Value (Current Prices)

Figure: 23

2010 Reciprocating Displacement Compressors
Intra-EU Import and Export Value (Current Prices)
2010 Machinery for Liquefying Air / Gases
Intra-EU Import and Export Value (Current Prices)

Figure: 24

2010 Steam and Sandblasting Machines
Intra-EU Import and Export Value (Current Prices)

Figure: 25

2010 Condensers for Steam and Other Vapour Power Units
Intra-EU Import and Export Value (Current Prices)
Figure: 26

![2010 Heat Exchangers Intra-EU Import and Export Value (Current Prices)]

Figure: 27

![2010 Fire Extinguishers Intra-EU Import and Export Value (Current Prices)]

Figure: 28
International and Internal Market Competitiveness (Extra and Intra-EU Trade) COMEXT DATA

Figure: 29

Figure: 30
Figure: 31

Figure: 32
Annex 2

**Figure: 35**

Valves
Extra-EU Imports and Exports (Constant 2005 Prices)

**Figure: 36**

Sample of Industrial Assemblies
Intra and Extra-EU Imports and Exports (Constant 2005 Prices)


Figure: 37

Figure: 38
Boilers
Intra and Extra-EU Imports and Exports (Constant 2005 Prices)

€Millions

0 500 1,000 1,500 2,000 2,500 3,000 3,500 4,000 4,500

1995 2000 2005 2010

Intra-EU Imports
Intra-EU Exports
Extra-EU Imports
Extra-EU Exports
Origin of EU Imports and Destination of EU Exports COMEXT DATA

Figure: 39

<table>
<thead>
<tr>
<th>Sample of Industrial Assemblies (Origin of Extra-EU Imports)</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>229,507,123</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>142,413,578</td>
</tr>
<tr>
<td>JAPAN</td>
<td>83,293,379</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>12,844,938</td>
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<tr>
<td>BRAZIL</td>
<td>8,920,743</td>
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<tr>
<td>RUSSIAN FED.</td>
<td>6,726,501</td>
</tr>
<tr>
<td>INDIA</td>
<td>4,763,444</td>
</tr>
<tr>
<td>CHINA</td>
<td>145,329,718</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>2,819,433</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample of Industrial Assemblies (Destination of Extra-EU Exports)</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>1,200,228,510</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>219,144,830</td>
</tr>
<tr>
<td>JAPAN</td>
<td>82,362,720</td>
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<tr>
<td>SOUTH KOREA</td>
<td>55,349,279</td>
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<tr>
<td>BRAZIL</td>
<td>29,044,343</td>
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<tr>
<td>RUSSIAN FED.</td>
<td>132,738,778</td>
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<tr>
<td>INDIA</td>
<td>177,305,256</td>
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<tr>
<td>CHINA</td>
<td>282,452,119</td>
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<tr>
<td>SOUTH AFRICA</td>
<td>81,742,428</td>
</tr>
</tbody>
</table>
Figure: 40

2010 Boilers
Origin of Extra-EU Imports

- REST OF WORLD
- UNITED STATES
- JAPAN
- SOUTH KOREA
- BRAZIL
- RUSSIAN FED.
- INDIA
- CHINA
- SOUTH AFRICA

<table>
<thead>
<tr>
<th>Boilers (Origin of Extra-EU Imports)</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>416,184,711</td>
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<td>UNITED STATES</td>
<td>23,621,603</td>
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<td>JAPAN</td>
<td>51,415,106</td>
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<td>SOUTH KOREA</td>
<td>83,902,956</td>
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<td>RUSSIAN FED.</td>
<td>2,397,860</td>
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<td>INDIA</td>
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<td>CHINA</td>
<td>72,181,856</td>
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<tr>
<td>SOUTH AFRICA</td>
<td>144,434</td>
</tr>
</tbody>
</table>

2010 Boilers
Destination of Extra-EU Exports

- REST OF WORLD
- UNITED STATES
- JAPAN
- SOUTH KOREA
- BRAZIL
- RUSSIAN FED.
- INDIA
- CHINA
- SOUTH AFRICA

<table>
<thead>
<tr>
<th>Boilers (Destination of Extra-EU Exports)</th>
<th>2010 Current Prices (€)</th>
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<tbody>
<tr>
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<td>JAPAN</td>
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<td>CHINA</td>
<td>174,349,608</td>
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<td>SOUTH AFRICA</td>
<td>10,713,237</td>
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</table>
Figure: 41

2010 Metal Containers and Containers for Liquids and Gas
Origin of Extra-EU Imports

2010 Metal Containers and Containers for Liquids and Gas
Destination of Extra-EU Exports

Metals Containers and Containers for Liquids and Gas (Origin of Extra-EU Imports)

<table>
<thead>
<tr>
<th>Region</th>
<th>2010 Current Prices ($)</th>
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<td>115,910,971</td>
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<tr>
<td>UNITED STATES</td>
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<td>JAPAN</td>
<td>1,446,089</td>
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<td>SOUTH KOREA</td>
<td>9,010,920</td>
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<td>BRAZIL</td>
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<td>CHINA</td>
<td>46,805,469</td>
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<td>SOUTH AFRICA</td>
<td>776,897</td>
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</table>

Metals Containers and Containers for Liquids and Gas (Destination of Extra-EU Exports)

<table>
<thead>
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<th>Region</th>
<th>2010 Current Prices ($)</th>
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<td>124,674,215</td>
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<td>JAPAN</td>
<td>57,153,613</td>
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<td>SOUTH KOREA</td>
<td>24,288,030</td>
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<td>BRAZIL</td>
<td>21,245,127</td>
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<td>RUSSIAN FED.</td>
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</tr>
<tr>
<td>INDIA</td>
<td>17,857,582</td>
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<tr>
<td>CHINA</td>
<td>91,978,030</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>11,389,789</td>
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</table>
Figure: 42

### 2010 Fire Extinguishers Origin of Extra-EU Imports

<table>
<thead>
<tr>
<th>Country</th>
<th>2010 Current Prices (€)</th>
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<tbody>
<tr>
<td>REST OF WORLD</td>
<td>4,152,787</td>
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<tr>
<td>UNITED STATES</td>
<td>18,386,751</td>
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<tr>
<td>JAPAN</td>
<td>298,305</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>169,822</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>122,172</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>1,177,608</td>
</tr>
<tr>
<td>INDIA</td>
<td>518,132</td>
</tr>
<tr>
<td>CHINA</td>
<td>52,549,749</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>86,038</td>
</tr>
</tbody>
</table>

### 2010 Fire Extinguishers Destination of Extra-EU Exports

<table>
<thead>
<tr>
<th>Country</th>
<th>2010 Current Prices (€)</th>
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<tbody>
<tr>
<td>REST OF WORLD</td>
<td>131,456,085</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>7,649,359</td>
</tr>
<tr>
<td>JAPAN</td>
<td>1,912,903</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>4,734,369</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>1,087,367</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>3,459,602</td>
</tr>
<tr>
<td>INDIA</td>
<td>4,611,475</td>
</tr>
<tr>
<td>CHINA</td>
<td>27,877,738</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>914,165</td>
</tr>
</tbody>
</table>
Figure: 43

### 2010 Heat Exchangers

**Origin of Extra-EU Imports**

- REST OF WORLD
- UNITED STATES
- JAPAN
- SOUTH KOREA
- BRAZIL
- RUSSIAN FED.
- INDIA
- CHINA
- SOUTH AFRICA

### 2010 Heat Exchangers

**Destination of Extra-EU Exports**

- REST OF WORLD
- UNITED STATES
- JAPAN
- SOUTH KOREA
- BRAZIL
- RUSSIAN FED.
- INDIA
- CHINA
- SOUTH AFRICA

---

<table>
<thead>
<tr>
<th>Heat Exchangers (Origin of Extra-EU Imports)</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>181,891,389</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>92,276,774</td>
</tr>
<tr>
<td>JAPAN</td>
<td>21,170,621</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>24,791,964</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>852,687</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>15,158,772</td>
</tr>
<tr>
<td>INDIA</td>
<td>11,602,139</td>
</tr>
<tr>
<td>CHINA</td>
<td>91,745,969</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>498,737</td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>Heat Exchangers (Destination of Extra-EU Exports)</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>873,422,499</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>140,929,158</td>
</tr>
<tr>
<td>JAPAN</td>
<td>20,036,798</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>74,100,264</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>47,552,328</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>135,614,129</td>
</tr>
<tr>
<td>INDIA</td>
<td>50,747,651</td>
</tr>
<tr>
<td>CHINA</td>
<td>215,676,419</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>14,545,487</td>
</tr>
</tbody>
</table>
Figure: 44

### Metal Tube and Pipe Fittings Origin of Extra-EU Imports

<table>
<thead>
<tr>
<th>Country</th>
<th>Value (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>241,187,568</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>156,617,513</td>
</tr>
<tr>
<td>JAPAN</td>
<td>16,686,514</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>24,710,638</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>17,804,012</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>5,019,665</td>
</tr>
<tr>
<td>INDIA</td>
<td>66,686,359</td>
</tr>
<tr>
<td>CHINA</td>
<td>414,114,824</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>1,047,256</td>
</tr>
</tbody>
</table>

### Metal Tube and Pipe Fittings Destination of Extra-EU Exports

<table>
<thead>
<tr>
<th>Country</th>
<th>Value (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>1,354,244,308</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>229,516,146</td>
</tr>
<tr>
<td>JAPAN</td>
<td>11,261,098</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>43,699,588</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>69,778,652</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>131,981,028</td>
</tr>
<tr>
<td>INDIA</td>
<td>55,669,447</td>
</tr>
<tr>
<td>CHINA</td>
<td>120,604,600</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>24,106,365</td>
</tr>
</tbody>
</table>
Figure: 45

### 2010 Metal Tubes and Pipes Origin Extra-EU Imports

- **REST OF WORLD**: 250,054,370
- **UNITED STATES**: 61,790,205
- **JAPAN**: 46,430,300
- **SOUTH KOREA**: 27,261,611
- **BRAZIL**: 808,862
- **RUSSIAN FED.** 27,607,993
- **INDIA**: 86,011,610
- **CHINA**: 203,573,551
- **SOUTH AFRICA**: 44,728,245

### 2010 Metal Tube and Pipes Destination of Extra-EU Exports

- **REST OF WORLD**: 1,060,091,156
- **UNITED STATES**: 489,847,035
- **JAPAN**: 9,604,700
- **SOUTH KOREA**: 116,547,590
- **BRAZIL**: 67,407,013
- **RUSSIAN FED.**: 51,543,978
- **INDIA**: 189,216,615
- **CHINA**: 290,377,337
- **SOUTH AFRICA**: 35,209,046
Figure: 46

2010 Pressure Regulators and Controllers
Origin of Extra-EU Imports

<table>
<thead>
<tr>
<th>Origin</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>22,283,747</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>20,466,049</td>
</tr>
<tr>
<td>JAPAN</td>
<td>4,222,029</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>235,183</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>49,338</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>24,053</td>
</tr>
<tr>
<td>INDIA</td>
<td>148,387</td>
</tr>
<tr>
<td>CHINA</td>
<td>6,084,197</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>100,258</td>
</tr>
</tbody>
</table>

2010 Pressure Regulators and Controllers
Destination of Extra-EU Exports

<table>
<thead>
<tr>
<th>Destination</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>79,943,805</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>71,790,310</td>
</tr>
<tr>
<td>JAPAN</td>
<td>52,704,721</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>16,909,885</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>4,973,978</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>10,811,469</td>
</tr>
<tr>
<td>INDIA</td>
<td>8,573,801</td>
</tr>
<tr>
<td>CHINA</td>
<td>46,234,658</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>25,336,809</td>
</tr>
</tbody>
</table>
Figure: 47

### 2010 Safety or Relief Valves
#### Origin of Extra-EU Imports

<table>
<thead>
<tr>
<th>Country</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>60,547,477</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>101,646,917</td>
</tr>
<tr>
<td>JAPAN</td>
<td>26,624,076</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>7,746,218</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>1,695,682</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>719,141</td>
</tr>
<tr>
<td>INDIA</td>
<td>2,477,221</td>
</tr>
<tr>
<td>CHINA</td>
<td>26,970,482</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>284,968</td>
</tr>
</tbody>
</table>

### 2010 Safety or Relief Valves
#### Destination of Extra-EU Exports

<table>
<thead>
<tr>
<th>Country</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>238,595,845</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>60,817,315</td>
</tr>
<tr>
<td>JAPAN</td>
<td>10,645,221</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>12,695,172</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>16,927,345</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>32,784,532</td>
</tr>
<tr>
<td>INDIA</td>
<td>9,595,761</td>
</tr>
<tr>
<td>CHINA</td>
<td>73,030,724</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>10,374,312</td>
</tr>
</tbody>
</table>
Figure: 48

### 2010 Valves Origin of Extra EU Imports

<table>
<thead>
<tr>
<th>Origin of Extra EU Imports</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>1,270,890,312</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>1,031,429,480</td>
</tr>
<tr>
<td>JAPAN</td>
<td>259,150,665</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>52,768,739</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>37,236,192</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>4,492,337</td>
</tr>
<tr>
<td>INDIA</td>
<td>137,503,513</td>
</tr>
<tr>
<td>CHINA</td>
<td>1,803,840,748</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>8,550,268</td>
</tr>
</tbody>
</table>

### 2010 Valves Destination of Extra EU Exports

<table>
<thead>
<tr>
<th>Destination of Extra EU Exports</th>
<th>2010 Current Prices (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>REST OF WORLD</td>
<td>5,961,446,787</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>1,434,383,488</td>
</tr>
<tr>
<td>JAPAN</td>
<td>150,318,248</td>
</tr>
<tr>
<td>SOUTH KOREA</td>
<td>279,058,047</td>
</tr>
<tr>
<td>BRAZIL</td>
<td>248,244,831</td>
</tr>
<tr>
<td>RUSSIAN FED.</td>
<td>801,863,810</td>
</tr>
<tr>
<td>INDIA</td>
<td>292,899,332</td>
</tr>
<tr>
<td>CHINA</td>
<td>1,432,269,086</td>
</tr>
<tr>
<td>SOUTH AFRICA</td>
<td>141,883,268</td>
</tr>
</tbody>
</table>
**ANNEX 3 – PED Business Survey**

**PED Business Survey (96 Responses)**

Please indicate your company type *(please tick all that apply)*

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Supplier</td>
<td>4</td>
<td>4.2</td>
</tr>
<tr>
<td>Designer</td>
<td>44</td>
<td>45.8</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>68</td>
<td>70.8</td>
</tr>
<tr>
<td>Installer</td>
<td>28</td>
<td>29.2</td>
</tr>
<tr>
<td>User</td>
<td>9</td>
<td>9.4</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>5.2</td>
</tr>
</tbody>
</table>

What type of pressure equipment do you produce / use? *(please tick all that apply)*

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vessels / Piping</td>
<td>71</td>
<td>74.0</td>
</tr>
<tr>
<td>Safety Accessories</td>
<td>29</td>
<td>30.2</td>
</tr>
<tr>
<td>Pressure Accessories</td>
<td>36</td>
<td>37.5</td>
</tr>
<tr>
<td>Industrial Assemblies</td>
<td>44</td>
<td>45.8</td>
</tr>
<tr>
<td>Consumer Assemblies</td>
<td>9</td>
<td>9.4</td>
</tr>
<tr>
<td>Boilers</td>
<td>24</td>
<td>25.0</td>
</tr>
<tr>
<td>Other</td>
<td>12</td>
<td>12.5</td>
</tr>
</tbody>
</table>

Can you describe how your company is organised? *(please tick all that apply)*

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based in one EU country (both production &amp; sales)</td>
<td>50</td>
<td>52.1</td>
</tr>
<tr>
<td>Production in more than one EU country</td>
<td>27</td>
<td>28.1</td>
</tr>
<tr>
<td>Sales in more than one EU country</td>
<td>44</td>
<td>45.8</td>
</tr>
<tr>
<td>Firm with branches outside Europe</td>
<td>40</td>
<td>41.7</td>
</tr>
<tr>
<td>Branch/ subsidiary of a Non-EU company</td>
<td>17</td>
<td>17.7</td>
</tr>
</tbody>
</table>

Total number of employees in your company

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 10</td>
<td>6</td>
<td>6.3</td>
</tr>
</tbody>
</table>
### Evaluation of the Pressure Equipment Directive Section Annex 3

#### A3

<table>
<thead>
<tr>
<th>Category</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 to 50</td>
<td>17</td>
<td>17.7</td>
</tr>
<tr>
<td>51-250</td>
<td>31</td>
<td>32.3</td>
</tr>
<tr>
<td>Over 250</td>
<td>42</td>
<td>43.8</td>
</tr>
<tr>
<td>No response</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>96</td>
<td>100.0</td>
</tr>
</tbody>
</table>

What proportion of the products that you produce / use fall under the scope of the PED?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20%</td>
<td>13</td>
<td>13.5</td>
</tr>
<tr>
<td>21-4%</td>
<td>14</td>
<td>14.6</td>
</tr>
<tr>
<td>41-60%</td>
<td>20</td>
<td>20.8</td>
</tr>
<tr>
<td>61-80%</td>
<td>23</td>
<td>24.0</td>
</tr>
<tr>
<td>81-100%</td>
<td>23</td>
<td>24.0</td>
</tr>
<tr>
<td>No response</td>
<td>3</td>
<td>3.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>96</td>
<td>100.0</td>
</tr>
</tbody>
</table>

What proportion of the pressure equipment that you produce / use is manufactured outside of Europe?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20%</td>
<td>59</td>
<td>61.5</td>
</tr>
<tr>
<td>21-4%</td>
<td>11</td>
<td>11.5</td>
</tr>
<tr>
<td>41-60%</td>
<td>16</td>
<td>16.7</td>
</tr>
<tr>
<td>61-80%</td>
<td>4</td>
<td>4.2</td>
</tr>
<tr>
<td>81-100%</td>
<td>2</td>
<td>2.1</td>
</tr>
<tr>
<td>No response</td>
<td>4</td>
<td>4.2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>96</td>
<td>100.0</td>
</tr>
</tbody>
</table>

In general, do you consider that pressure equipment manufactured outside the EU is of a high quality?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly agree</td>
<td>2</td>
<td>2.1</td>
</tr>
<tr>
<td>Agree</td>
<td>22</td>
<td>22.9</td>
</tr>
<tr>
<td>Neutral</td>
<td>37</td>
<td>38.5</td>
</tr>
</tbody>
</table>

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Evaluation of the Pressure Equipment Directive

Annex 3

Selected Open Responses to the Above Question

- It depends on the country;
- It depends on the company and their understanding of quality requirements;
- US equipment meets safety requirements;
- Well known companies tend to produce quality products;
- It depend on the country - USA, Canada, Korea, Japan meet the same quality standards as Europe. But from new markets like India/Cina the traceability and quality are lower
- We believe that outside the EU they do not fully understand the PED 97/23/EC and the quality could be lower;
- You can't answer this question with a tick. Equipment manufactured in Japan, USA, Korea is generally good quality. Equipment manufactured in China may be of a lower quality;
- You have to source and follow-up to be safe;

Is the PED more effective than the previous system of national regulation?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly agree</td>
<td>13</td>
<td>13.5</td>
</tr>
<tr>
<td>Agree</td>
<td>36</td>
<td>37.5</td>
</tr>
<tr>
<td>Neutral</td>
<td>23</td>
<td>24.0</td>
</tr>
<tr>
<td>Disagree</td>
<td>17</td>
<td>17.7</td>
</tr>
<tr>
<td>Strongly disagree</td>
<td>3</td>
<td>3.1</td>
</tr>
<tr>
<td>Don't know/no response</td>
<td>4</td>
<td>4.2</td>
</tr>
<tr>
<td>Total</td>
<td>96</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Selected Open Responses to the Above Question

- One regulation for the EU is positive instead of separate regulations in each country.
- One common system supersedes national interests;
Although the previous national regulations caused problems by being different the present system is no better as many notified bodies still act as if the national regulations apply and frequently apply less stringent surveillance to companies in their own country. The interpretations of the PED by the notified bodies also varies. This can often be seen when equipment from several countries/notified bodies are assembled in a plant. Unless the end user is strongly involved significant differences can be observed. In addition many engineers in notified bodies have insufficient understanding of process conditions to evaluate use of materials or the influence of process conditions. Manufacturers of vessels and piping for larger units or plants have normally no understanding of process conditions and constraints.

The PED is more effective on operation, inspection and risks analysis but less effective on materials, mfg control, and calculation.

National regulation had less problems regarding interpretation and application.

The UK regulations achieved the same function.

There is a very poor information system. Only few companies understand the requirements. It seems to me that only the metal market is oriented to fulfil the PED philosophy while the plastic market is totally unaware.

Very difficult to know the QA/QC level of PED products. No effective quality guarantee from NoBo system.

What, if any, are the barriers to an effective application of the PED? Please can you prioritise the potential barriers below from 0 (the barrier does not exist) to 5 (very strong barrier)

<table>
<thead>
<tr>
<th>Barriers</th>
<th>No opinion</th>
<th>5-very strong barrier</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
<th>0-the barrier does not exist</th>
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<td>19</td>
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</tbody>
</table>

Selected Open Responses to the Above Question

How should strong barriers be overcome?
• Application of all regulations equally and fairly by all parties;
• One regulation for inspection regimes instead of national regulations (example Cahier Technique France)
• The EU should stop national regulations outside PED. For example in Germany and Austria you have to choose TUV as NoBo. For example in France, Greek and Spain there are tens of NoBos which may not meet the standards. Major NoBos acting outside EU apply very free ofPED Guidelines, the PED and approve CE marking as ASME being equivalent to the PED;
• For major plant transfer the responsibility to the end user or the engineering company which have a more complete understanding of how the equipment should be used and what dangers are involved in the use. For individual units not supplied to major end users the responsibility should still be with the manufacturer when the units are sold for "general use";
• More direct intervention by the EU to ensure local regulations are not used to maintain National Standards;
• The directives and standards are interpreted different between different notified bodies. More special PED Guidelines are required.
• The same in-service regulation in Europe should be introduced;
• Training and education of personnel in notified bodies should be improved;
• Unifying criteria for the selection and operation of Notified Bodies

What proportion of the pressure equipment that you produce / use has been manufactured to EN standards?

<table>
<thead>
<tr>
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</thead>
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<td>21-4%</td>
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<td>41-60%</td>
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<td>61-80%</td>
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<tr>
<td>Total</td>
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Do you consider that using EN standards for designing pressure equipment leads to overall lower production costs in comparison with other standards and codes?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td>19</td>
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</table>
Are you aware of any problems that manufacturers have experienced in placing pressure equipment on the market in another EU Member State other than the one where it was produced?

<table>
<thead>
<tr>
<th>Options</th>
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<th>%</th>
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<tbody>
<tr>
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<tr>
<td>Total</td>
<td>96</td>
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</tr>
</tbody>
</table>

Selected Open Responses to the Above Question

- Denmark - They require a separate third party (notified body, DNV Denmark) to do a full PED approval, even though this has already been performed. They also have their own interpretations of the standards, which is not the same as our notified bodies (DNV Norway and Inspecta Norway)
- France : Higher UTS values required & extra X ray requirements
- France: AFIAP requirements for pressure test;
- France is protective of its own industry;
- Germany - Insists that safety valves must have individual certificates and unique serial numbers;
- Germany QA module and notified body given by buyer instead of manufacturer;
- Germany if AD Merkblatt is not used as design code;
- in service inspections requesting certificates and additional data which are not required for PED in Italy, Netherlands, France;
- Italy. The problem was the interpretation of point 7.5. of Annex I in steam boiler application.
- Poland, does not recognise the new legislation i.e. by the local authorities (UDT). Germany, acceptance of PED certified products only if verified by TÜV according to AD-Merkblatt
- Some countries/notified bodies have required more rigid in service inspection when products are made to EN standards or by foreign companies.

To what extent does the PED incur administrative burdens and costs for businesses?
Annex 3

Options | Nº | %
---|---|---
Very high | 3 | 3.1
High | 32 | 33.3
Neutral | 32 | 33.3
Low | 20 | 20.8
Very low | 3 | 3.1
Don't know/no response | 6 | 6.3
Total | 96 | 100.0

Selected Open Responses to the Above Question

- Costs are often higher for certified products, compared to the same, but not certified, product.
- Few end users are very concerned about EU directives (PED, MD, ...) when buying refrigeration systems, leading to unfair business.
- High costs of management (tests, documents and so on) than the old national regulation.
- If you follow the directive from the beginning the total cost will decrease. The main problem is the way contracts are written - the scope is split and is complicating things and it is difficult to coordinate.
- We are a major process plant engineering, procurement and construction contractor (for refinery, oil & gas and petrochemicals) who does most work outside Europe. PED is useful in being able to design with confidence for use in various countries. Most clients do not use EN standards but use ASME. However since clients define the standards we should work to, we are rarely asked to consider EN standards. Also fabricators outside Europe are unfamiliar with EN. We do not work in France or Germany as clients in those countries prefer to use their own country contractors. We understand that in Germany there are "in use" requirements that can discriminate against products but have had no experience ourselves of that.
- We find it difficult to use the EN design standards fully as raw material delivered to harmonised standards often are more difficult to get, have longer lead times and are more expensive.
- In my experience I would not rely solely on CE marking as a form of assurance. The additional QA applied is at my cost.
- Extra discussions with manufacturer and notified bodies to explain process needs, often with several notified bodies repeating the same arguments. Own inspection could not be reduced as cases where notified bodies have accepted deviations from specification (which were process related) have been occurring. Linguistic problems are well known.
**ANNEX 4 – PED Stakeholder Survey**

**PED Stakeholder Survey (53 Responses)**

Please indicate what best describes your position

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<thead>
<tr>
<th>Options</th>
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<td>Standardisation Expert or Body</td>
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</tr>
<tr>
<td>Pressure Equipment Expert or Institution</td>
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<td>Other</td>
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<td><strong>Total</strong></td>
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In which country are you based?

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<th>Country</th>
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In general, do you consider that pressure equipment manufactured outside the EU is of a high quality?

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<tr>
<td>Strongly disagree</td>
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<td>5.7</td>
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<tr>
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<tr>
<td><strong>Total</strong></td>
<td>53</td>
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</tbody>
</table>

Selected Open Responses to the Above Question

- Chinese and Turkish companies producing pressure equipment contact us with request to be authorized to perform NDT and DT including Conformity Assessment of their production. After we have explained in details the requirements of Directives for Pressure Equipment, Pressure Vessels and Transportable Pressure Equipment and the procedures to be followed, our correspondence usually stops. This makes me think that companies from outside EU make attempts to produce and introduce to European market pressure equipment of unclear quality;

- I have bad experiences with Chinese pressure equipment but there are imported vessels from other countries that are of a good quality;

- It should be case by case assessed: it depends on the application sector (consumer product, serial product, specific industry product, ...), on the origin country, on the involvement of the user and notified body;

- PE manufactured outside EU can be of variable quality depending on the manufacturer and the location. The answer given is for some of the countries located in Asia;

- Some players from China, India and South Korea are advancing. Imports from China and India do not always comply with PED;

- Pressure Equipment manufactured outside the EU and which is put on the market in the EU is generally safe. Quality goes beyond safety.

- There still are some manufacturers (China/India) that are not producing their pressure equipment according to the European and Japanese quality standards;

Is the PED more effective than the previous system of national regulation?
Evaluation of the Pressure Equipment Directive

Annex 4

<table>
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<tr>
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<tr>
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<td><strong>Total</strong></td>
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</tr>
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</table>

Selected Open Responses to the Above Question

- All operators can have the same framework. Exchange of information as well as possible comparison works are easier and more effective;
- All pressure equipment are now regulated > 0,5 bar;
- As a system, yes, for sure, but only when correctly applied;
- EU Joining of Bulgaria and adoption of PED led to implementation of new norms and standards. These new requirements made us improve the technological level of personnel qualification and equip our laboratories for NDT and DT with new technical devices for testing and inspection;
- In the Refrigeration, Heating, Ventilation and Air Conditioning (RHVAC) Industry we are still experiencing a lack of enforcement in our country this influences the effectiveness of the regulation enormously;
- More effective for the free movement of goods;
- Many technical barriers were effectively removed;
- The requirements are satisfactory but the market surveillance process has become more complicated and bureaucratic and we don't have enough resources to carry it out efficiently;
- There is big difference between notified bodies. The use of EN- standards should be mandatory.
What, if any, are the barriers to an effective application of the PED? Please can you prioritise the potential barriers below from 0 (the barrier does not exist) to 5 (very strong barrier)

<table>
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<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<td>%</td>
<td>Nº</td>
<td>%</td>
<td>Nº</td>
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<td>national in-service inspection regimes</td>
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<td>5</td>
<td>9.4</td>
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</tbody>
</table>

Selected Open Responses to the Above Question

How should strong barriers be overcome?

- Concise clear guidance with examples. For example; three notified bodies gave three different opinions regarding the CE marking of pipework. Perhaps there should be a directive on in-service inspection for the community. Why keep the simple pressure vessel directive can this not be covered by the PED? This would also remove the issue of simple pressure vessels being used for fluids other than air or nitrogen which has been an issue our company has raised a few times on CO2 installations.

- Inspectors of notified bodies must have the same level of knowledge of EN-standards and they must past the same examination.

- A better and more consistent control on accreditation bodies and notified bodies. Most of the accreditation bodies have poor knowledge of Directives, incompetent staff etc. This has as a result accreditations/notifications to be granted to inspection bodies that shouldn’t get them and which subsequently are offering very low quality of services. A thorough market research could prove that a number of pressure equipment (vessels, piping, assemblies etc.) is being CE marked without complying with PED.

- A very strong barrier to effective application of the PED in the RHVAC industry in the
Netherlands is enforcement. Almost 50% of the RHVAC installations/equipment are not complying with the PED in the Netherlands due to a lack of enforcement by the authorities. This could be overcome by implementing a web-based quality control and enforcement system in which all RHVAC installation are registered. This system enables governmental and local authorities to enforcement all regulations regarding to RHVAC installations/equipment. There also is an enormous difference in application of the PED in the EU member states. This causes an uneven playing field for Dutch contactors/suppliers when they are crossing the border.

- Actually NoBo Notification schemes may be different depending by which are the Member states as well as market surveillance processes. Common rules could be established in order to guarantee the same approach

- More cooperation between NBs, manufacturers and authorities. More PED Guidelines or a revision of some clauses of the PED.

- Specific investigations of allegations and /or reported "near misses" with results published, possibly with (legal) sanctions against "offenders". Examples of particular countries are well-known. Certain Notified Bodies never participate in the Conformity Assessment Body Forum and several are known to sanction unacceptable practices, However but there is never the (independent) resource or commitment to investigate these allegations and apparently no sanctions that could be applied

- PED should replace all national rules.
What proportion of the pressure equipment that you oversee or relate to your area of speciality is designed to EN standards?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
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<td>7.5</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Can you estimate what type of pressure equipment is likely to be designed to EN standards? Please can you prioritise the below pressure equipment from 0 (very unlikely to be designed to EN standards) to 5 (very likely to be designed to EN standards)

<table>
<thead>
<tr>
<th>Options</th>
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</tr>
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Do you consider that using EN standards for designing pressure equipment leads to overall lower production costs for manufacturers in comparison with other standards and codes?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>16</td>
<td>30.2</td>
</tr>
<tr>
<td>No</td>
<td>22</td>
<td>41.5</td>
</tr>
<tr>
<td>Don't know/no response</td>
<td>15</td>
<td>28.3</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>100.0</td>
</tr>
</tbody>
</table>
Are you aware of any problems that manufacturers have experienced in placing pressure equipment on the market in another EU Member State other than the one where it was produced?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>14</td>
<td>26.4</td>
</tr>
<tr>
<td>No</td>
<td>39</td>
<td>73.6</td>
</tr>
<tr>
<td>No response</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>100.0</td>
</tr>
</tbody>
</table>

**Selected Open Responses to the Above Question**

- Austria, France and Germany for "political" reasons related to in-service rules or as a result of lack of understanding in the receiving county;
- France DM-T/P 32974, deviation with PED (additional);
- Germany: difference of periodicity for periodic inspections;
- In France: CE marking using a Particular Material Appraisal from a foreign Notified Body not fully accepted by authorities;
- Lack of understanding on the testing of assemblies. French body expecting the assembly to be hydrotested;
- Still German customers may request German rules;
- The problems have occurred in France and Poland. Additional requirements were required in order to privilege local manufacturers.

To what extent does the PED incur administrative burdens and costs for businesses?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very high</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>High</td>
<td>10</td>
<td>18.9</td>
</tr>
<tr>
<td>Neutral</td>
<td>29</td>
<td>54.7</td>
</tr>
<tr>
<td>Low</td>
<td>5</td>
<td>9.4</td>
</tr>
<tr>
<td>Very low</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>Don’t know/no response</td>
<td>8</td>
<td>15.1</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>100.0</td>
</tr>
</tbody>
</table>
Please add any additional comments

- At the time of development of the Directive, there was a large internal market. The focus should now be changed to the Global Marketplace and new rules devised;

- Harmonization of Notified Bodies' practices in assessment of PED conformity (PQR, WPS, EPM, Design...) would be very helpful;

- PED has great importance and among other things: 1) Improve the functioning of the EU internal market in practice and free movement within the Community in pressure equipment sector 2) Strengthening of market surveillance at European level 3) Improve transparency in the conformity assessment 4) Improve and strengthen the pressure equipment safety level in pressure equipment sector 5) Ensure greater coherence and consistency between directives. PED Guidelines have great importance and very support the correct interpretation, application and uniform interpretation and implementation of the Directive on pressure equipment (PED);

- The increasing competition of emerging countries has meant the appearance of new players which are not necessarily of full guarantee as they rely their competitiveness on low price rather than quality and service. A stronger observation of the quality assessment systems of manufacturers should be part of the agenda. A more strict market surveillance mechanism should be enforced by the Commission, including the participation of Member States;

- I design locomotive type boilers mostly as replacements for historic items. There are no EN standards that are applicable and very few relevant national standards. There is currently only one notified body in the UK with sufficient experience to be able to appraise such designs which may become a problem in the future.

- In the field of industrial valves, harmonised European Standards are not commonly asked by end users or EPCs, because of very long experience with ASME and API for example. As a result, "European" materials are not common and are expensive. Another peculiarity is that valves standards foresee the use of ASME grades, but these grades are not "harmonized". As a consequence, there are different interpretation on the conformity of valves made of ASME materials between manufacturers, NBs and authorities.

- The relationship of the PED with other regulations shall be ensured when the other are revised. Especially, the alignment to NLF and CLP are required.
ANNEX 5 - PED Installation Industry Survey

PED Installation Industry Survey

_The Survey Mainly Reflects the Views of the Netherlands Refrigeration and Air Conditioning Installation Industry_\(^{136}\) (30 Responses)

Please indicate your company type (please tick all that apply)

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Supplier</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>Designer</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>6</td>
<td>20.0</td>
</tr>
<tr>
<td>Installer</td>
<td>22</td>
<td>73.3</td>
</tr>
<tr>
<td>User</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

What type of pressure equipment do you produce / use? (Please tick all that apply)

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vessels / Piping</td>
<td>17</td>
<td>56.7</td>
</tr>
<tr>
<td>Safety Accessories</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>Pressure Accessories</td>
<td>11</td>
<td>36.7</td>
</tr>
<tr>
<td>Industrial Assemblies</td>
<td>14</td>
<td>46.7</td>
</tr>
<tr>
<td>Consumer Assemblies</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>Boilers</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>6.7</td>
</tr>
</tbody>
</table>

Can you describe how your company is organised? (Please tick all that apply)

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based in one EU country (both production &amp; sales)</td>
<td>21</td>
<td>70.0</td>
</tr>
<tr>
<td>Production in more than one EU country</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Sales in more than one EU country</td>
<td>7</td>
<td>23.3</td>
</tr>
</tbody>
</table>

\(^{136}\) Netherlands Association of Refrigeration Engineering and Air Treatment Companies (NVKL)
Firm with branches outside Europe                4  13.3  
Branch/ subsidiary of a Non-EU company          2  6.7

**Total number of employees in your company**

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 10</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>10 to 50</td>
<td>13</td>
<td>43.3</td>
</tr>
<tr>
<td>51-250</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>Over 250</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>No response</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>30</td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

**What proportion of the products that you produce / use fall under the scope of the PED?**

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20%</td>
<td>8</td>
<td>26.7</td>
</tr>
<tr>
<td>21-4%</td>
<td>8</td>
<td>26.7</td>
</tr>
<tr>
<td>41-60%</td>
<td>6</td>
<td>20.0</td>
</tr>
<tr>
<td>61-80%</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>81-100%</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>No response</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>30</td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

**What proportion of the pressure equipment that you produce / use is manufactured outside of Europe?**

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20%</td>
<td>14</td>
<td>46.7</td>
</tr>
<tr>
<td>21-4%</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>41-60%</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>61-80%</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>81-100%</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5</td>
<td><strong>197</strong></td>
</tr>
</tbody>
</table>
### In general, do you consider that pressure equipment manufactured outside the EU is of a high quality?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly agree</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>Agree</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>Neutral</td>
<td>12</td>
<td>40.0</td>
</tr>
<tr>
<td>Disagree</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Strongly disagree</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Don't know/no response</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

### Is the PED more effective than the previous system of national regulation?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly agree</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Agree</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>Neutral</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>Disagree</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>Strongly disagree</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>Don't know/no response</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>
What, if any, are the barriers to an effective application of the PED? Please can you prioritise the potential barriers below from 0 (the barrier does not exist) to 5 (very strong barrier)

<table>
<thead>
<tr>
<th>Inconsistent:</th>
<th>0 - The barrier does not exist</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5 - Very strong barrier</th>
<th>No opinion</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>enforcement of the rules by government authorities</td>
<td>3</td>
<td>10.0</td>
<td>4</td>
<td>13.3</td>
<td>2</td>
<td>6.7</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>interpretation of the Directive and requirements by Notified Bodies</td>
<td>2</td>
<td>6.7</td>
<td>6</td>
<td>20.0</td>
<td>3</td>
<td>10.0</td>
<td>13</td>
<td>43.3</td>
</tr>
<tr>
<td>application of the EU guidelines</td>
<td>6</td>
<td>20.0</td>
<td>6</td>
<td>20.0</td>
<td>4</td>
<td>13.3</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>national level guidelines</td>
<td>4</td>
<td>13.3</td>
<td>6</td>
<td>20.0</td>
<td>7</td>
<td>23.3</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>national in-service inspection regimes</td>
<td>6</td>
<td>20.0</td>
<td>3</td>
<td>10.0</td>
<td>3</td>
<td>10.0</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>interaction with the Transportable Pressure Equipment Directive</td>
<td>10</td>
<td>33.3</td>
<td>3</td>
<td>10.0</td>
<td>4</td>
<td>13.3</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>interaction with the Simple Pressure Vessels Directive</td>
<td>11</td>
<td>36.7</td>
<td>4</td>
<td>13.3</td>
<td>2</td>
<td>6.7</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>interaction with the Machinery Directive</td>
<td>9</td>
<td>30.0</td>
<td>3</td>
<td>10.0</td>
<td>5</td>
<td>16.7</td>
<td>6</td>
<td>20.0</td>
</tr>
</tbody>
</table>

What proportion of the pressure equipment that you produce / use has been manufactured to EN standards?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-20%</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>21-4%</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>41-60%</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>61-80%</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>81-100%</td>
<td>17</td>
<td>56.7</td>
</tr>
<tr>
<td>No response</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Do you consider that using EN standards for designing pressure equipment leads to overall lower production costs in comparison with other standards and codes?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>20</td>
<td>66.7</td>
</tr>
<tr>
<td>No</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>Don’t know/no response</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>
Are you aware of any problems that manufacturers have experienced in placing pressure equipment on the market in another EU Member State other than the one where it was produced?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>11</td>
<td>36.7</td>
</tr>
<tr>
<td>No</td>
<td>19</td>
<td>63.3</td>
</tr>
<tr>
<td>No response</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

To what extent does the PED incur administrative burdens and costs for businesses?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very high</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>High</td>
<td>22</td>
<td>73.3</td>
</tr>
<tr>
<td>Neutral</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Low</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Very low</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Don’t know/no response</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Summary of comments from the NVKL association members (Netherlands)

- The PED has made regulation of the installation industry more complicated;
- The regulation lacks effectiveness due to a lack of even enforcement in the Netherlands;
- There is a lack of a level playing field within Europe in relation to foreign contractors/installers;
- Consistent and effective enforcement by the authorities will improve the effectiveness of the PED and result in a level playing field in all MS of the EU;
- There are different interpretations of the directive in the MS and different elaboration of the rules in national regulations;
- The PED creates an administrative burden for business (especially for small companies);
- There is a lack of alignment with other EU-regulations regarding air conditioning and refrigeration installations (F-Gas Regulation, Ozone Depleting Substance Regulation, Energy Performance of Buildings Directive, Renewable Energy Sources Directive)
The Selection of Indicators for the Pressure Equipment Directive

One of the aims of evaluation has been to highlight a relevant set of indicators with a view to assisting the development of an on-going assessment of the Directive and thus contributing to the process of evidence-based policy making. This will help DG Enterprise and Industry to assess the ongoing performance of the sector and the implementation of the Directive.

The appropriate selection of indicators should take into account the guidance of the Commission and DG Enterprise and Industry that has already been established to support the development of such frameworks. The Secretariat General’s ‘Practical Guide on Objectives and Indicators’ emphasises the need for a practical approach to the definition of objectives and indicators and sets out a number of helpful examples of how this approach can be applied in particular circumstances.

In addition there is guidance that has already been developed by CSES specifically for DG Enterprise and Industry that should be observed. This includes the ‘Operational Guidance on Indicators’ (released in February 2010) and the framework offered by the ‘Operational Guidance on Formulating the Objectives and Indicators of the Management Plan’, (released in October 2010). These reports echo some of the findings that have already been established in the existing Commission documentation and reinforce and further develop a number of principles that are of direct relevance to DG Enterprise and Industry. As specified by the previous research, in formulating the indicators, there should be recognition of the Intervention Logic which sets out the objectives, implementation mechanisms and intended results of the policy or measure intended for assessment. At an operational level, it helps to frame two central questions:

- What is the specific legislation or measure under consideration trying to achieve?
- What can best illustrate the extent to which the objectives are in fact being achieved?

In responding to these questions there are a number of practical considerations that should be taken into account. Indicators should be developed with due regard to the principle of proportionality, they should be easy to measure and be kept as simple as possible. There should also be consideration of the administrative burden imposed, the time and resources necessary for the collection of the information needed and the possible data constraints. As a result:

- Indicators should not disrupt the measures they are trying to promote;
- Existing indicators and existing data should be used where possible;
- There should not be too many indicators. They are meant to assist understanding of how policy is developing, not obscure it in a mass of indigestible detail;

It is also worth remembering that indicators are not intended of themselves to give a complete picture. They are intended to ‘indicate’ important developments and sometimes will only do so indirectly, when it is not possible to capture the direct effects. The proposed indicators should contribute to the effective communication of the achievements of EU policy, illustrate its responsiveness to the needs of enterprises and the broader community and contribute to the effective discharge of the requirements of accountability on the part of those responsible for implementing the legislation. Finally, it is important to recognise that for indicators to have meaning they need to be stable over time and establish continuity in the monitoring system.
Pressure Equipment Directive Indicators

The proposed indicators are listed below, along with indications of where the corresponding data are to be found:

The Performance and Competitiveness of Industry and the Internal Market

*Growth in Real Economic Output* (% change in *Production Value EUR* from previous year, *at constant prices*) The production value variable relates to the annual value of goods sold and mirrors a major indicator in the DG Enterprise and Industry Management Plan. The ongoing performance of European industry can be assessed based on changes in the aggregate of selected PRODCOM codes that are outlined in table 5.1 in the evaluation report (*relevance – quantitative section*). These relate to specific product groups (further assessment of individual subsectors can be undertaken through the examination of disaggregated data). The GDP Deflator (relating to the 2005 index) can be used to identify the rate of real growth.

*Development of the Internal Market (Intra-EU Exports EUR)* The intra-EU exports variable provides data on the annual value of goods exported between the Member States. The ongoing performance of the Internal Market (and the relative performance of individual Member States) can be assessed based on the product group aggregates of selected PRODCOM codes that are outlined in table 5.1 (*relevance – quantitative section*). Further assessment of individual subsectors can be undertaken through the examination of disaggregated data. The GDP Deflator (relating to the 2005 index) can be used to identify the rate of real growth. This indicator mirrors the ‘Volume of intra-EU 27 trade’ in the Management Plan.

*International Competitiveness (Exports)* The extra-EU export variable provides data on the annual value of goods exported between the EU and specified international trading partners. The ongoing performance of extra-EU exports can be assessed based on the aggregate of selected SITC codes that relate to specific product groups (within the COMEXT database) that are outlined in table 5.1 (*relevance – quantitative section*). Further examination of individual subsectors can be undertaken through the examination of disaggregated data. The GDP Deflator (relating to the 2005 index) can be used to identify the rate of real growth.

*International Competitiveness (Imports)* The extra-EU trade variables provide data on the annual value of goods imported to the EU from specified international trading partners. The ongoing value of extra-EU imports can be assessed overall (along with the identification of the top three trading partners) based on the aggregate of selected SITC codes that relate to specific product groups (within the COMEXT database) that are outlined in table 5.1 (*relevance – quantitative section*). Further examination of individual subsectors can be undertaken through the examination of disaggregated data. The GDP Deflator (relating to the 2005 index) can be used to identify the rate of real growth.

Enforcement of the Directive and the New Legislative Framework

*The number of notifications under the Safeguard Clause* (Article 8) provides national authorities with the means to develop European-wide responses in response to the identification of non-conforming products with a view to removing the product from the Internal Market. The number of occasions that this has been called upon to develop a response will provide an indication of the commitment of Member States to appropriately enforce the Directive.

137 Currently, it appears that there are a number of data gaps at Member State level. Therefore production value data may continue to relate to the performance of the EU 27 only.
The number of market surveillance reports being made available on RAPEX and ICSMS. The number of reports and product warnings on Member State RAPEX and ICSMS could be monitored. This would indicate the level of surveillance activity, the nature of the responses and the extent of non-conforming products on the market.

Number of legal actions against organisations that operate contrary to the legislative requirements of the PED. The number of legal actions against illegally operating organisations will provide an indication of the extent to which the requirements of the Directives for serious failings are being implemented.

Total number of NB notifications and number of withdrawals of notification. This would allow for comparison of the performance between Member States and between NBs (the performance variables may also be monitored more informally, including the level of attendance at CABF meetings and the extent to which conformity assessment documentation coherently relates to the associated pressure equipment).

Total number of certificates withdrawn by NBs from manufacturers. Assessing the reporting mechanism within the CABF for certificates withdrawn by NBs from manufacturers would allow for monitoring of the extent to which NBs are holding poorly performing manufacturers to account.

The Promotion, Development and Use of Innovative European Standards

Number of (SME) experts participating in Technical Committees. The number of experts (and those representing SMEs) participating in technical committees should be monitored. This will provide an indication of the quality and representativeness of the standards under preparation.

Rate of national uptake of European standards. The rate of uptake and promotion of EN standards through national bodies should be monitored. This will provide an indication of the anticipated level of uptake by industry.

Rate of uptake of European standards by industry. The extent of uptake across various pressure equipment sectors should be monitored (CEN surveys and data collected from NBs). This should identify areas of the market that may require specific attention in order to address the problems of poor uptake.