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**EVALUATION**

# OF THE PRESSURE EQUIPMENT DIRECTIVE (2014/68/EU) AND THE SIMPLE PRESSURE VESSELS DIRECTIVE (2014/29/EU)

{SWD(2026) 328 final}

# Table of Contents

1. INTRODUCTION ..... 3
2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION? ..... 5
2.1 Description of the intervention and its objectives ..... 5
2.2 Point(s) of comparison ..... 9
3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD? ..... 9
3.1 Evolution of the market for pressure equipment ..... 9
3.2 Implementation of the PED and SPVD – state of play ..... 11
4. EVALUATION FINDINGS (ANALYTICAL PART) ..... 14
4.1 To what extent was the PED/SPVD successful and why? ..... 14
4.2 How did the PED and SPVD make a difference and to whom? ..... 32
4.3 Are the PED and SPVD still relevant? ..... 33
5. WHAT ARE THE CONCLUSIONS AND LESSONS LEARNED? ..... 34
5.1 Conclusions ..... 34
5.2 Lessons learned ..... 39
ANNEX I: PROCEDURAL INFORMATION ..... 42
ANNEX II. METHODOLOGY AND ANALYTICAL MODELS USED ..... 42
ANNEX III. EVALUATION MATRIX AND, WHERE RELEVANT, DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS (BY CRITERION) ..... 44
ANNEX IV. OVERVIEW OF BENEFITS AND COSTS ..... 54
ANNEX V. STAKEHOLDERS CONSULTATION - SYNOPSIS REPORT ..... 67

# Glossary

| | |
|---|---|
| AdCo PED | Administrative Cooperation Group for PED/SPVD |
| CAB | Conformity assessment body |
| CABF | Conformity Assessment Bodies Forum PED/SPVD |
| CE | European Conformity |
| CEN | European Committee for Standardization |
| CEN TC | European Committee for Standardization – Technical Committee |
| CENELEC | European Committee for Electrotechnical Standardization |
| COMEXT | Database on international trade in goods |
| DG GROW | Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs |
| DoC | Declaration of Conformity |
| EA | European cooperation for Accreditation |
| EAM | European approval for materials |
| EC | European Commission |
| EEA | European Economic Area |
| EFTA | European Free Trade Association |
| ESO | European Standardisation Organisation (CEN, Cenelec, ETSI) |
| ESR | Essential Safety Requirement |
| EU | European Union |
| FTE | Full-time equivalent |
| GAR | Gas Appliances Regulation |
| hEN | Harmonised standard |
| ICSMS | Information and Communication System for Market Surveillance |
| ISO | International Organization for Standardization |
| JRC | Joint Research Centre |
| LVD | Low Voltage Directive (2014/35/EU) |
| MD | Machinery Directive (2006/42/EC) |
| MR | Machinery Regulation - Regulation (EU) 2023/1230 |
| MS | Member State |
| NA | Notifying authority |
| NAB | National accreditation body |
| NANDO | New Approach Notified and Designated Organisations |
| NB | Notified Body |
| NLF | New Legislative Framework |
| PED | Pressure Equipment Directive (2014/68/EU) |
| PMA | Particular material appraisal |
| RTPO | Recognised third-party organisation |
| SME | Small and medium-sized enterprise |
| SPVD | Simple Pressure Vessels Directive (2014/29/EU) |
| TPED | Transportable Pressure Equipment Directive (2010/35/EU) |
| UI | User inspectorate |
| UN SDGs | United Nations Sustainable Development Goals |
| WGP | Working Group Pressure |
| WPG | Working Party Guidelines – subgroup of Working Group Pressure |
| WPM | Working Party Materials – subgroup of Working Group Pressure |

## 1. INTRODUCTION

**The main purpose** of the evaluation is to provide an informed analysis of the current performance of the legislation on stationary pressure equipment:

- Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment[1] (the Pressure Equipment Directive – PED);
- Directive 2014/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels[2] (the Simple Pressure Vessels Directive – SPVD).

The evaluation assesses whether the legislation is still fit for purpose and whether it has delivered **the objectives of guaranteeing the free movement in the internal market of the products falling within its scope while ensuring a high level of safety** for products presenting pressure risks.

The evaluation is **retrospective and covers a period of 10 years** following the alignment of both Directives with the New Legislative Framework (NLF)[3] in 2014. A joint evaluation of the PED and SPVD was performed, as the objectives for both Directives are the same and involve the same stakeholders.

In terms of **geographical scope**, the evaluation covers the EU Member States, three EFTA Countries (Iceland, Liechtenstein and Norway), Türkiye in the context of its Customs Union with the EU, and Switzerland by virtue of the mutual recognition agreement with the EU.

The PED regulates a very wide range of equipment presenting pressure risks. It covers items of equipment such as pressure vessels, piping, safety and pressure accessories, as well as assemblies[4]. The broad scope of the PED means that it applies to industrial equipment (e.g. storage vessels for industrial gases, process equipment in the chemical and petrochemical industry, and steam boilers in power stations) as well as to some consumer goods (e.g. fire extinguishers and pressure cookers).

The SPVD has a limited scope and regulates simple pressure vessels for storing compressed air or nitrogen. Typical applications are the storage vessels for compressed air in pneumatic machinery or air braking systems for vehicles.

For both Directives, the evaluation examines:

— effectiveness (whether the EU action has achieved its objectives);

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1 Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164, ELI: http://data.europa.eu/eli/dir/2014/68/oj).

2 Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45, ELI: http://data.europa.eu/eli/dir/2014/29/oj).

3 https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en

4 'Assemblies' means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional system.

— efficiency (what are the costs and benefits);

— relevance (whether the Directive responds to stakeholders' current and future needs);

— internal coherence (how well the various components of the Directive work together) and external coherence (how well the Directive works with other initiatives);

— EU added value (what are the benefits of acting at EU level).

The evaluation examines the potential for simplification and includes an assessment of unnecessary burdens, with a particular focus on small and medium-sized enterprises (SMEs).

This Staff Working Document builds on the evaluation study[5] of the PED and SPVD that was carried out for the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) by Ecorys and Capgemini in 2024-2025.

The evaluation study used different research tools to allow the evidence to be verified and cross-checked in accordance with the principle of triangulation. The methods used include extensive desk research and several consultation activities involving stakeholders. Information was collected via a call for evidence, a targeted online survey, interviews and five case studies for typical products.

A detailed description of the methodology and the main sources of information for this evaluation are provided in Annex II.

***Data limitations***

The limited availability of sufficiently granular market data makes it impossible to calculate reliably the overall costs and benefits of the PED and the SPVD. These gaps were partially mitigated in the evaluation study through stakeholder consultations and case studies.

The evaluation faced a number of data limitations that affected the depth and precision of its findings. A key challenge was the fragmented and incomplete availability of accident and enforcement data across Member States. The Information and Communication System for Market Surveillance (ICSMS)[6] database, intended as a central EU tool for market surveillance coordination, was found to be underutilised and inconsistently populated and to lack standardised reporting practices. Many Member States either do not contribute regularly or fail to follow common encoding protocols, making cross-country comparisons unreliable. Data were particularly scarce for the SPVD, with many stakeholders lacking sufficient familiarity with it or facing difficulties disentangling insights for the PED and the SPVD.

[5] European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Ecorys, C Capgemini, Campana, C., Ciocan, A. et al., *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report*, Publications Office of the European Union, 2026, https://data.europa.eu/doi/10.2873/2844065

[6] https://webgate.ec.europa.eu/single-market-compliance-space/market-surveillance.

## 2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION?

### 2.1 Description of the intervention and its objectives

The objective of both the PED and the SPVD is to ensure the free movement of goods falling within their scope while guaranteeing a high level of safety. Because of the importance and widespread use of pressure equipment for industrial applications and for certain consumer goods, restrictions on the free movement of these products between Member States can have significant negative consequences for the internal market.

As a result of the risks arising from pressure, equipment falling within the scope of the Directives must meet essential safety requirements and undergo stringent conformity assessment procedures to ensure the safety of the products.

Conformity assessment is the responsibility of the manufacturer and, in most cases, requires the involvement of an independent third party – a conformity assessment body, which can be a notified body or a user inspectorate. The different control principles are set out in detail in the conformity assessment modules described in the annexes to the Directives and depend on a risk classification of the equipment by type, volume, pressure, the classification of the fluids it contains and the state of matter of that fluid (liquid or gas).

A product that fulfils the requirements of the Directives may be made available and put into service in all Member States. National laws may not restrict the free movement of compliant products because of pressure-related safety hazards. Nevertheless, Member States may prescribe certain safety precautions for the use of pressure equipment in national law, provided that this does not require the equipment to be modified in a way that is contrary to or goes beyond the harmonised product requirements laid down in the PED or SPVD.

Both Directives were aligned with the New Legislative Framework (NLF) for product requirements in 2014.

The general objectives of the NLF are to ensure a high level of protection of public interests and the free movement of goods throughout the EU within a flexible and innovation-friendly legal framework by setting technology-neutral essential requirements and leaving the detailed technical aspects of implementation to voluntary European harmonised standards.

The PED was initially adopted in 1997 and was evaluated in 2012. The initial version of the SPVD was adopted in 1987 and consolidated in 2009, but it has not been fully evaluated before[7]. When the Directives were aligned with the NLF in 2014, the PED and SPVD were still considered to be fit for purpose and were not modified. They were therefore only aligned with the horizontal provisions of the NLF.

Alignment with the NLF was expected to provide the following benefits:

[7] Communication from the Commission to the Council and the European Parliament, Review of the application of the Simple Pressure Vessels Directive (87/404/EEC) in relation to the Pressure Equipment Directive (97/23/EC), COM(2006) 106 final of 10 March 2006, which concluded at that time that there was a strong case for maintaining the SPVD and the PED as separate directives.

- increasing consistency and coherence with other Union harmonisation legislation by introducing clear definitions and using standard provisions to deal, for example, with formal objections to standards or safeguard procedures;
- improving the quality of conformity assessment services through the accreditation of notified bodies and improving the monitoring of notified bodies by national notifying authorities[8];
- making the enforcement of EU legislation more efficient and effective by improving market surveillance at national level to reduce the incidence of non-compliant products on the market;
- clarifying the meaning of the CE marking and enhancing its credibility by setting out general principles and inserting standard provisions into the sectoral legislation.

In addition, the PED was also aligned with Regulation (EC) No 1272/2008[9] (the CLP Regulation). This was a purely technical alignment because Directive 67/548/EEC, which formed the basis for the classification of fluids in the PED, was repealed and replaced by the CLP Regulation in June 2015. The criteria for fluid classification in the PED were selected to minimise the impact of the changes introduced by the CLP Regulation on the classification of the pressure equipment itself.

**Intervention logic**

The intervention logic visualises and illustrates the links between needs, objectives, inputs, activities, outputs, results and impacts. It covers both Directive 2014/68/EU (the PED) and Directive 2014/29/EU (the SPVD).

The two Directives were developed to address several needs within the European Union. These needs included: (i) reducing trade barriers and administrative costs for industries; (ii) increasing competitiveness in the global market; and (iii) overcoming the lack of harmonised safety standards and uneven market surveillance practices across Member States. To tackle these issues, the Directives aim to ensure the free movement and circulation of pressurised products while maintaining high safety standards. To achieve these general objectives, the Directives have set specific goals. These include ensuring that Member States implement the provisions harmoniously and outlining essential safety requirements for pressure equipment, while facilitating the free circulation of these products in the EU market.

Implementing these Directives requires various inputs, such as financial resources and staff at both EU and national level, as well as active involvement by industry stakeholders. These inputs are essential to support the transposition and enforcement of the Directives.

These activities lead to specific outputs. The successful transposition of the PED and SPVD into national law is the primary output. Outputs also include up-to-date, comprehensive and clear guidelines, an up-to-date list of references of European harmonised standards and established rules on penalties for infringements.

[8] The rules set out in the NLF with regard to the operation of notified bodies and accreditation were expected to ensure equal conditions for conformity assessment bodies and to avoid unfair competition, which undermines the quality of conformity assessment.

[9] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

This leads to increased harmonisation of national provisions on safety for pressure equipment, improved clarity and common understanding of technical requirements, and better enforcement in the internal market and at external borders through effective market surveillance and customs control. In the long term, the impacts of the Directives are interlinked with their overarching objectives. Their impacts include a reduction in the number of incidents and casualties, improved movement of and trade in pressure equipment in the internal market, and an overall improvement in safety standards for these products.

However, the effectiveness of the Directives can be influenced by various external factors. These include the introduction of new technologies (e.g. technologies related to the hydrogen economy), changes in the demand for pressure equipment and growing environmental awareness. Additionally, the PED and SPVD are implemented alongside other legislative instruments and policy initiatives, such as the NLF, the Regulation on accreditation and market surveillance, the Market Surveillance Regulation, the EU Green Deal[10] and the UN Sustainable Development Goals (SDGs)[11]. Other relevant legislation includes other product safety directives, such as the Machinery Directive (2006/42/EC)[12] and the Transportable Pressure Equipment Directive (2010/35/EC)[13].

The intervention logic diagram is set out in the figure below.

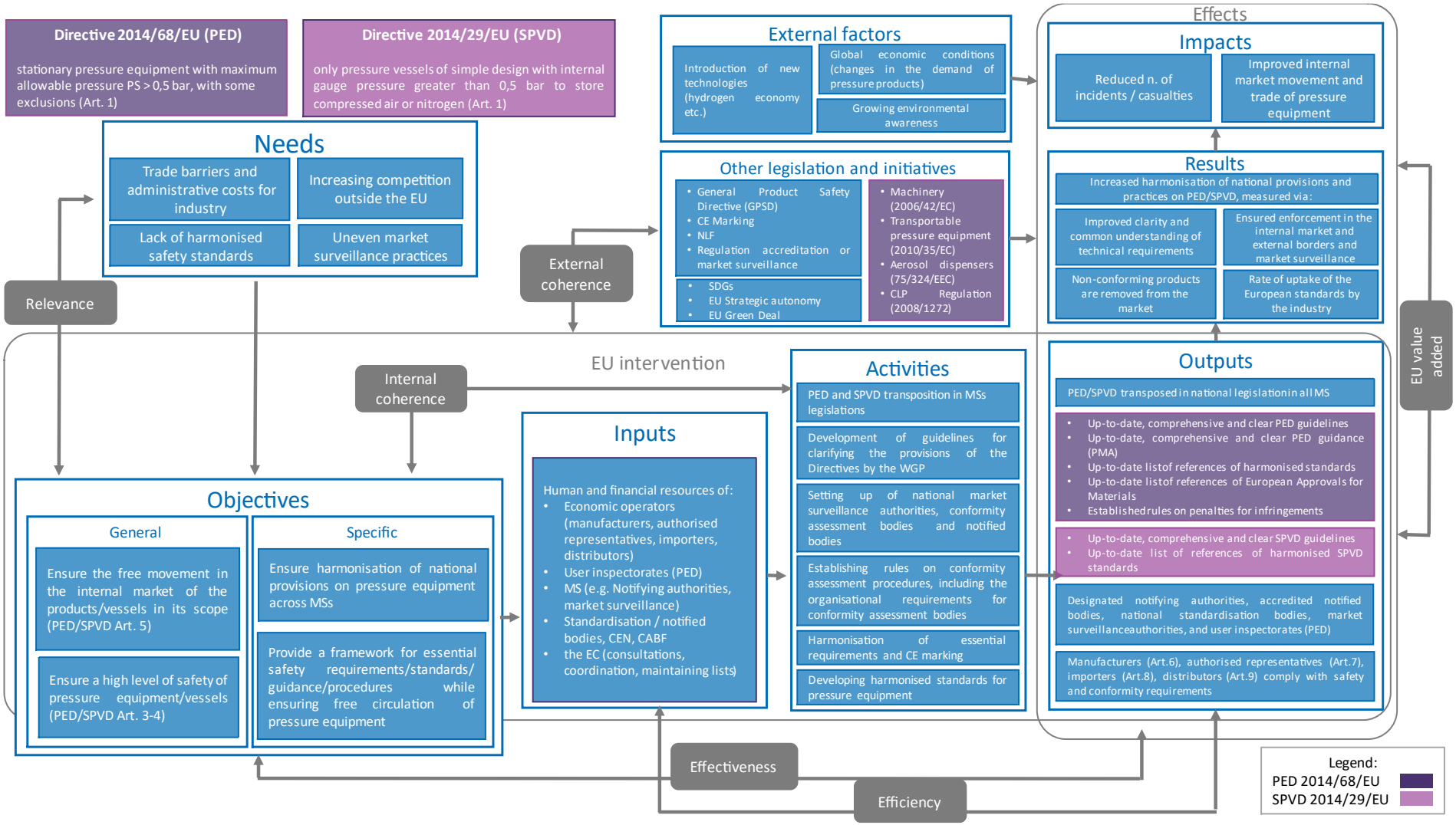
[10] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en.

[11] https://sdgs.un.org/goals.

[12] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending D Directive 95/16/EC (OJ L 157, 9.6.2006, pp. 24-86, ELI: http://data.europa.eu/eli/dir/2006/42/oj).

[13] Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 3 30.6.2010, pp. 1-18, ELI: http://data.europa.eu/eli/dir/2010/35/oj).

## PED/SPVD intervention logic diagram



### 2.2 Point(s) of comparison

Before the initial adoption of the PED (1997) and the SPVD (1987), Member States had their own national legislation to ensure the safety of pressure equipment. Economic operators selling their products across the EU had to comply with different requirements under national legislation, which hindered trade and made it costly to adjust the equipment to the specificities of national legislation. Since the adoption of the PED and the SPVD, this situation has improved substantially. The alignment of both Directives with the NLF in 2014 was another step towards further harmonisation.

An evaluation of the PED took place in 2012 and is used as point of reference. The SPVD, however, has never been fully evaluated since its initial adoption in 1987.

This evaluation mainly covers the period after the alignment of the PED and SPVD with the NLF in 2014, but intends to examine all aspects of the Directives, including, for example, their scope and the essential safety requirements, which have not been changed since the initial adoption of the PED (in 1997) and the SPVD (in 1987).

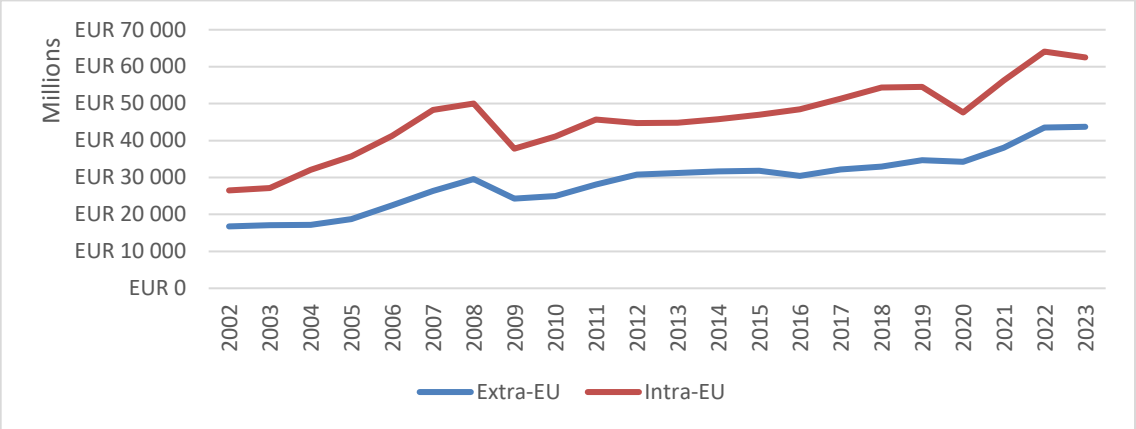
No systematic or comprehensive quantitative market data are available for products falling within the scope of the Directives. However, qualitative data were collected during the various steps of the evaluation study. This means that it is possible to carry out an assessment on the basis of the evaluation criteria, for example by means of indicators such as the number of accidents, the uptake of European harmonised standards, the alignment of the Directives with market and technological trends, the number of products removed from the market by the national market surveillance authorities, or the coherence with other product safety legislation through the harmonisation of conformity assessment procedures.

## 3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD?

### 3.1 Evolution of the market for pressure equipment

Both intra-EU trade (trade within the EU) and extra-EU trade (trade with non-EU countries) in pressure equipment have grown steadily since 2002, indicating a continuous expansion of trade activity in the sector. Notably, **intra-EU trade has grown by 28.9% since 2016, when the recast of the PED/SPVD came into full effect.** This growth cannot be directly attributed to the PED/SPVD, since the intra-EU trade value was even higher before the 2008-2009 crisis, and extra-EU trade has grown even more since 2016 (by 43.5%). **However, the trade data clearly suggest that the Directives are enablers of free movement in the internal market.** This is shown in the graph below, which illustrates the evolution of intra-EU and extra-EU trade for products covered by the PED/SPVD from 2002 to 2023, expressed in million EUR at current prices. The graph also shows that the biggest market disruptors were the 2008-2009 crisis and the COVID-19 crisis. However, trade managed to rebound to above pre-crisis levels in 2022-2023. Intra-EU trade remains higher than extra-EU trade, which shows the importance of the internal market for pressure equipment.

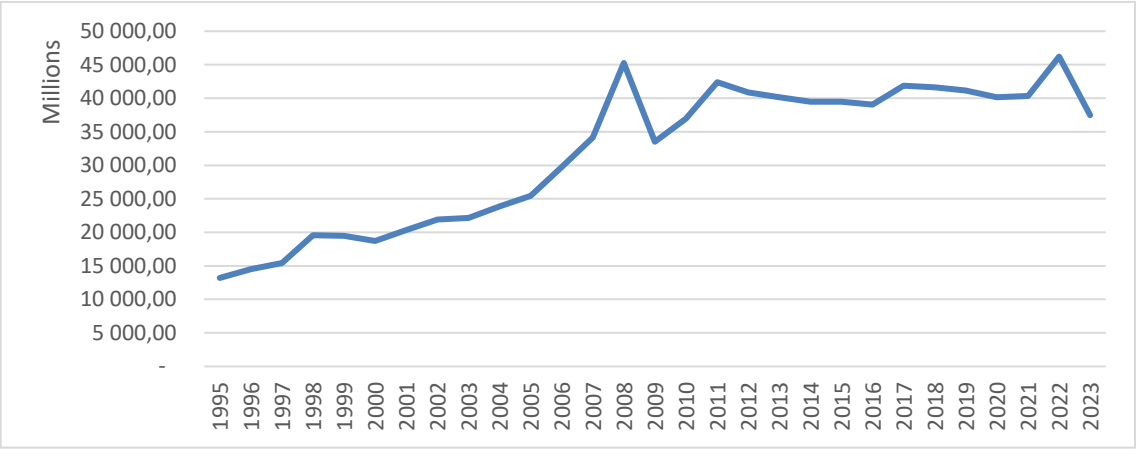
**Evolution of intra-EU and extra-EU (EU14) trade in pressure equipment (2002-2023) – in million EUR, current prices**




*Source: Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 45*, based on Eurostat EU trade since 2002 by SITC DS-059331.

At the same time**, pressure equipment production values in the EU have stagnated since 2008**. As shown in the graph below, production value of pressure equipment are higher than in the 1990s but have remained below 2008 levels (with the exception of 2022). This general trend cannot be attributed to the recast of the pressure directives, since they entered into force only in 2016. Overall, as for the trade data above, the production data show that the trends are dictated by market dynamics rather than legislative changes.

**Evolution of the pressure equipment industry (1995-2023) EU14 – production values (in million EUR)**[14]




*Source: Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 45*, based on Eurostat PRODCOM Production list DS-056120.

[14] To ensure consistency, the focus is on data from the **EU15** (excluding the United Kingdom). This provides a constant sample of countries, which allows a clearer comparison over time and avoids the potential distortions caused by the accession of new Member States.

### 3.2 Implementation of the PED and SPVD – state of play

Both the PED and the SPVD have been fully implemented in all Member States and EFTA countries. Their alignment with the definitions and procedures set out in the NLF has created a more coherent legislative framework. It has also made it easier to ensure the compliance of equipment subject to multiple product safety regulations, such as, for example, the Machinery Directive, the Low Voltage Directive and the Gas Appliances Regulation.

The definition of 'manufacturer' in the PED and the explicit inclusion of equipment for own use have resulted in some discussion about the scope of the Directive. There has also been discussion in the expert group on pressure equipment[15] on the correct interpretation of recital 7 of the PED and the exclusion from the scope of the Directive of the assembly of pressure equipment on the site and under the responsibility of a user who is not the manufacturer (such as in the case of industrial installations). An infringement procedure was initiated in 2018 against one Member State because the national transposition measures had changed the scope of application for certain assemblies under the PED. The Member State concerned adapted the national transposition measures accordingly. No other infringement procedures are currently pending.

The alignment of the PED with the CLP Regulation was based on an extensive impact assessment study[16] and did not create any problems for the implementation of the PED. It has not led to any new safety gaps, and no substantial economic consequences were reported by stakeholders. A specific PED guideline[17] was adopted in 2014 to enable a smooth transition to a classification of fluids based on the CLP Regulation.

The number of formal and informal complaints by stakeholders regarding the implementation or enforcement of the Directives is very low, and they mainly concern the consistent application of the Directives. Although the alignment of the PED and SPVD did not change the scope of application or the essential safety requirements, several stakeholders raised questions about the scope, the interpretation of some essential safety requirements and the conformity assessment of complex assemblies. This for example concerns air conditioning equipment and some types of boilers. Some questions cannot be fully addressed by specific PED or SPVD guidelines and it is challenging to develop such guidance in full compliance with the Directives.

An important issue is the inconsistent interpretation of the scope of application of the PED to machinery integrating pressurised components or sub systems and whether such machinery should be assessed as a PED assembly. Other points of discussion arising between manufacturers and national authorities concern possible conflict or overlap with

15 Working Group Pressure (WGP).

16 Impact Assessment Study on the Alignment of the Pressure Equipment Directive to the CLP Regulation.

17 PED Guideline B-41 (https://ec.europa.eu/docsroom/documents/63154).

the national in-service inspection rules when putting equipment into service, in particular for PED assemblies.

The increased use of accreditation as the preferred route for notification of conformity assessment bodies was one of the direct consequences of alignment with the NLF rules affecting them. Over the evaluation period, the rate of notifications based on accreditation has steadily increased but has not reached 100% because accreditation is not mandatory. The notification procedures are defined at national level, and the harmonised standards listed in document EA 2/17 M:2020 (EA Document on Accreditation for Notification Purposes)[18] are not mandatory for the national notifying authorities. Consequently, there are still substantial differences in the notification process for conformity assessment bodies for the PED and SPVD amongst the different Member States.

Alignment with the NLF was intended to improve market surveillance activities and lead to better coordination at European level. The adoption of the Market Surveillance Regulation[19] in 2019 has also made a positive contribution to creating a better framework for market surveillance and enhancing cooperation with the customs authorities. The change in the market structure, namely increased production in and imports of equipment from third countries, combined with increased sales via online platforms (e-commerce), is particularly challenging for the national market surveillance and customs authorities.

Some indicators point to a potentially increasing level of activity of market surveillance authorities for PED and SPVD. In particular, the number of notifications in ICSMS for the sectors has consistently been above average compared to aggregated ICSMS data for all sectors since 2021. Furthermore, 2024 has been the year with the highest number of notifications for PED. However, usage of ICSMS remains inconsistent across Member States, and this should thus be interpreted with caution as it may be an artefact of such diverging usage patterns, or an intensified usage of ICSMS as opposed to increased market surveillance.

The safeguard clause has been used only a few times during the evaluation period: once for the SPVD (simple pressure vessels used in brake systems of heavy vehicles) and twice for the PED (industrial heat exchangers and portable fire extinguishers). The case relating to industrial heat exchangers was resolved through bilateral exchanges between the authorities. The case relating to portable fire extinguishers is currently still under investigation. It should be noted that the European Commission intervenes only if a Member State objects to a measure taken by an authority in another Member State. For nearly all measures taken at national level, there are no objections from another Member State. It appears, however, from the available data in the ICSMS that a measure taken

[18] https://european-accreditation.org/wp-content/uploads/2018/10/ea-2-17-m.pdf.

[19] https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/market-surveillance_en.

against a particular product in one Member State is only rarely applied in other Member States (despite the obligation in the PED[20] and SPVD[21]).

The vast majority of the initial PED and SPVD guidelines (non-legally binding) have been reviewed and updated in line with the aligned PED and SPVD and adopted by the expert group on pressure equipment Working Group Pressure (WGP)[22]. The number of additional PED guidelines proposed for adoption to the expert group is limited. This is mainly because the alignment of the PED with the NLF did not change the scope or the essential safety requirements. The review of the SPVD guidelines resulted in a simplification, with the withdrawal of several guidelines which were no longer relevant. It should be noted though that, in recent years, the development of additional PED guidelines (as requested by some stakeholders) has been hampered by the lack of technical experts and the challenge of ensuring that the guidelines are consistent with the legislation.

In parallel with the alignment of the PED and SPVD with the NLF in 2014, Regulation (EU) No 1025/2012 on European standardisation[23] (the Standardisation Regulation) also entered into force during the evaluation period. The process of developing harmonised standards[24] (hENs) is now fully aligned with the new Standardisation Regulation, providing a clearer but more stringent legal environment.

During the evaluation period, there have not been any formal objections to a European harmonised standard under the PED or SPVD, mainly because of the proactive work done by stakeholders in the standardisation process to ensure that the standards comply with the legislation.

The development of harmonised standards is, however, progressing slowly, with regular updates of standards taking place, mainly for the PED. For the SPVD, the main product standards for simple pressure vessels[25] are still under revision by the European Committee for Standardization (CEN). In particular for some technological areas, the slow development of standards is particularly problematic as it can hinder the dissemination and adoption of new technologies. This concerns in particular standards for heat pumps and cooling equipment using fluorinated gases or their alternatives, where

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20 Article 40 PED – Procedure for dealing with pressure equipment or assemblies presenting a risk at national level.

21 Article 35 SPVD – Procedure for dealing with vessels presenting a risk at national level.

22 Working Group Pressure Equipment (E01347).

23 Regulation (EU) No 1025/2012 on European standardisation.

24 As defined in Article 2(1)(c) of Regulation (EU) No 1025/2012 on European standardisation, '"harmonised standard" means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation'.

25 EN 286 series, Simple unfired pressure vessels design to contain air or nitrogen.

the uptake of more climate-friendly refrigerants is slowed down due to slow developments in corresponding standards[26].

## 4. EVALUATION FINDINGS (ANALYTICAL PART)

This section sets out the analytical part of the joint evaluation of the PED and SPVD.

Many findings are similar for both Directives, e.g. for topics relating to the NLF, the standardisation policy or market surveillance. Where a distinction is to be made between the PED and the SPVD, the Directive is clearly indicated.

### 4.1 To what extent was the PED/SPVD successful and why?

This section relates to the assessment of the effectiveness, efficiency and coherence of the PED and SPVD with the overall legislative framework and other legislation that may apply to the products.

The Directives have a dual objective:

1) guaranteeing the free movement in the internal market of products falling within their scope;
2) ensuring a high level of safety for products presenting pressure risks.

#### *Effectiveness*

#### *The effectiveness of the PED and SPVD in ensuring a high level of safety for products falling within their scope*

On the basis of the results of the evaluation support study, it can be concluded that the Directives ensure a high level of safety for pressure equipment falling within their scope.

The evaluation study report shows a consensus among stakeholders that the PED and SPVD have contributed significantly to ensuring a high level of safety[27]. A key indicator of safety problems would be the number of accidents involving pressure equipment. During the evaluation period, there is no indication of an increase or decrease in the number of accidents. It should, however, be noted that accident data are not systematically collected and/or reported at national level. There is no EU-level accident database, nor is there an obligation on the national authorities or the manufacturers to report such accidents. There are no comprehensive database and no other way of comparing accident statistics across countries or time periods. Nevertheless, the available data from four Member States (Bulgaria, France, Slovakia and Finland) consistently show that accidents are rare in both absolute and relative terms (i.e. when compared with

[26] Compare also the Report from the Commission on barriers posed by codes, standards and legislation to using climate-friendly technologies in the refrigeration, air conditioning, heat pumps and foam sectors (COM(2016) 749 final).

[27] *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 50-54.*

the total number of accidents reported for products regulated under other product safety legislation). The national market surveillance authorities reported only very few accidents over the past 10 years. The accidents reported related, for example, to breathing apparatus, portable fire extinguishers and accidents in process installations. Each time an accident occurs, an in-depth investigation must be conducted to identify the root cause. There is no indication that the accidents were the result of a systemic fault in the requirements laid down by the Directives. Accidents mainly occurred because of incomplete application of the essential safety requirements or incomplete conformity assessment or for reasons which are not linked directly to the legislation itself but rather to a failure to follow basic safety rules when operating or maintaining equipment.

For those accidents for which information could be collected, no causal link was found between the accidents and inadequate provisions in the legislation.

### *The effectiveness of the PED and SPVD in ensuring the free movement of products in the internal market*

On the basis of the results of the evaluation support study, it can be concluded that the Directives generally ensure the free movement of pressure equipment and simple pressure vessels in the internal market.

**The evaluation study report shows a broad consensus amongst stakeholders that the Directives have contributed significantly to the functioning of the internal market by harmonising the technical and legal requirements and removing obstacles to cross-border trade**[28]. These findings are also supported by the market analysis on intra-EU trade as shown above in Section 3. The consensus spans all three respondent groups in the targeted survey: businesses (approximately 70% of the 86 responses), authorities (approximately 70% of the 49 responses) and conformity assessment bodies (approximately 90% of the 56 responses). Most responses from SMEs are also positive, but slightly less positive than the overall population of business respondents. The responses for the SPVD are very similar.

Despite the positive contribution of the PED/SPVD to the functioning of the single market, approximately 30% of the businesses that participated in the targeted survey (i.e. 61 out of 199) reported experiencing problems in buying or selling pressure equipment on the European market, while 58% reported no problems in this regard. More problems were reported in other countries (38 responses) than in the business's country of origin (28 responses). This is also the case for industry associations, with 7 associations (out of 50) reporting that business members had encountered problems with selling/buying pressure equipment across borders.

Some businesses / business associations reported inconsistencies in the interpretation of the Directives and standards across EU Member States, different levels of rigidity of

[28] *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 101.*

market surveillance, and a need for more guidance, e.g. to deal with emerging technologies such as additive manufacturing and remote inspections.

### *The effectiveness of European harmonised standards and guidance*

The implementation of the PED and SPVD is facilitated by European **harmonised material and product standards** (hENs). Once the references of a harmonised standard have been published in the L series of the Official Journal, the standard provides for presumption of conformity with the essential safety requirements (ESR) covered by it. The concept is that the legislation only specifies the ESR to be met, while the standard describes the technical solutions to achieve compliance. It should be noted that a harmonised standard does not always cover all the applicable ESR for a certain product. Only the clauses of the standard referred to in the Annex Z of the standard provide presumption of conformity with the directive.

The manufacturer can use European harmonised standards or parts thereof giving presumption of conformity to the essential safety requirements of the directives. The manufacturer may choose any other standard, private code or technical solution but in such cases the manufacturer must demonstrate compliance with the applicable essential safety requirements as laid down in Annex I to the Directives. The presumption of conformity of hENs facilitates the conformity assessment process and reduces the costs for the manufacturers. If a hEN is used, the conformity assessment process is easier, because there is less checking required by the notified bodies (NBs)[29]. There is general agreement among business respondents (82%, 164 out of 199 respondents) that using hENs is indeed an efficient way to comply with the legal requirements on the European market. This opinion is also shared by SMEs (82%, 54 out of 66 respondents). There is general agreement amongst stakeholders that harmonised standards (including those for materials) ensure that products meet a consistent level of safety, making cross-border trade easier and more efficient.

While specific data on the use of harmonised standards for pressure equipment is limited, there is evidence that the uptake of European harmonised standards is increasing on the European market. The results of the business survey, covering both Directives, show that for 50% of the businesses (out of a total of 199 respondents), more than 80% of the pressure equipment that businesses produce or work with is produced according to European harmonised product standards. To put this into perspective, the results of the previous study performed for the PED evaluation in 2012 gave this percentage as 33.3% (out of a total of 96 respondents).

**Harmonised implementation of the PED/SPVD is also facilitated by guidance documents**: PED/SPVD guidelines endorsed by the expert group on pressure equipment (WGP) and recommendations (CABF-R) agreed in the coordination group of conformity

[29] Under the PED, NBs are still involved if the equipment is classified in category II or higher under the PED and where a harmonised standard is used.

assessment bodies (CABF PED/SPVD)[30]. Guidance documents relate to many aspects (such as scope of application, categorisation and classification of equipment, essential safety requirements, conformity assessment procedures, etc.). Even though the guidance is not legally binding, stakeholders consider the PED/SPVD guidelines and CABF recommendations to be useful instruments for implementing the Directives. Some stakeholders consider that additional guidance is needed, while others consider that the number of PED guidelines is already too high to be practical and should be reduced by incorporating the guidelines into the legislation in the future. The PED guidelines were revised after the alignment of the PED with the NLF in 2014. Since 2015, discussions have arisen about whether the PED guidelines are sufficiently consistent with the legislation. These discussions, which were mainly driven by market surveillance authorities, have halted the further development of the PED guidelines as a tool to support the implementation of the legislation.

### *Effectiveness of the enforcement of the Directives*

**The effectiveness of the legislation also depends on the market surveillance authorities and the customs authorities**, which largely complement each other in enforcing the Directives in the internal market and at the EU's external borders.

Market surveillance activities are increasing, as reflected by the increasing number of cases registered in the ICSMS, but the intensity of market surveillance for the PED and SPVD is still rather low, and substantial differences remain in the level of activity in the Member States. This can be explained by the limited resources allocated to market surveillance for the pressure equipment sector. Most respondents to the survey of market surveillance authorities reported **issues relating to insufficient staff** (16 out of 25 respondents) and **insufficient financial resources to purchase samples** (13 out of 25 respondents). Several market surveillance authorities consider that more human and financial resources are needed to enforce the PED and SPVD more effectively. Pressure equipment is not a priority field for market surveillance authorities. Even for relatively simple consumer products, such as pressure cookers or fire extinguishers, some market surveillance inspectors have difficulties understanding the requirements of the Directives and how to enforce them. For complex business-to-business industry products, the learning curve is even steeper, longer and more expensive because it requires specialised technical training. These challenges are even more pronounced for market surveillance authorities in smaller countries, as they face difficulties in ensuring a sufficient pool of technical knowledge. Similarly, budget constraints make it difficult to access technical resources and purchase standards.

**Coordination between market surveillance authorities at EU level has improved a lot over the evaluation period through regular meetings of the ADCO[31] group for**

[30] CABF PED/SPVD: the Conformity Assessment Bodies Forum for the PED/SPVD.

[31] ADCO: Adminstrative Cooperation.

**the PED and SPVD and the ADCO chairs group**. However, further improvement of communication between market surveillance authorities and notified bodies is needed, particularly across different countries.

Another important aspect is **enforcement by customs authorities at the EU's external borders**. This encompasses: (i) the challenges of carrying out controls on products entering the EU market; (ii) the complexities of managing a diverse range of imported goods with varying compliance requirements; and (iii) the operational difficulties that the authorities designated to carry out controls on products entering the EU under Article 25(1) of Regulation (EU) 2019/1020 face in maintaining effective oversight at entry points. Designated authorities in Member States, usually the customs authorities, carry out controls based on risk analysis covering all legislation listed in Annex I to Regulation (EU) 2019/1020, including the legislation on pressure equipment. These controls may result in close cooperation with the market surveillance authorities if suspicious products are identified. The market surveillance authorities are responsible for assessing product compliance and decisions are communicated back to the customs authorities, which can take appropriate measures, such as refusing to release the product for free circulation (i.e. the product does not enter the internal market) or requesting modification of the product to make it compliant or any other action needed to allow it to enter the market. In practice, coordination between authorities within countries, including between market surveillance authorities and customs authorities, was generally considered to function properly. However, further digitalisation of communication between authorities, including those in another Member State, could further improve this process.

Despite the generally good cooperation between market surveillance and customs authorities, **several businesses / business associations expressed dissatisfaction with the level of compliance of pressure equipment coming from third countries**. Market surveillance and customs authorities confirmed difficulties receiving the necessary documents for products produced in third countries. For products sold on online platforms, it is often even more difficult to obtain the necessary information about product compliance, technical documentation and manufacturer details.

### *Issues limiting the effectiveness of the Directives*

**The evaluation study identified some issues limiting the effectiveness of the Directives[32].** These are mostly known problems already discussed in the Working Group Pressure (WGP), other coordination groups for market surveillance (e.g. ADCO) and the Conformity Assessment Bodies Forum (CABF PED/SPVD).

[32] *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 153.*

A key concern raised in all consultations and by all stakeholders is **the lack of a harmonised approach to applying the concept of PED assemblies** as defined in Article 2 (6), PED[33], despite the existing PED guidelines and other guidance documents.

Incomplete harmonisation is also an issue for some aspects related to conformity assessment, such as:

- differences in the quality of the conformity assessment as a result of differing interpretations of the Essential Safety Requirements (ESRs)[34] and the conformity assessment modules by conformity assessment bodies[35];
- differences in the accreditation/notification requirements and processes and the level of qualification of conformity assessment body personnel.

Businesses indicated that some **notified bodies (NBs) interpret the essential safety requirements and conformity assessment modules differently**. This results in quality variations in conformity assessments, different levels of testing, and poor-quality technical documentation and operating instructions. Authorities expressed concerns that the performance of NBs varies widely and that oversight of NBs by national authorities differs across countries.

**Harmonisation of accreditation / notification of conformity assessment bodies has not been fully achieved**. The use of accreditation as a basis for notification increased substantially after the alignment of the PED and SPVD with the NLF. Since accreditation is not mandatory, the notification process for NBs is not fully harmonised and consistent across Member States. Even if accreditation is used to support the notification, some national notifying authorities deviate from the general approach laid down in document EA 2/17 M:2020[36]. National accreditation bodies must apply EA 2/17 M:2020, but in line with the NLF (which defines the overall framework for accreditation and notification), the national notifying authority may deviate from that document and decide to notify in accordance with a procedure that requires only one or two, rather than three, accreditation certificates. This results in partial harmonisation and means that, for conformity assessment bodies, the cost of notification varies from country to country.

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33 Definition in Article 2, point (6), PED: '"assemblies" means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole'.

34 For example (but not limited to) differences in the evaluation of ESR 4.2(b) (particular material appraisal), ESR 4.1(a) (material toughness) and ESR 4.3 (certificate requirements for stainless steel).

35 The PED provides for three types of third-party bodies: notified bodies (NBs), user inspectorates (UIs) and recognised third-party organisations (RTPOs). UIs and RTPOs are specific to the PED. UIs should not be confused with 'in-house accredited bodies' as defined in the NLF. RTPOs are not conformity assessment bodies but have a specific role with regard to permanent joining and non-destructive testing (NDT) qualifications. The SPVD provides only for notified bodies.

36 EA-2/17 M: 2020, EA Document on Accreditation for Notification Purposes, https://european-accreditation.org/wp-content/uploads/2018/10/ea-2-17-m.pdf.

**Harmonised standards (hENs) are used by the national accreditation bodies to certify the conformity assessment bodies**. Applying harmonised standards (primarily EN ISO/IEC 17065, EN ISO/IEC 17020, or EN ISO/IEC 17021 and EN ISO/IEC 17024) for certification, inspection, or laboratory testing activities, and supplementing them with specific requirements outlined in the legislation, strengthens the accreditation process. However, **the use of hENs in the accreditation process is not harmonised across Member States**. Conformity assessment bodies consider the accreditation requirements imposed by mandatory document EA 2/17 M:2020 not to be optimal. Several NBs expressed the need to simplify/reduce the standards assigned to the modules under EA 2/17 M:2020. Members of the Conformity Assessments Bodies Forum (CABF PED/SPVD) have formally raised concerns to the European co-operation for Accreditation (EA) about the choice of harmonised standards for accreditation in the pressure equipment sector.

There is no consensus on the **minimum qualification requirements for conformity assessment body personnel across the EU**. Accreditation bodies in each Member State independently determine which qualifications are acceptable. This results in varying skills levels among the staff of notified bodies. Such differences will persist unless common standards are agreed by the notified bodies (CABF PED/SPVD), the accreditation bodies and the national notifying authorities. This is an even bigger problem for local inspectors employed by **subsidiaries of conformity assessment bodies in third countries**.

### ***Efficiency***

**The findings of the evaluation study confirm that implementation of the PED and the SPVD is generally cost-effective, meaning that the benefits outweigh the costs arising from the Directives[37].**

The PED and SPVD have made a demonstrable contribution to the free movement of goods in the EU internal market, as evidenced by strong growth in intra-EU trade and a broad consensus among stakeholders. The Directives have been widely recognised by businesses, authorities and conformity assessment bodies as a key enabler of regulatory alignment, reduced fragmentation and simplified market access.

The Directives have delivered clear benefits for all stakeholder groups. For businesses, they have facilitated market access and reduced administrative burdens by harmonising requirements. For authorities, they have supported consistent enforcement and improved safety oversight. For conformity assessment bodies, they have provided a stable regulatory framework and clearer procedures for certification and inspection.

In addition to facilitating the free movement of pressure equipment, the PED and SPVD have also contributed to maintaining a high level of safety across the EU.

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37 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 155-157*

Evaluating market efficiency gains under the PED and SPVD involves considering how these legislative frameworks have facilitated intra-EU trade by streamlining regulatory requirements. This can be viewed in terms of avoided fragmentation, i.e. the reduction in the administrative and technical barriers that manufacturers would otherwise have faced when placing products on different national markets. While these harmonised rules likely contribute to lower overall compliance burdens and more predictable market access, quantifying these benefits is inherently complex. This is especially true given the long-standing nature of the Directives, which makes it difficult to reconstruct how divergent national legislation might have developed in their absence or to estimate the costs that would have been incurred without EU-level harmonisation. While the benefits of the Directives cannot be quantified, the costs linked to the PED and SPVD have been quantified to the extent possible (see below). Nevertheless, this does not allow for a quantitative comparison of costs and benefits.

Under both Directives, compliance and enforcement costs are distributed among businesses, conformity assessment bodies and authorities. Direct compliance costs are the costs that need to be borne to comply with the provisions of the Directives. They are composed of adjustment costs and administrative costs. Enforcement costs are associated with activities linked to the implementation of the Directives, including monitoring and inspections. Indirect costs arising from the Directives are incurred in related markets or experienced by citizens, agencies and other stakeholders who are not targeted by the Directives. Annex IV gives an overview of the cost and benefit items arising from the requirements of the PED and SPVD, broken down by stakeholder and cost type. For each stakeholder group, the costs are identified, quantified and analysed below, including as regards their processing and affordability.

Businesses incur direct compliance costs to comply with PED and SPVD, namely adjustment and administrative costs. The largest drivers of compliance costs stemming from the directives identified by businesses and business associations comes from third-party conformity assessment (137 out of 200 responses, administrative cost), followed by conformity assessment by the manufacturer (95 responses, adjustment cost) and the preparation of technical documentation and the EU declaration of conformity (88 out of 200 responses, administrative cost)[38]. The **average compliance costs for activities under the PED generally account for less than 1% of the turnover for pressure equipment across the companies surveyed**. When broken down by company size, administrative costs relating to both the PED and the SPVD remain negligible, regardless of the size of the company. In absolute terms, costs from third-party assessments range from EUR 3,000 to 300,000 for small companies, and EUR 5,000 to 250,000 for large companies, averaging at EUR 64,900 and EUR 66,000 respectively. Conformity assessment by the manufacturer in-house comes in at an average of EUR 288,000 for

[38] *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 87. Question asked to company: "Out of the list below, please choose up to three activities that are the biggest cost drivers to ensure compliance with the pressure equipment legislation."*

large companies and EUR 106,000 for small companies. The preparation of technical documentation and EU declaration of conformity on the other hand averages at EUR 297.000 for large companies and EUR 213.000 for small companies[39]. It is noteworthy that these costs are cumulative rather than alternatives, as even if conformity is assessed by a Notified Body, internal preparatory activities would be needed, akin to in-house conformity assessment.

However, the average costs vary significantly, given the very wide range of products. Some products are serially produced (e.g. fire extinguishers, pressure accessories such as valves, and medium-sized stationary LPG storage vessels for domestic use), while others are unique customised products based on technical specifications from the user (e.g. reactor vessels, heat exchangers, and piping designed for a specific application in an industrial environment). The value of an item of pressure equipment may be as low as EUR 5 but may just as easily amount to hundreds of thousands of euros for large and complex storage vessels. The costs for conformity assessment also vary a lot, depending on the complexity of the product to be assessed and whether a third party is involved. It is therefore only possible to draw general conclusions and give percentages for the various cost components. When compared with the overall cost of the product, the costs of complying with the PED typically come to between 1% and 3%.

In the case of the **SPVD, the compliance framework is generally perceived by SMEs and large companies as manageable and proportionate in terms of its impact on production costs and timelines**. For serial production of simple pressure vessels, the cost of compliance is estimated at approximately 2% of the vessel's total production cost.

**Businesses face costs relating to technical documentation, EU declarations of conformity, and instructions and safety information.** The number of full-time equivalents (FTEs) required for technical documentation and EU declaration of conformity under the PED and SPVD is directly linked to the complexity of the products, ranging from simple and serially produced items to complex assemblies consisting of hundreds of components. This means that the costs vary widely depending on the complexity of the product.

The yearly costs of purchasing harmonised standards represent only a very small proportion of the turnover for pressure equipment, and in absolute numbers averages at EUR 6,800 or large companies and EUR 3,250 for small companies. On the basis of the estimates in the evaluation study, the average costs for both Directives combined amount to only 0.031% of the turnover for pressure equipment, while the cost of conformity assessment amounts to between 1% and 3% on average[40].

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39 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 91-94.*

40 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 91-94, p. 155.*

**Conformity assessment bodies** (CABs) **identify accreditation (an administrative cost) as the primary cost driver for them under the two Directives.** Accreditation (30% of costs) and initial notification (6% of costs) together account for 36% of the reported total costs. Depending on the size of the CABs and the scope of notification, there is a substantial difference in the reported costs. In absolute terms, the initial accreditation costs for smaller CABs are EUR 20 000. Larger CABs report initial accreditation costs in the range of EUR 30 000 to EUR 70 000.

Other main cost drivers identified include adjustment costs such as **continued compliance** (20%) (e.g. ensuring adherence to standards and updating procedures) and **training** (20%), and **administrative costs** other than accreditation (e.g. documentation, record-keeping and reporting) (17%). The purchasing of standards is still a significant cost but is limited to 6% of the overall costs.

The costs for the SPVD are lower than for the PED, which is logical as the SPVD has only a limited scope and is less complex. The costs of maintaining accreditation and notification differ for CABs across Member States, depending on the scope of the notification (the range of products and conformity assessment modules) and whether the Member States require accreditation to be based partially or fully on document EA 2/17 M:2020.

The only costs **authorities** incur under the PED and SPVD are **enforcement costs**, namely information, monitoring and inspection costs. On the basis of 44 replies, the most substantial costs reported by **authorities** under the PED and SPVD include **training personnel** (21%) and carrying out **inspections and controls** (19%). While **market surveillance authorities** predominantly identified carrying out inspections and controls as the main cost driver, **competent authorities** identified training personnel as the primary cost driver. Laboratory testing and administration, and reporting are also cost-intensive activities.

**The evaluation study did not find evidence of an excessive regulatory burden across the different stakeholder groups**[41]. Businesses and business associations acknowledged that, while compliance with the PED and SPVD entails certain costs, these are **justified by the safety standards** they help uphold, and the overall benefits of the internal market outweigh the regulatory costs. **Notified bodies emphasised the importance of regulatory compliance for ensuring impartiality and considered the associated administrative burden to be reasonable**. Most national authorities indicated that the Directives strike an appropriate balance between regulatory requirements and policy objectives.

Businesses (170 replies, of which 104 from large companies and 66 from SMEs) declared that the **administrative obligations are not particularly burdensome, noting that the current systems are generally manageable, especially considering that the**

41 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 96-99.*

**PED and SPVD have simplified procedures compared with previous national-level non-harmonised approaches**. Furthermore, input from the survey shows that, even without the PED and SPVD, the majority of manufacturers would continue key compliance-related activities: 138 manufacturers (80%) would still prepare technical documentation and instructions and safety instructions, 96 manufacturers (48%) would follow non-regulatory standards, 85 manufacturers would perform some form of conformity assessment and 79 manufacturers would issue a declaration of conformity. This suggests that core safety and quality procedures are driven not only by compliance with the Directives but also by customer expectations and internal standards[42]. These findings are corroborated by industry associations (at EU and national level), which all believe that manufacturers would still draw up instructions, safety information and technical documentation.

**The analysis of the potential for simplification and reducing the administrative burden reveals both convergence and divergence between SMEs and large companies**. Both groups prioritise increasing the use of digital tools and platforms and simplifying documentation requirements. Large companies show a stronger preference for digitalisation (57 responses or 35%) than SMEs (29 responses or 31%). This is likely to be due to their greater capacity to integrate digital systems and absorb upfront costs. In contrast, SMEs place greater importance on simplifying documentation requirements (34 responses or 36%, compared with 40 responses or 30% for large companies). This reflects their more limited administrative resources and greater sensitivity to procedural complexity. Both groups give nearly equal weight to streamlining the compliance certification process, with 22% of large companies and 21% of SMEs identifying it as a key measure. This represents a shared challenge for companies of all sizes. Flexibility in the selection of conformity assessment modules is a lower priority for both, though it is slightly more relevant for large firms (14 responses or 9%, versus 7 responses or 7%). While both SMEs and large companies agree on the main burden-reduction strategies, SMEs are more focused on reducing the procedural load through simplification, while large companies lean more towards digital solutions[43]. Potential for simplification through digital means lies mainly in uniform and clear rules for the provision of compliance documentation such as instructions for use and declarations of conformity in a digital format as well as clarification on the use of remote technologies for inspection of welds.

**Conformity assessment bodies** identified some processes that could benefit from potential simplification or the use of new tools. **Increasing the use of digital tools and platforms and streamlining the notification process** are the primary areas where there is a potential for reducing the administrative burden. CABs also noted significant discrepancies in how Member States apply and interpret accreditation obligations,

42 'Business as usual' (BAU) costs.

43 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 102.*

leading to legal uncertainty and administrative inefficiency. Several CABs called for the revision or elimination of document EA-2/17 M:2020, a reduction in the frequency of audits by the national accreditation bodies, simplification of scope extension processes, and broader use of digital platforms for audit preparation and reporting[44].

Authorities largely reported that there are no major avenues to cut enforcement costs, but proposed several smaller scale measures[45]. These include enhanced cooperation through an improvement of existing IT systems, to make information exchange and document sharing easier. This could cut enforcement costs by reducing redundancies and taking advantage of synergies. Authorities further suggested making documents needed for inspections available digitally through a unified platform such as a Digital Product Passport[46].

Further simplification measures could in particular relate to the identification and assessment of assemblies of pressure equipment. As identified for example in the section on coherence below, the hierarchy of 1) determining if a product is in scope, 2) determining if it is an assembly of pressure equipment and should be part of a global conformity assessment, 3) determining the applicable category it belongs in, which has an effect on the needed conformity assessment, remains a main cause of diverging interpretation and misunderstandings of PED in particular. This can lead to increased costs as more time is needed to interpret and understand requirements, including relevant legal advice, and products may be under- or overclassified, leading either to higher compliance costs than necessary, as a more stringent conformity assessment than needed was chosen, or potential safety gaps, if less stringent requirements are applied. Resolving such unclear cases could thus indirectly cut compliance costs for companies and cut enforcement costs for authorities as it would be easier to determine the applicable rules. However, this remains complex, as any solution would have to be adapted, unambiguous and practical for a wide range of products, production models, and kinds of economic operators.

**The current mechanisms for stakeholder involvement (**Working Group Pressure, ADCO PED/SPVD and CABF PED/SPVD) **are generally seen as efficient and valuable platforms**. Stakeholders widely regard these groups as effective tools for supporting implementation and fostering alignment across Member States.

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44 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 105f.*

45 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 106.*

46 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 107.*

## *Coherence*

The internal coherence of the technical requirements and procedures within the Directives is generally very good. Both Directives have a clearly defined set of essential safety requirements and suitable conformity assessment procedures. The conformity assessment procedures depend on the hazard classification of the equipment and take full account of its technical characteristics. They are proportionate and become more stringent as the hazard level increases. The PED provides for the full range of conformity assessment procedures as defined in the NLF, allowing the manufacturer to choose the most cost-effective procedure. For the SPVD, the choice of conformity assessment procedures is limited but fully adapted to ensuring a cost-effective solution for these serially produced products.

In many cases, risks related to pressure are not the only risks associated with these products. Non-pressure-related safety risks could arise, for instance as a result of the presence of moving parts, electrical components or flammable gases. Because these risks are present in the same product, the PED and SPVD often apply in parallel with other harmonisation legislation. In such cases, the products must comply with several sets of safety requirements and conformity assessment procedures, which may create inconsistencies and lead to additional costs for economic operators.

The most relevant harmonisation legislation that may apply together with the PED are the directives or regulations on machinery[47], equipment for potentially explosive atmospheres (ATEX)[48], gas appliances[49], low-voltage equipment[50], radio equipment[51], lifts[52] and medical devices[53]. The PED explicitly excludes transportable pressure equipment (which is covered by the Transportable Pressure Equipment Directive

47 Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery.

48 Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres.

49 Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels.

50 Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

51 Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment.

52 Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts.

53 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

(TPED)[54]) but PED assemblies may integrate transportable equipment (certified under the TPED) in a stationary pressure system.

Because its scope is more limited, the SPVD is less likely to interfere with other harmonisation legislation. For example, integrating simple pressure vessels into machinery is rather straightforward and does not significantly impact conformity assessment under the Machinery Directive.

**However, the evaluation identified some inconsistencies in the application of the PED to equipment that is subject to other product safety legislation**. The evaluation identified a variety of problems, some related to the scope of the legislation and others to inconsistencies in the marking requirements, the EU declaration of conformity requirements, the level of alignment with the NLF or procedural obligations relating to documentation[55].

The analysis led to the conclusion that there are **no substantial or structural incoherences between the PED and most of the other harmonisation legislation. An important issue was, however, identified regarding the coherence of PED and the Machinery Directive (MD).**

### *Coherence between the PED and the Machinery Directive*

The Machinery Directive is not aligned with the NLF, leading to inconsistencies with the PED. Some definitions, procedures and marking requirements in the Machinery Directive differ from those in the PED.

Furthermore, there is uncertainty among stakeholders about the correct legal application of the PED and Machinery Directive to machinery which incorporates pressure equipment. The situation is substantially different depending on the risk classification of the pressure equipment in category I or the higher categories (II, III, IV) under PED as explained in detail below.

***For pressure equipment in Category I under PED and included in machinery subject to the Machinery Directive*** *the legislation is clear and only the Machinery Directive applies (Such pressure equipment is excluded from the scope of the PED by Article 1(2)(f)(i) PED if the Machinery Directive applies.).*

*It should be noted that some representatives of conformity assessment bodies express dissatisfaction with this and similar exclusions from the scope of the PED as specified in*

[54] Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment.

[55] *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 17, 128-132.*

*Article 1 PED*[56]*. The exclusion is considered impractical, since pressure risks must nevertheless be addressed. In practice, the manufacturers effectively still follow the requirements set out in the PED, since category I equipment can still present significant pressure risks. Excluding such equipment from the PED means that the essential safety requirements of the PED (e.g. material toughness criteria which are only spelled out in the PED) no longer apply. However, neither the desk research nor the consultations have identified any concrete evidence of safety gaps for category I pressure equipment integrated into machinery. Although less specific than the PED, the Machinery Directive also specifies essential safety requirements preventing pressure risks*[57]*. Furthermore, also the PED does not require a notified body to be involved in the conformity assessment of category I equipment. It only requires Module A, i.e. internal production controls by the manufacturer*[58]*. This is equivalent to the requirements of the Machinery Directive for most types of machinery. Therefore, the exclusion of category I equipment from the PED if the Machinery Directive applies does not result in less stringent conformity assessment by the manufacturer.*

***For pressure equipment in category II and higher, both the PED and the Machinery Directive must be applied in parallel****, unless the exemption set out in Article 1(2)(j)*[59] *PED applies.*

*The evaluation identified* ***conflicting industry practices and legal uncertainty about the correct application of the legislation****. It emerged from the evaluation study that many manufacturers, especially those more familiar with the Machinery Directive, do not carry out the global conformity assessment that the PED prescribes for an assembly when integrating individual (PED-certified) items of pressure equipment into a machine*[60]*.*

*This industry practice has its basis in informative notes 1 and 2 in PED Guideline C-13, but* ***a literal reading of the PED requires a global conformity assessment to be carried out for assemblies falling under the PED*** *when items of pressure equipment are integrated into machines (unless the exemption set out in Article 1(2)(j) PED applies).*

(56) Similarly, Article 1(2)(f) excludes category I pressure equipment covered by the Lifts Directive (point ii), Low Voltage Directive (point iii), Medical Devices Directive (point iv), Gas Appliances Directive (point v) or ATEX Directive (point vi).

(57) Point 1.3.2 of Annex I to the Machinery Directive.

(58) Article 14(2)(a) PED

59 Article 1(2)(j) PED: 'equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor'.

60 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 130f.*

*From a safety point of view, the pressure-related risks warrant the application of the PED to such assemblies. On the other hand, there is no evidence that the industry practice of applying solely the Machinery Directive has resulted in actual safety gaps or accidents.*

***Applying the PED to machinery in parallel with the Machinery Directive could significantly increase costs for machinery containing high pressure hydraulic or pneumatic components where the integrated items of pressure equipment are classified higher than category I**. Typical examples are construction machinery (e.g. bulldozers and cranes) or agriculture machinery. In such cases, a PED notified body should be involved in the conformity assessment of the machinery as a PED assembly whereas conformity assessment under the Machinery Directive can be conducted by the manufacturer without the involvement of a third party. This would increase the cost of the conformity assessment and possibly also affect the production schedule as a result of delays in design, manufacturing and testing. This would further increase the costs for the manufacturer.*

**The interaction between the PED and the Machinery Directive** (in the future, the Machinery Regulation) **should be clarified to ensure legal clarity and to avoid inconsistent application of exemptions**. There are arguments for strictly applying both legal acts in parallel, but also for implementing more flexible exemptions if the application of one legal act (the Machinery Regulation) would be sufficient to ensure the safety of the product[61]. A more in-depth impact assessment and technical study would be required to determine an unambiguous and cost-effective solution guaranteeing the safety of the products.

### *Coherence between the PED and SPVD*

Simple pressure vessels are excluded from the scope of the PED by virtue of Article 1(2)(c)[62] thereof. The scope of the SPVD is defined on the basis of the design of the vessel, but the definition also reflects its intended use, namely that the vessel contains air or nitrogen, stays below a defined capacity and working pressure, and within defined temperature limits. Pressure vessels not meeting the criteria defined in the SPVD fall within the scope of the PED.

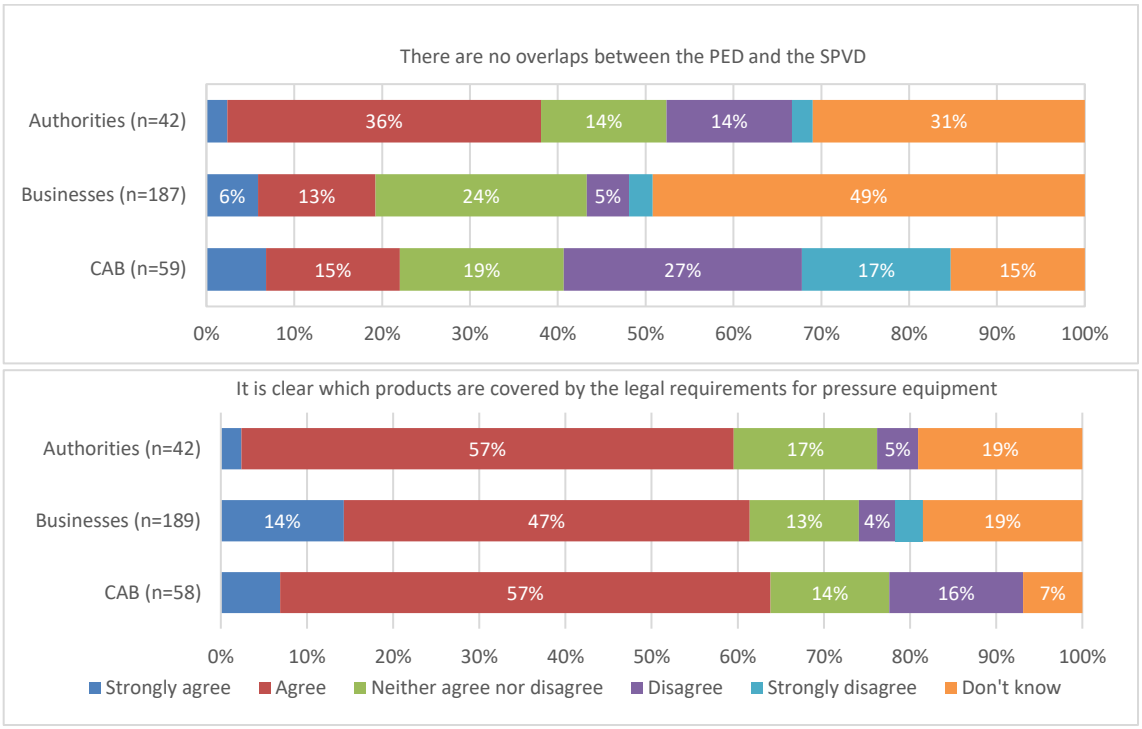
Consultation of stakeholders on the clarity of the scope of the SPVD and PED and the overlap between them indicates some diverging views, with a substantial number of authorities (42 replies or 36%) and notified bodies (59 replies or 22%) considering that there is some overlap. Out of 187 replies, only 19% of businesses consider that there is

[61] Such flexibility already exists in the PED, for example for engines where 'pressure is not a significant design factor' (Article 1(2)(j) PED).

[62] Simple pressure vessels covered by Directive 2014/29/EU of the European Parliament and of the Council.

no overlap, but 49% indicated that they did not know. Most stakeholders agree that the scope of application (which products are covered by which legislation) is clear.

Evaluation of the PED/SPVD – agreement with the statements on the clarity of the scope of the SPVD and PED and the overlap between them




*Source*: Evaluation of PED/SPVD – Figure 21

**There is, however, uncertainty among stakeholders as to whether the PED or the SPVD applies to certain specific products.** This is the case for oil separators used in some types of compressors. An oil separator is a pressurised vessel containing a mixture of compressed air and oil. SPVD Guideline 1 states that vessels containing air with a contaminant can still be classified as simple pressure vessels, even if the contaminant dissociates from the air and is removed during operation of the vessel. Stakeholders have opposing opinions on whether the fluid in an oil separator can still be classified as air with contaminants or whether it should be considered a storage vessel within the scope of the PED.

Market surveillance authorities, coordinated through the Administrative Cooperation Group for the PED (PED AdCo), hold the view that oil separators should be assessed in accordance with the PED rather than the SPVD. Business representatives defended the opposite view, referring to a long-standing industry practice based on the fact the SPVD entered into force roughly 10 years before the PED. The entry into force of the PED brought about a change of interpretation of the scope of the SPVD, which not all stakeholders agree with or are aware of. **Without a legally binding clarification, this incoherence of interpretations is unlikely to be resolved.**

**Given these disagreements and the overheads of maintaining a separate directive for a narrowly defined class of products, the question is raised whether the PED and SPVD should be merged.** The reason for having two directives is historical rather than because of legal or technical necessities. The fact that PED and SPVD establish different rules for similar products could, in itself, be perceived as an incoherence.

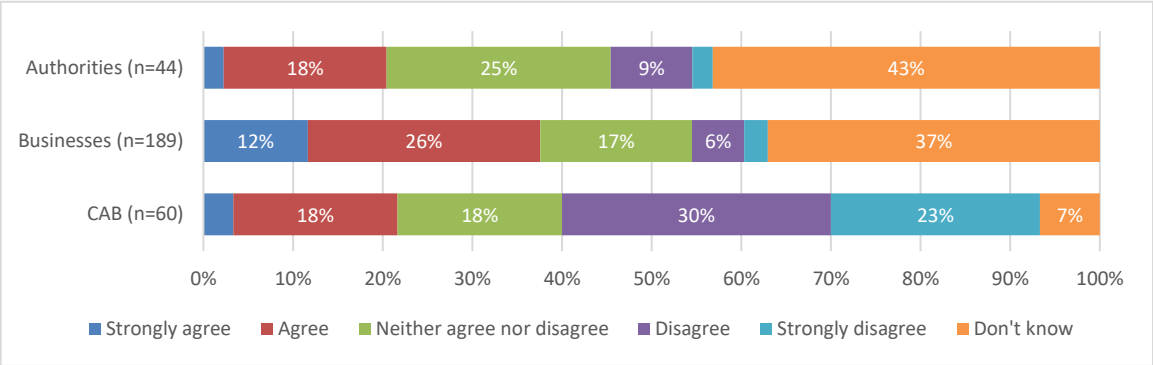
Nevertheless, a merger would have practical consequences for economic operators which may outweigh the benefits of increased consistency. In 2006, the European Commission found 'no clear justification in favour of the merger option' but also did not exclude the possibility of a merger in a future revision[63]. The 2014 recast of the two Directives did not opt for a merger, as it focused on alignment with the NLF without changing the substantive rules on product safety.

The stakeholder consultations confirmed that **there is no consensus on whether the Directives should be merged:**

- **38% of the businesses and associations** that responded to the survey **agree or strongly agree that the division between the SPVD and the PED is justified**. Only 8% disagree or strongly disagree. The remaining respondents either chose 'neither agree nor disagree' (17%) or gave no response (37%). The preference for keeping the Directives separate is because **a merger would lead to adjustment costs and would not bring clear benefits to manufacturers.**
- Conformity assessment bodies have a stronger preference for merging the Directives. 53% of the respondents disagree or strongly disagree that the division is justified, while only 22% agree or strongly agree that the division is justified. **Notified bodies must maintain separate accreditations/notifications for each piece of harmonisation legislation, which comes with significant costs**.
- Among the authorities that responded to the survey, there was no clear preference for or against merging the Directives.

Stakeholders' views on whether the division between the PED and SPVD is justified are shown in the following chart:

63 Communication from the Commission to the Council and the European Parliament, Review of the application of the Simple Pressure Vessels Directive (87/404/EEC) in relation to the Pressure Equipment Directive (97/23/EC), COM(2006) 106 final of 10 March 2006.




*Source: Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 143.*

### 4.2 How did the PED and SPVD make a difference and to whom?

The EU added value of both Directives is beyond doubt. The results of the evaluation study confirmed that the Directives have brought benefits to the EU internal market, in terms of both free movement of products and safety[64].

Stakeholders generally agree that an equal level of safety could not have been achieved by national legislation alone. Out of 43 correspondents from authorities, 49% consider that the safety level improved by the harmonisation and cannot be achieved by national legislation. Of the 59 CABs that responded, 51% support this view. Businesses have a less strong view. Of the 40 businesses that responded, 40% consider that the impact on safety was rather limited.

Stakeholders see the removal of barriers to trade as the main benefit. Of the 38 businesses that responded, 74% consider that this could not be achieved solely by regulation at national level. Similar views were stated by authorities (42 replies, 81 %) and the CABs (59 replies, 81%).

There is also consensus amongst stakeholders that the harmonisation of the legal requirements at EU level has lowered the costs for European businesses. Out of 58 replies, 76 % of the CABs share this view. Equally high numbers are found for the economic operators (38 replies, 61%) and the authorities (43 replies, 58 %).

By harmonising the requirements, the Directives have simplified compliance procedures for manufacturers, enabling them to adhere to a single regulatory framework across the EU. This has facilitated cross-border trade within the EU. Harmonisation has eliminated the complexity of navigating diverse national regulations and the challenges of undergoing multiple national conformity assessments. This has led to a significant reduction of both costs and administrative burdens, as well as reducing delays in market entry. As a result, manufacturers can now access multiple Member State markets, which

64 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, 159f.*

has not only facilitated the free circulation of goods but also enhanced competition within the EU.

While the PED and SPVD have made significant contributions to improving the functioning of the internal market, some implementation challenges remain as a result of differences in the conformity assessment and uneven market surveillance practices across Member States.

If the PED and SPVD were to be repealed, there is a strong consensus among stakeholders that the consequences would be predominantly negative. Out of 196 replies, 64 % of the businesses and out of 59 replies, 81% of the CABs consider that the impact on their organisation would be negative. The primary concerns relate to the reintroduction of fragmented national regulations, which could lead to inconsistent safety standards, higher certification and administrative costs, and reduced recognition of conformity assessments across the EU.

### 4.3 Are the PED and SPVD still relevant?

Since the introduction of PED (in 1997) and the SPVD (in 1987), the Directives have facilitated free movement and guaranteed product safety. In the future, there will still be a need to maintain the high level of safety for these high-risk products and to ensure free movement in the internal market. As a result of changes in the market, with increased imports of pressure equipment from third countries, product safety based on essential safety requirements and stringent conformity assessment procedures will become more important.

Competent and market surveillance authorities confirmed that **the PED and SPVD have been successful largely as a result of the early recognition by Member States of the high-risk nature of pressure equipment.** Prior to the adoption of the PED and SPVD, every Member State already regulated the safety of pressure equipment because of the inherent high risk. The requirements and the conformity assessment procedures were different in each Member State. The PED and SPVD harmonised the technical requirements and introduced strong third-party conformity assessment procedures to be applied in all Member States. The PED and SPVD are fully aligned with the horizontal requirements of the NLF and should benefit from further improvements to the NLF in the future.

**There is a consensus that the essential safety requirements and conformity assessment procedures in the PED allow for the use of new manufacturing methods and new materials, meaning that the Directive is able to adapt to technological and scientific developments. However,** a few challenges have been identified in keeping pace with technological advancements (e.g. use of non-metallic materials, additive manufacturing and remote inspections). There is also a concern that fluids with increasing relevance in industrial applications, such as hydrogen, may not be accurately classified under the current system, posing potential safety and compliance risks. Some stakeholders highlighted the need to update the Directive to take account of these

innovations, even though the professional associations representing manufacturers consider that the essential safety requirements and conformity assessment procedures are sufficiently clear, flexible and future-proof. In their view, the technical details should be defined in European harmonised standards and not in the legislation reflecting the overall philosophy of the New Legislative Framework.

**For the SPVD specifically, there is more uncertainty about its relevance to new materials and new manufacturing methods.** Conformity assessment bodies underlined that the SPVD does not explicitly cover cyclic loading conditions, which are critical for equipment exposed to repeated stress. The materials allowed under the SPVD for simple pressure vessels are limited to non-alloy quality steel, non-alloy aluminium or non-age hardening aluminium alloys. Other materials are not accepted, inhibiting innovation and alignment with modern industry practices. The SPVD does not address the evaluation of assemblies, such as compressed air systems, as these are covered by other legislative acts (e.g. on machinery). However, this raises the question of whether the SPVD should address the risks that arise when a simple pressure vessel is integrated into another system, as the PED does with the concept of assemblies. From the manufacturers' perspective, a few companies that participated in the survey consider the SPVD to be outdated and to offer only limited flexibility in accommodating innovative manufacturing methods or advanced design techniques, particularly when compared with the more comprehensive and adaptable requirements in the PED.

## 5. WHAT ARE THE CONCLUSIONS AND LESSONS LEARNED?

### 5.1 Conclusions

The main conclusions of the evaluation, structured per evaluation criterion, are as follows.

#### *Effectiveness*

Overall, the **PED and the SPVD have been effective in facilitating the free movement of pressure equipment within the EU internal market**. Intra-EU trade in pressure equipment has shown strong growth since the recast Directives came into force in 2016, and a majority of stakeholders (including businesses, authorities and conformity assessment bodies) agree that the Directives contribute to the functioning of the single market[65]. Harmonised standards and conformity assessment procedures have helped align regulatory requirements, reducing administrative burdens and facilitating cross-border trade. Nevertheless, some obstacles remain, including inconsistencies in interpretation, for example regarding PED assemblies.

The Directives have also **contributed to a high level of safety for pressure equipment** in the EU. Despite data limitations, accident statistics from several Member States (e.g.

[65] European Union, Single market. Available at: https://european-union.europa.eu/priorities-and-actions/actions-topic/single-market_en.

Bulgaria, France, Slovakia and Finland) show that incidents involving pressure equipment are rare, especially in comparison with other regulated product sectors. The few reported accidents are often attributed to operational shortcomings rather than legislative gaps. The evaluation found no evidence of structural safety problems with pressure equipment. However, some non-conformities identified by market surveillance authorities show that some products do not adequately address the pressure hazard but are nevertheless placed on the market.

Although the PED and the SPVD have **improved harmonisation of pressure equipment legislation, some inconsistencies persist across Member States**. While many stakeholders appreciate the harmonised legal framework and guidance documents, the survey results and case studies confirm that differences remain in how conformity assessment procedures are interpreted and applied in different Member States, particularly by notified bodies. These differences affect key aspects such as documentation, risk classification and evaluation of essential safety requirements. Such variations lead to unequal burdens for manufacturers, differing conformity results, and sometimes unfair competition among notified bodies. The lack of uniform qualification standards for notified body personnel contributes to these disparities. Most, but not all, Member States require accreditation of conformity assessment bodies (as encouraged under Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products), meaning that harmonisation has not been fully achieved in this area. Furthermore, while considered very useful, guidance documents such as the PED/SPVD guidelines are still prone to interpretation.

**Harmonised standards (hENs)** are widely seen as essential tools for complying with the PED and the SPVD. Businesses overwhelmingly confirm the usefulness of hENs, with more than half reporting that 80% or more of their pressure equipment is manufactured in accordance with these standards. The use of hENs has increased since the last evaluation in 2012, and stakeholders (including SMEs) confirm their importance in simplifying compliance and enabling consistent product quality across the single market. However, the slow pace of developing and updating standards is considered a downside of the hEN.

**Enforcement of the PED and the SPVD within the EU also varies between Member States**. Some Member States have robust market surveillance practices, while others are much less active. With all the caveats about their comprehensiveness, the data from the ICSMS and national surveillance reports reveal disparities in the number and scope of inspections. Countries like Germany, France and Poland conduct most checks, while smaller Member States with less resources perform fewer checks or operate reactively, examining only problematic cases. Most Member States face challenges, such as insufficient staffing, limited budgets and poor access to standards, which hinder their ability to carry out in-depth inspections. On the other hand, **coordination between market surveillance authorities and customs authorities is generally effective but infrequent and often lacks digital integration**. At the EU's external borders, customs authorities sometimes have difficulties effectively identifying non-compliant pressure equipment because of mismatches between product definitions and customs codes. The

use of misleading, unregulated (voluntary) certificates issued by some conformity assessment bodies further complicates enforcement, as some importers falsely present non-certified equipment as compliant with the legislation. Products from third countries are more frequently cited as non-compliant. The businesses and authorities surveyed called for better cross-border cooperation, more technical training, greater use of digital tools and stricter follow-up mechanisms to address enforcement gaps and prevent non-compliant equipment from circulating freely within the internal market.

### *Efficiency*

**Stakeholders perceive the implementation of the PED and the SPVD as generally cost-effective, meaning that the benefits outweigh the costs arising from the Directives.**

For businesses, the Directives have eased market access and reduced administrative burdens by standardising requirements. Public authorities benefit from more consistent enforcement and enhanced safety oversight. Conformity assessment bodies now operate in a more stable regulatory environment, with clearer certification and inspection procedures. Although stakeholders face various regulatory and administrative costs, these are generally considered proportionate to the benefits, such as improved safety, legal certainty and stronger internal market integration. These costs typically represent around 1-3% of the total costs of a product as placed on the market. The costs of complying with and enforcing the Directives are shared across businesses, conformity assessment bodies, and authorities responsible for inspection and monitoring. Smaller conformity assessment bodies may face disproportionate burdens, but the majority of the bodies surveyed consider their obligations manageable.

**For businesses, the highest compliance costs stem from conformity assessment procedures and related documentation requirements**. However, these costs typically remain below 1% of annual turnover, and most of the companies surveyed consider them justified in view of the market access and safety guarantees the Directives provide. Administrative burdens are generally perceived as low to moderate, with many firms already carrying out similar safety procedures voluntarily, irrespective of any regulatory requirements. **Authorities** face modest but necessary expenditure for training, inspections and accreditation of conformity assessment bodies, with annual staffing costs varying significantly by Member State. Despite limited resources, most authorities report that current efforts are sufficient, though challenges persist regarding oversight of online sales and consistent enforcement.

**Stakeholder consultation and survey data reveal no strong evidence of an excessive regulatory burden**. Instead, most stakeholders highlight the scope for improving efficiency through targeted simplification, particularly digitalisation of documentation and procedures, harmonisation of documentation practices, and clearer guidance on complex procedures such as the assessment of assemblies. Notified bodies also suggest

reforming the accreditation framework to better reflect sector-specific needs and reduce inconsistencies across Member States.

**The role of harmonised standards is central to the Directives' cost-effectiveness**. These standards (although voluntary) are widely used, with strong stakeholder support. They are not viewed as major cost drivers but rather as enabling tools that reduce legal uncertainty and streamline compliance. The average cost of purchasing standards remains low relative to turnover and is offset by the benefits of simplified conformity assessment and improved market access.

Lastly, the **current stakeholder involvement mechanisms,** including the Working Group Pressure, the coordination group of conformity assessment bodies (CABF PED/SPVD) and the administrative cooperation group of national market surveillance authorities (AdCo PED/SPVD), are seen as valuable and efficient forums for dialogue, coordination and harmonisation. While participation varies and could be broadened, particularly in the case of the CABF, these groups are instrumental in resolving emerging issues and ensuring consistency across Member States. Calls for more frequent meetings and greater involvement by accreditation bodies reflect a desire to further strengthen these mechanisms.

### ***Relevance***

Across stakeholders, **there is agreement that the PED and the SPVD remain relevant to current needs. Authorities, conformity assessment bodies and businesses** see the Directives as very important for facilitating the free movement of pressure equipment in the internal market and for effectively ensuring safety. Findings confirm that **the PED remains relevant** and essential across key sectors, such as power plants, process plants in the chemical/petrochemical/pharmaceutical industries, machinery, etc. While the Directives are generally seen as fit for purpose, challenges remain, including inconsistent practices across notified bodies and limited market surveillance. Stakeholders, particularly in the gas industry, stressed the PED's role in enabling market access and called for updates to reflect developments in the hydrogen economy. Competent authorities highlighted the Directive's strong alignment with NLF principles and its success as a result of early harmonisation and third-party involvement in conformity assessments. Similarly, the **SPVD is considered effective and appropriate** for managing risks in simple pressure vessels, supported by harmonised rules and alignment with the NLF.

**In terms of technological and scientific development, the PED remains generally justified and relevant and is seen as being supportive of innovation**. More than half of businesses agree that the Directive's scope is justified, and half believe its essential safety requirements are up to date. The PED remains relevant and is flexible enough to accommodate many emerging technologies, provided that the harmonised standards are updated accordingly. Hydrogen technologies present unique material challenges that current PED standards only partially address. Stakeholders are calling for clearer

guidance to ensure safe application across new hydrogen use cases. On the other hand, some new manufacturing and testing methods have been more challenging to accommodate under the PED. This is the case, for example, for additive manufacturing and remote inspections. Updates of the harmonised standards may not suffice to enable the compliant use of these technologies.

**The SPVD is less adaptable to technological and scientific developments, specifically when it comes to new materials and new manufacturing methods.** Stakeholders indicate that some materials allowed under the SPVD are outdated, inhibiting innovation and the adoption of modern industry practices.

**Uncertainty remains about whether digital processes and digitised documentation comply with the requirements of the PED and the SPVD.** Stakeholders expressed the need to align the Directives with modern regulatory approaches to digitalisation, such as those introduced under the Machinery Regulation, and suggested that tools like the Digital Product Passport could provide a harmonised and transparent solution for digital data management.

### *Coherence*

The PED and the SPVD are well integrated into the broader framework of EU harmonisation legislation. Products that present risks arising from pressure often also have other risks associated with them, for instance, from the presence of moving parts, flammable gases or electrical components. These risks are covered by other EU harmonisation legislation. The PED and SPVD must work well together with that other legislation, which often applies to the same product in parallel, to create a coherent regulatory framework on which businesses and the public can rely. The alignment of the PED and the SPVD with the NLF ensures their coherence with other harmonisation legislation. **Stakeholders report a satisfactory level of coherence with other harmonisation legislation.**

The findings nevertheless draw attention to two significant areas of inconsistency, in particular relating to PED assemblies. Firstly, **recital 7 of the PED states that the assembly of pressure equipment on the site and under the responsibility of a user who is not the manufacturer is excluded from the scope of the Directive, but this exclusion is not clearly reflected in the enacting terms of the Directive**. This creates ambiguity, leading to inconsistent interpretations between Member States, depending on whether the preamble to the PED is taken into account in the national transposition.

Secondly, **there are inconsistent approaches to the conformity assessment of pressure equipment integrated in machinery**. It has been the established industry practice, facilitated by a note in a PED guideline, to conduct the conformity assessment of pressure equipment integrated into machinery solely under the Machinery Directive. However, according to the interpretation of the PED by some authorities, a global conformity assessment as PED assembly should additionally be performed to meet the requirements of the PED. They therefore question whether the interpretation provided in

the PED guideline is consistent with the Directive. The many facets of the issue mean that any solution would have to navigate the complexities of clearly analysing safety implications, estimating and minimising administrative costs for business and maintaining legal certainty. Because of this, a more in-depth impact assessment and technical study would be required to determine an unambiguous and cost-effective solution guaranteeing the safety of the products. Further reflection and analysis by Commission services would thus be necessary to avoid disproportional administrative burden while ensuring safety.

The PED and the SPVD are generally consistent with each other, but there are some uncertainties regarding their scope. **Some stakeholders have suggested merging the PED and the SPVD** to simplify the applicable legislation and reduce the need for double accreditation and notification of notified bodies. Nevertheless, this idea has been **met with a mixed response** because of concerns about potential disruption to established practices, potential safety issues and increased costs for manufacturers.

### *EU added value*

The PED and the SPVD have delivered **EU added value by fostering harmonisation, ensuring safety and enabling the smooth functioning of the single market**. The harmonised legal framework they established has replaced a fragmented set of national regulations, thereby reducing administrative burdens, lowering compliance costs and streamlining conformity assessment procedures for manufacturers across the EU. Stakeholders broadly agree that these achievements would not have been possible with national legislation alone. Most businesses, authorities and conformity assessment bodies stress that, without the Directives, consistent safety standards, regulatory certainty and barrier-free trade within the EU would be severely compromised. The survey responses and stakeholder consultations clearly highlight that **repealing the Directives would have a predominantly negative impact**. It would likely result in a return to divergent national rules, increased certification costs, duplication of conformity procedures and reduced mutual recognition across borders. This would harm market access, stifle innovation and reduce competitiveness, particularly for smaller businesses and Member States with less resources.

## 5.2 Lessons learned

Several key lessons have been identified on the basis of the findings and conclusions of the evaluation.

**The benefits of digitalisation have not yet been fully realised in the PED/SPVD framework**. In terms of efficiency and simplification, most stakeholders highlighted opportunities to improve efficiency through digitalisation. There is untapped potential to increase efficiency and traceability by integrating digital tools and processes. As discussed with various stakeholders during the final interviews and workshop, there are

horizontal digitalisation initiatives[66] at EU level which span various legislative instruments and would inevitably provide guidance and positively affect the PED/SPVD.

The part of the Omnibus IV legislative package on common specifications and digital documentation will help create legal certainty for economic operators in the environment of PED and SPVD by creating clear rules and possibilities for the digital provision of instructions for use and the Declaration of Conformity. However, sectoral digitalisation challenges will remain, such as missing clarity on the use of remote inspection technologies by Notified Bodies to examine the quality of products, in particular welds, from a distance.

**Digitalisation is also a challenge for those applying the PED/SPVD.** Despite the existence of comprehensive guidelines and support platforms, not all economic operators appear to be aware of these online resources. While some Member States have attempted to address uncertainties through national websites with translated guidance, some authorities emphasised the need for a more user-friendly and centralised EU platform. The PED and SPVD guidelines are available in three languages on the Europa website, but there is, for example, no central repository of non-harmonised national in-service inspection regulations which could also affect the procedures and requirements for putting into service simple pressure vessels, items of pressure equipment or assemblies.The evaluation underscores the importance of maintaining an active and well-coordinated community of pressure equipment experts, particularly through platforms like the Conformity Assessment Bodies Forum (CABF) and the Administrative Cooperation Group (AdCo). These groups play a critical role in harmonising interpretations, exchanging practical experiences and resolving ambiguities in the implementation of the PED and SPVD. Given the technical complexity and evolving nature of pressure technologies, consistent expert collaboration is essential to ensure uniform enforcement, technical competence and a common understanding across all Member States. However, the evaluation study found that coordination activities at EU level[67] have diminished in recent years, resulting in a backlog of unanswered questions and fragmented national approaches, and undermining legal certainty for manufacturers and notified bodies[68]. All stakeholders (including businesses, conformity assessment bodies and national authorities) stressed the need to revitalise these expert groups, ensure regular meetings and strengthen EU-level coordination mechanisms to preserve the integrity and effectiveness of the regulatory framework.

**Recurrent and pressing issues:** there are some structural issues, which, if addressed, would further increase harmonisation across the internal market.

- One of the most frequently cited concerns is the **slow pace of updating harmonised standards** and **delays in developing or revising guidance**

66 https://single-market-economy.ec.europa.eu/publications/digitalisation-and-alignment-common-specifications_en.

67 Most notably the Working Group Pressure (WGP) and the Working Party Guidelines (WPG).

68 *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 19, 161*.

**documents**. The voluntary nature of harmonised standards leads to fragmented interpretations, and the long timelines for updates by standardisation bodies exacerbate the problem. Similarly, guidance documents intended to clarify the Directives are typically not updated swiftly enough because the process of reaching consensus is lengthy. This is due to various reasons, for example the technicality of the subject, limited availability of experts to develop the guidance and legal scrutiny of the documents.

- A widely reported issue concerns the **interpretation of assemblies under the PED.** This remains a misunderstood and inconsistently applied concept across Member States and notified bodies, resulting in divergent conformity assessment practices and an unequal burden on manufacturers.
- The notions of 'own use' and **installations 'on the site and under the responsibility of a user** who is not a manufacturer' should be clarified.
- **To ensure legal certainty, the PED should be aligned with the latest version of the CLP Regulation**, which affects the classification of fluids and the hazard category of the equipment under the PED.
- There is **no EU-wide consensus on minimum qualification requirements** for personnel involved in conformity assessments, resulting in varying levels of expertise and oversight quality.
- The lack of harmonisation also extends to the accreditation process for conformity assessment bodies, particularly regarding **document EA 2/17 M:2020**[69], which prescribes the standards for accrediting conformity assessment bodies. Many stakeholders, especially conformity assessment bodies, criticised EA 2/17 M:2020 for being overly complex, inconsistently applied and not fully adapted to the stationary pressure equipment sector.
- Several authorities and businesses raised concerns about **non-compliant pressure equipment entering the EU from third countries**, particularly via **online marketplaces**. These products may be falsely CE-marked or backed by **non-regulated (voluntary) certificates**, making it difficult for customs and market surveillance authorities to verify them.

Many of the above-mentioned issues are of a horizontal nature and legislative proposals to improve the legal framework are currently under preparation. Specifically, this concerns proposals for the revisions of the New Legislative Framework[70], the Market Surveillance Regulation[71] and the Standardisation Regulation[72].

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69 https://european-accreditation.org/wp-content/uploads/2018/10/ea-2-17-m.pdf.

70 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14715-Product-legislation-ensuring-futureproof-rules-revision-of-the-New-Legislative-Framework-NLF-_en.

71 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14807-Market-surveillance-and-compliance-of-products-evaluation-and-possible-revision-of-Regulation-EU-2019-1020_en.

72 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14511-Standardisation-Regulation-revision_en.

## ANNEX I: PROCEDURAL INFORMATION

### *1. Lead DG, Decide reference and, if relevant, Work Programme reference*

DG for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW).
Decide entry PLAN/2023/689.

### *2. Derogations granted and justification*

Not applicable.

### *3. Organisation and timing*

The evaluation report for the PED/SPVD directives was planned for Q4 2025 in the Commission Work Programme.

A call for evidence ran from 23.05.2024 to 20.06.2024.
Interservice Steering Group meetings took place on 29.03.2023, 14.09.2023, 24.04.2024, 6.11.2024, 26.02.2025, 4.06.2025 and 11.03.2026.

The following Commissions services participated: SG, SJ, DG TAXUD, DG TRADE, DG COMP, DG ENV, DG CLIMA, DG GROW, DG MOVE, DG RTD, JRC.

In line with better regulation principles, an Interservice Consultation ran between 23.06.2026 and 06.07.2026. Where possible, all comments from the different Commission services were considered.

### *4. Consultation of the Regulatory Scrutiny Board (if relevant)*

*Not relevant.*

## ANNEX II. METHODOLOGY AND ANALYTICAL MODELS USED

The evaluation builds on the supporting study carried out by an external contractor Capgemini/Ecorys[73].

The study employed a combination of different approaches to gather data and information from stakeholders as explained below.

In line with Better Regulation requirements, the directives were evaluated considering the five criteria of relevance, effectiveness, efficiency and coherence of the initiative, and its EU added value. The evaluation applied a comprehensive mixed-methods approach, integrating both qualitative and quantitative techniques to assess the implementation and performance of the

[73] *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report.*

PED and SPVD. This included desk research, database screening, and an extensive consultation process to gather data and qualitative information on the implementation and performance of the two directives in relation to the five evaluation criteria mentioned above.
The stakeholder consultation strategy included the following tools:

- Call for Evidence (C4E)
- Target surveys
- Targeted interviews, including case study interviews
- Expert Panel (for case studies)
- Validation workshop

Consultations in the scope of this study were implemented between May 2024 and June 2025. The contractor was able to reach out to a representative number of the various stakeholders. Additional effort was spent on the case studies and expert panels resulting in valuable more in-depth insights for some product categories and confirming the more general finding collected via the targeted surveys and interviews.

The evaluation faced several data limitations that affected the depth and precision of its findings. A key challenge was the fragmented and incomplete availability of accident and enforcement data across Member States. The ICSMS[74] database, intended as a central EU tool for market surveillance coordination, was found to be underutilised, inconsistently populated, and lacking standardised reporting practices. Conclusion in this report related to safety of the product is therefore not only based on the findings of the study report but also on the long-standing experience and exchanges with stakeholders in the expert groups.

There is a limited availability of market data at sufficient granularity, which makes it impossible to calculate in a reliable manner the overall costs and benefits of the PED and SPVD. These gaps were partially mitigated in the evaluation study through stakeholder consultations and case studies[75].

[74] https://webgate.ec.europa.eu/single-market-compliance-space/market-surveillance

[75] *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 163.*

## ANNEX III. EVALUATION MATRIX AND, WHERE RELEVANT, DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS (BY CRITERION)

| | Evaluation questions | Judgement criteria | Indicators | Main sources | Evaluation tools |
|---|---|---|---|---|---|
| | • Q1. Effectiveness: How effective was the measure (the directives - PED and SPVD) in achieving its objectives? | | | | |
| | 1.1 To what extent have the directives (PED and SPVD) contributed to ensuring the free movement in the internal market of the products in their scope?<br><br>Which obstacles to the internal market for pressure equipment still remain? Have they had unintended positive or negative consequences or collateral effects? | 1.1.1 Free trade in the internal market of pressure equipment and simple pressure vessels<br>1.1.2 Stakeholders agree that the directives contributed to ensuring the free movement in the internal market of the products in their scope | 1.1.1 Trends on yearly Trade statistics (e.g. on piping, safety valves, fire extinguishers)<br>1.1.2 Stakeholder opinion on the directives' contribution to the functioning of the internal market | 1.1.1 Eurostat (Comext) and/or UN Comtrade<br>1.1.2 Stakeholder consultations | • Desk research<br>• Descriptive statistics on trade<br>• Baseline comparisons<br>• Interviews, surveys |
| | 1.2 To what extent have the directives (PED and SPVD) contributed to ensuring a high level of safety of the products in their scope? | 1.2.1 Reduced number of incidents, casualties and injuries involving pressure equipment before and after the implementation.<br><br>1.2.2 Stakeholders agree that the directives ensure a high level of safety of the products in their scope | 1.2.1 Number of accidents/casualties<br><br>1.2.2 Stakeholder opinion on the directives' contribution to the functioning of the internal market | 1.2.1.1 ICSMS/EU Safety Gate<br><br>1.2.1.2 ARIA database (French database on industrial accidents) and other national databases<br><br>1.2.2 Stakeholder consultations | • Desk research<br>• Descriptive statistics on incidents<br>• Baseline comparisons<br>• Interviews, surveys |

| | Evaluation questions | Judgement criteria | Indicators | Main sources | Evaluation tools |
|---|---|---|---|---|---|
| | 1.3 To what extent have the directives achieved their specific objectives:<br><br>1.3.1 Ensure harmonisation of pressure hazard regulation in Member States national legislation<br><br>1.3.2 Provide a framework for high level of safety<br><br>Linked to 1.3.1 - To what extent has the different implementation of the directives in Member States impacted the effectiveness of the directives in achieving their objectives? Is there national gold-plating that hampers the internal market? | 1.3.1.1 Interpretation of the PED/SPVD is uniform (transposition and implementation) across different Member States<br><br>1.3.1.2 Countries accredit (or notify) notified bodies and set up well-functioning market surveillance authorities<br><br>1.3.1.3 Conformity assessment procedures are consistent in quality and methodology<br><br>1.3.1.4 Extent to which Member States interpret the guidelines consistently<br><br>1.3.1.3 Stakeholders agree that the directives ensure harmonisation of addressing pressure hazards of national legislation<br><br>1.3.2.1 PED/SPVD Guidelines provide the necessary requirements / standards / guidance documents<br><br>1.3.2.2 The number of NBs, UIs and RTPOs is sufficient to serve the demand for conformity assessment services.<br><br>1.3.2.3 Extent to which the industry has using the European harmonised standards.<br><br>1.3.2.4 Stakeholders agree that the directives provide a high level of safety | 1.3.1.1 Instances where discrepancies in interpretation are reported<br><br>1.3.1.2 Number of notified bodies and market surveillance authorities<br><br>1.3.1.3 Cases in which a discrepancy in the procedures has been reported<br><br>1.3.1.4 Reported interpretation discrepancies<br><br>1.3.1.3 Stakeholders opinion regarding the harmonisation of national legislations<br><br>1.3.2.1 Clarity and common understanding of technical requirements<br><br>1.3.2.2 Adequate number of Notified Bodies, User Inspectorates and Recognised Third-Party Organisations (RTPOs)<br><br>1.3.2.3 Rate of uptake of the European harmonised standards by the industry<br><br>1.3.2.4 Stakeholders' opinion on the question if the directives provide the necessary framework for essential safety requirements / standards / guidance | 1.3.1.1 National legislations<br><br>1.3.1.2 NANDO database<br><br>1.3.1.3 Stakeholders consultations<br><br>1.3.2.1 PED/SPVD Guidelines<br><br>1.3.2.2 NANDO database<br><br>1.3.2.3 – 1.3.2.4 Stakeholders consultations | • Desk research<br><br>• Baseline comparisons<br><br>• Interviews, surveys |

| | Evaluation questions | Judgement criteria | Indicators | Main sources | Evaluation tools |
|---|---|---|---|---|---|
| | 1.4 To what extent do European harmonised standards contribute to the effective implementation of the directives? | Exploratory question – the answers will be based on the data gathering and analysis for the other evaluation questions under Effectiveness. | | | |
| | 1.5 How effective is the enforcement of the directives? What are the different challenges in identifying products which are non-compliant with the PED and SPVD both during import (enforcement at EU external borders) and within the EU market (enforcement within the EU internal market)? | 1.5.1 Extent to which enforcement in the internal market is uniform<br><br>1.5.2 Non-conforming products are removed from the market via the safeguard procedure<br><br>1.5.3 Ensured enforcement in the external borders | 1.5.1.1 Number of inspections conducted<br><br>1.5.1.2 Number/share of non-conforming products identified<br><br>1.5.2.1 Number of products remedied<br><br>1.5.1.2 Number of enforcement actions (withdrawn equipment, recalled equipment)<br><br>1.5.1.3 Number of restrictive measures per Member State and size of penalties<br><br>1.5.2.1 Number of notifications under the Safeguard Clause<br><br>1.5.2.2 Number of legal actions against economic operators for breach of PED/SPVD.<br><br>1.5.3 Number of customs authority notifications and market surveillance reports on (potentially) non-compliant products (to the extent the information can be publicly shared), including on imported products | 1.5.1.1 Notified Bodies, User Inspectorates and Recognised Third Party Organisations<br><br>1.5.2 National authorities / Safety Gate / ICSMS<br><br>1.5.3 To be explored with customs and market surveillance authorities | • Desk research<br><br>• Interviews, surveys |

| | Evaluation questions | Judgement criteria | Indicators | Main sources | Evaluation tools |
|---|---|---|---|---|---|
| | 1.6 What are the factors that have influenced positively and negatively the achievements observed? Are there any aspects/means/actors that render certain aspects of the directives more or less effective than others, and – if there are – what lessons can be drawn from this? | 1.6.1 There are identifiable factors that have (had) a positive impact on the achievements observed<br><br>1.6.2 There are identifiable factors that have (had) a negative impact on the achievements observed | 1.6.1 Factors that have (had) a positive impact on the progress towards the objectives<br><br>1.6.2 Factors that have (had) a negative impact on the progress towards the objectives | 1.6.1 Evidence of factors having positive/negative impact on progress towards objectives<br><br>1.6.2 Stakeholder opinion on factors having positive/negative impact on progress towards objectives | • Desk research<br>• Interviews, surveys |
| | 1.7 Are there any unintended effects of the directives? | 1.7.1 There are sizeable identifiable unexpected/ unintended effects | 1.7.1 Identifiable unexpected/ unintended effects | 1.7.1 Evidence of unexpected / unintended effects<br><br>1.7.1 Stakeholder opinion on unexpected / unintended effects | • Desk research<br>• Interviews, surveys |
| Efficiency | Q2 Efficiency: were the benefits achieved at a reasonable cost? | | | | |

| | Evaluation questions | Judgement criteria | Indicators | Main sources | Evaluation tools |
|---|---|---|---|---|---|
| | 2.1 What are the regulatory and administrative costs and are they affordable for the various stakeholder groups? What does this represent in terms of administrative and reporting burdens? | 2.1.1 Assessment of cost-effectiveness for business<br>2.1.2 Evaluation of costs incurred by administrations<br>2.1.3 Burden of compliance surveillance<br>2.1.4 Efficiency of regulatory timelines<br>2.1.5 Affordability and impact of costs on consumers and authorities | 2.1.1 Costs for businesses (incl. SMEs) – Technical documentation costs (Documentation and record keeping<br>2.1.2 Costs for administrations (standardisation, market surveillance customs, notifying authorities)<br>2.1.4 Timelines of PED/SPVD-related procedures, e.g. time needed to Notified Bodies for accepting/refusing new solutions of design or assessment of conformity for pressure equipment proposed by manufacturers<br>2.1.5. Costs for EU authorities and institutions | 2.1.1-2.1.5 Stakeholders input – particularly case studies and surveys<br>2.1.2-2.1.4 Documents of national authorities and EU institutions | • Surveys<br>• Case studies<br>• Descriptive statistics<br>• Analysis of Costs and benefits |
| | 2.2 Is there evidence that the PED and SPVD have caused unnecessary regulatory burden? | 2.2 Evidence of regulatory burdens that could be avoided | 2.2.1 Excessive procedures/timelines<br>2.2.2 Excessive reporting requirements | 2.1.1-2.2.2 Stakeholders' input – particularly case studies and surveys<br>2.2.2 National regulatory procedures | • Surveys<br>• Case studies<br>• Analysis of Costs and benefits<br>• Interviews |
| | 2.3 To what extent have the PED and SPVD been cost-effective? Are the costs proportionate to the benefits attained? What are the factors influencing the proportionality of costs? What is the role of harmonised European standards in PED and SPVD in cost terms? | 2.3.1 The benefits are proportionate to (or outweigh) the costs<br>2.3.2 Extent to which the harmonised European standards in PED and SPVD have influenced costs | 2.3.1 Cost-Benefit Ratio<br>2.3.2 Costs related to the harmonised European standards in PED and SPVD in cost terms | 2.3.1 Analysis of Costs and Benefits<br>2.3.2 Stakeholder input - case studies, surveys, interviews | • Analysis of Costs and benefits<br>• Surveys<br>• Case studies<br>• Interviews |

| | Evaluation questions | Judgement criteria | Indicators | Main sources | Evaluation tools |
|---|---|---|---|---|---|
| | 2.4 What aspects of the measure are the most inefficient and most efficient in terms of resources that are mobilised by stakeholders during the different phases of the process? | Exploratory question, building on 2.1-2.3 | | As above | As above |
| | 2.5 How efficient are the current mechanisms for stakeholder involvement (the Working Group Pressure (WGP), Working Party Guidelines (WPG), Working Party Materials (WPM), CEN Pressure Equipment Advisory Nucleus, the conformity assessment bodies Forum for PED/SPVD, Administrative Cooperation Group AdCo PED/SPVD)? | 2.5 The benefits associated with the current mechanisms for stakeholder involvement outweigh the costs | 2.5 Benefits associated with the current mechanisms for stakeholder involvement | 2.5 Stakeholder input - surveys, interviews | • Surveys<br>Interviews |
| Relevance | Q3 Relevance: do the objectives correspond to the current needs? | | | | |
| | 3.1 To what extent are the directives relevant vis-à-vis the original objectives/needs? | 3.1.1 Degree of integration of the pressure equipment/simple pressure vessels on the internal market<br>3.1.2 Degree of safety of pressure equipment for industrial users and consumers | 3.1.1 Average growth in intra-EU exports and imports of pressure equipment over the last decade<br>3.1.2 Information and evidence of safety needs not covered by the directives | • Eurostat<br>• Comtrade/Comext<br>• PED/SPVD Guidelines<br>• Stakeholder consultations | • Descriptive statistics<br>• Desk research<br>• Interviews, survey |

| | Evaluation questions | Judgement criteria | Indicators | Main sources | Evaluation tools |
|---|---|---|---|---|---|
| | 3.2 To what extent are the directives relevant vis-à-vis the current/future needs, in particular:<br>3.2.1 Is there a demand / potential for more cross-border trade between Member States?<br>3.2.2 To what extent have the PED and SPVD followed / allowed for technological and scientific development?<br>3.2.3 What is the contribution of the directives to the Sustainable Development Goals?<br>3.2.4 Are the directives enabling the digital and green transition ('do no significant harm' and 'digital by default' principles)? | 3.2.1 Trends of cross-border trade between Member States show growing demand<br><br>3.2.2 Level of freedom for the development of new designs and solutions of pressure products for manufacturers<br><br>3.2.3 Degree of directives' alignment with SDGs targets, in particular<br>○ SDG 9: Industry, Innovation, and Infrastructure<br><br>3.2.4 Compliance with the DNSH and 'digital by default' principle is ensured by the existing procedures | 3.2.1.1 Imports/exports (intra and extra-EU) of pressure equipment in Member States over the last decade<br><br>3.2.1.1 Size of production for selected products under the scope of the directives.<br><br>3.2.3.1 Assessment of the level of R&D investments within industries affected by the PED/SPVD (SDG 9)<br><br>3.2.4.1 Opinions/evidence on the impact of increasing hydrogen transport on the categories of equipment currently covered by the directives.<br><br>3.2.5.1 Information on procedures and application of the DNSH and 'digital by default' principles | • Eurostat/Comtrade<br>• PED/SPVD Guidelines<br>• Stakeholder consultations<br>• Case studies | • Descriptive statistics<br>• Desk research<br>Interviews, survey |
| | 3.3 Is there any issue with the scope of the directives?<br>3.3.1 Are all relevant products covered?<br>3.3.2 Are the scopes of the directives described sufficiently clearly?<br>3.3.3 Are there any products not included that should be covered under the directives? | 3.3.1 The pressure products outlined under the scope of the directives is exhaustive<br>3.3.2 The directives provide clear description of the scopes and definition of all terms and products<br>3.3.3 The directives are up to date and they incorporate all relevant products | 3.3.1 Pressure equipment not covered by the directives<br><br>3.3.2 Opinions on the viability of a potential merger between the SPVD and PED<br><br>3.3.3 Opinions on the extension of the SPVD and PED to cover other products / processes | • Stakeholder consultations<br>• PED/SPVD Guidelines<br>Case studies | • Interviews<br>Desk research |

| | Evaluation questions | Judgement criteria | Indicators | Main sources | Evaluation tools |
|---|---|---|---|---|---|
| Coherence | Q4 Coherence: Are there any issues of coherence within the measure or with others having similar objectives? | | | | |
| | 4.1 To what extent are the PED and SPVD consistent with other legislation applying to the same or closely related products? In particular:<br>- the Transportable Pressure Equipment Directive<br>- the Aerosol Dispensers Directive<br>- the Machinery Directive<br>- Regulation (EC) No 1272/2008 (CLP regulation)<br>- other legal acts listed in Art. 1(2) of the PED<br>Are there any inconsistencies, overlaps or gaps? | 4.1.1 The scope of the PED is clearly delineated against other legislation<br>4.1.2 The requirements of the PED and SPVD do not conflict with the requirements of other legislation applying to the same products<br>4.1.3 The exclusions from the scope of the PED in Art. 1(2) do not lead to gaps in the essential safety requirements<br>4.1.4 The requirements relating to pressure hazards create a coherent regulatory framework<br>4.1.5 The alignment with the CLP Regulation creates a coherent regulatory framework | 4.1.1 Evidence of incorrect or contested classification of products as falling under either directive<br>4.1.1 Stakeholders perceive the classification of products as clear and certain<br>4.1.2 Evidence of conflicting or inconsistent product requirements, stemming from the directives<br>4.1.3 The harmonised requirements leave no significant risks related to pressure unaddressed<br>4.1.4 The essential safety requirements (e.g. for materials used, mitigation measures) and conformity assessment procedures are similarly strict for products of similar risk<br>4.1.5 The risk classification according to different fluids ensures a similar level of safety for products of similar risk | • Legal texts and supporting documents, incl. guidelines of the WGP<br>• Market surveillance reports (where available) and similar data from authorities or sectoral associations<br>• Stakeholder consultations<br>Previous evaluations (of the PED and other legislative acts) | The focus of the study will be coherence in the practical application of the directives. The analysis will rely on market data, practice manuals, and information provided by stakeholders. These resources will help identify instances of incorrect or disputed product classification, as well as cases of conflicting or inconsistent product requirements.<br>If the available evidence suggests that any such issues are caused by incoherence in the legal texts or guidelines, an assessment of coherence in the abstract will be carried out. |

| | Evaluation questions | Judgement criteria | Indicators | Main sources | Evaluation tools |
|---|---|---|---|---|---|
| | 4.2 To what extent are the PED and SPVD consistent with horizontal EU legislation, and in particular with the New Legislative Framework? Are there any inconsistencies, overlaps or gaps? | 4.2.1 The provisions of the PED and SPVD are coherent with horizontal rules on product safety requirements, conformity assessment, and market<br>4.2.2 The harmonised standards reflect the essential requirements imposed by the PED and SPVD | 4.2.1 Evidence of incoherence of the PED and SPVD with horizontal rules or duplication of rules<br>4.2.2 Evidence of non-conformity despite adherence to harmonised standards | • Legal texts and supporting documents (guidelines, harmonised standards)<br>• NANDO database<br>• Stakeholder consultations | |
| | 4.3 To what extent are the PED and SPVD internally coherent? Are there any inconsistencies, overlaps or gaps? | 4.3.1 The provisions of the PED are internally coherent<br>4.3.2 The provisions of the SPVD are internally coherent | 4.3.1 Evidence of gaps or inconsistencies in the PED, in particular as regards the risk classification (Art. 13 PED) and the associated essential safety requirements and conformity assessment procedures<br>4.3.2 Evidence of gaps or inconsistencies in the SPVD, in particular as regards the classification of products according to PS x V (Art. 13 SPVD) and the associated conformity assessment procedures | • Legal texts and supporting documents (guidelines, harmonised standards)<br>• Market surveillance reports<br>• Stakeholder consultations<br>Previous evaluation of the PED | |
| EU added | Q5 EU added value: what is the additional EU value added? | | | | |

| | Evaluation questions | Judgement criteria | Indicators | Main sources | Evaluation tools |
|---|---|---|---|---|---|
| value | 5.1 What is the added value of the PED and SPVD compared to what could be achieved at merely national level? | 5.1.1 Identifiable evidence that Member States acting alone meet equivalent objectives to the ones purposed by PED/SPVD<br><br>5.1.2 Identifiable evidence that the PED/SPVD ensures efficiency/effectiveness gains compared to Member States acting individually | 5.1.1 Stakeholders opinion on the possibility for Member States acting alone to meet the same objectives of the PED/SPVD<br><br>5.1.2 Stakeholder opinion on efficiency/effectiveness gains driven by the PED/SPVD compared to Member States acting individually | • Stakeholder consultations<br>National authorities (for information on national initiatives) | • Desk research<br>Interviews, surveys |
| | 5.2 Do the needs and challenges addressed by them continue to require (harmonisation) action at EU level? | 5.2 Identifiable evidence that EU level action is required to ensure harmonisation across Member States regulations | 5.2.1 Stakeholder opinion on the extent to which EU level action is needed to meet the objectives of the PED/SPVD<br>5.2.1 Evidence of cross-border / transnational problems that can be solved at EU level | Stakeholder consultations | • Desk research<br>Interviews, surveys |
| | 5.3 What would be the most likely consequences of repealing the PED and SPVD? | 5.3 Identifiable evidence of significant consequences of repealing PED/SPVD | 5.3.1 Stakeholder opinion on the consequences of repealing PED/SPVD<br>5.3.2 Effectiveness / efficiency gains to be lost in case of repealing | Stakeholder consultations | • Desk research<br>Interviews, surveys |

## ANNEX IV. OVERVIEW OF BENEFITS AND COSTS

***The table below shows the mapping of cost and benefit items relevant in the analysis of the efficiency of the PED and SPVD:***

| Main Category | Sub-Type | Obligation | Name | Stakeholder affected | One-off/recurrent | Indicators for quantification | Data collection for quantification |
|---|---|---|---|---|---|---|---|
| Direct compliance costs | Adjustment cost | Produce equipment compliant with safety requirements of directives (Article 6(4)) | Design and production modifications | Manufacturer | One-off/recurrent | FTEs / EUR invested | Case studies |
| Direct compliance costs | Adjustment cost | Produce equipment compliant with safety requirements of directives (Article 6(4)) | Testing | Manufacturer | Recurrent | FTEs/ EUR | Survey |
| Direct compliance cost | Administrative cost | Produce equipment compliant with safety requirements of directives (Article 6(4)) | Certification as a part of the conformity assessment process | Manufacturer | Recurrent | FTEs/EUR | Survey |
| Direct compliance costs | Adjustment cost | Manufacturers shall draw up technical documentation (Article 6(2)) | Technical documentation | Manufacturers | Recurrent | FTEs / EUR invested | Survey and Case study |
| Direct compliance | Adjustment cost | The personnel responsible for carrying out conformity assessment tasks shall have sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified (Article 24(7.a)) | Staff training | Manufacturers CABs | Recurrent | FTE/EUR/% | Case study / Survey |
| Direct compliance | Adjustment cost | Pressure equipment or assemblies which are in conformity with harmonised standards shall be presumed to be in conformity with the essential safety requirements covered by those standards or parts thereof, referred to in Annex I (Art. 12(1)) | Purchasing standards | Manufacturers CABs | Recurrent | EUR | Survey/interviews |
| Direct compliance | Administrative cost | The application for notification shall be accompanied by a description of the conformity assessment activities, the | Accreditation | CABs | Recurrent | EUR | Case study/survey |

| Main Category | Sub-Type | Obligation | Name | Stakeholder affected | One-off/recurrent | Indicators for quantification | Data collection for quantification |
|---|---|---|---|---|---|---|---|
| | | conformity assessment module or modules and the pressure equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24 or Article 25 (Article 28(2) | | | | | |
| Direct compliance | Administrative cost | Application for notification (Article 28) and Notification procedure (Article 29) | Notification | CABs | Recurrent | EUR | Case study/survey |
| Enforcement cost | Information and monitoring | Article 21, 22, 23, 29, 32, 33, 35, 37 (notifying authorities),<br>Article 44, 45, 47, 49 | Coordination of the implementation | Competent Authorities, Market surveillance authorities | Recurrent | FTEs | Survey |
| Direct compliance costs | Administrative Costs | Record keeping (Article 6, 8, 10, 17) | Documentation and record-keeping<br><br>Compliance reporting | Manufacturer Importer (businesses other than manufacturers) | Recurrent | FTEs / EUR | Surveys |
| Enforcement costs | Information and monitoring, inspections | Market surveillance (Chapter 5) | Surveillance of market compliance | Market surveillance authorities (of Member States) | Recurrent | FTEs / salary costs | Surveys (interviews) |
| Enforcement Costs | Information and monitoring, inspections | Conformity assessment oversight (Chapter 4 - Article 20) | Costs for designating and monitoring notified bodies | Member States /Notifying Authorities of Member States | Recurrent | FTE | Studies (interviews) |
| Direct regulatory benefits | Health and safety improvements | | Reduced Risk of Accidents and Improved Workplace Safety | Businesses, users, and citizens | Recurrent | Stakeholder perception / Number of accidents/fatalities | Desk research / interviews / case studies / public consultation (to the extent feasible) |
| Direct regulatory benefits | Harmonisation across the EU | | Free movement of pressure equipment | Businesses, users, and citizens | Recurrent | Trade statistics / Stakeholder perception | Desk research / interviews / case studies / public consultation (to the extent feasible) |

| Main Category | Sub-Type | Obligation | Name | Stakeholder affected | One-off/recurrent | Indicators for quantification | Data collection for quantification |
|---|---|---|---|---|---|---|---|
| Direct regulatory benefits | Societal welfare | | Consumer Confidence | Users, and citizens | Recurrent | Stakeholder perception | Desk research / interviews / case studies / public consultation (to the extent feasible) |

The table below provides an overview of relevant costs and benefits based on the information collected in the evaluation study[76]

| | | | Citizens/Consumers | | Businesses | | Administrations | | Conformity assessment bodies | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Quantitative | Comment | Quantitative | Comment | Quantitative | Comment | Quantitative | Comment |
| **DIRECT COMPLIANCE COSTS** | | | | | | | | | | |
| **Direct compliance costs (adjustment cost)** | **Conformity assessment by Notified Bodies or other third parties** | **One-off** | - | - | **SMEs:** €3,000-€300,000 (€64,900 on average) per company<br>**Large companies:** €5,000-€250,000 (€66,000 on average) per company | The variation depends on the company size, on the product type, and on the regional market | - | - | - | - |

[76] *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 236-240.*

| | | | Citizens/Consumers | | Businesses | | Administrations | | Conformity assessment bodies | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Purchase of standards** | **Recurrent** | - | - | **SMEs**: €1,000-€10,000 (€3,250 on average) per year per business<br><br>**Large companies**: €200-€15,000 (€6,800 on average) per year per business | The purchase of standards is a recurrent cost. However, cost quantification was based on initial costs, as companies did not provide estimates of annual recurring costs. It can reasonably be assumed that when new standards are purchased, the recurrent costs are similar to the initial costs. | - | - | **PED:** €960,000 per year at the EU level on average<br>**SPVD:** €67,500 per year at the EU level on average | The purchase of standards is a recurrent cost. However, cost quantification was based on initial costs, as companies did not provide estimates of annual recurring costs. It can reasonably be assumed that when new standards are purchased, the recurrent costs are similar to the initial costs. |
| **Direct compliance costs (administrative costs)** | **Accreditation - PED** | **One-off** | - | - | - | - | - | - | Around €6.080.000 at the EU level | This includes accreditation costs incurred by CABs. |
| | **Accreditation - PED** | **Recurrent** | | | | | | | Around €3.200.000 at the EU level per year | |
| | **Accreditation - SPVD** | **One-off** | | | | | | | **One-off:** Around €324.000 at the EU level | |
| | **Accreditation - SPVD** | **Recurrent** | | | | | | | **Not available** | |

| | | | Citizens/Consumers | | Businesses | | Administrations | | Conformity assessment bodies | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Notification - PED** | **One-off/Recurrent** | | | | | | | **One-off**: Around €800,000 at the EU level<br>**Recurrent**: n/a | |
| | **Administration and reporting (documentation and record-keeping, compliance reporting)** | **Recurrent** | | | **PED:**<br>**SMEs:** €1,000-€130,000 (€64,000 on average) per year per company<br><br>**Large companies**: €1,000-900,000 (€221,750 on average) per year per company | These data include administration and reporting average costs for businesses, which excludes technical documentation and include among others, translations and record-keeping | | | | |
| **ENFORCEMENT COSTS** | | | | | | | | | | |
| **Enforcement costs** | **Market surveillance PED**<br><br>**Notification, accreditation and supervision of CABs** | **Recurrent** | - | - | | | **Both PED and SPVD**: Around €5.310.000 per year at EU level | This includes all enforcement expenses by market surveillance authorities and competent authorities. | | |

| | | | Citizens/Consumers | | Businesses | | Administrations | | Conformity assessment bodies | |
|---|---|---|---|---|---|---|---|---|---|---|
| **DIRECT REGULATORY BENEFITS** | | | | | | | | | | |
| **Direct benefits**[77] | | **Recurrent** | | Direct benefit in the higher safety of simple pressure vessels and pressure equipment in the market | | Direct benefit in higher safety of pressure equipment in the market (manufacturers are also users of pressure equipment). | | | | |
| | | **Recurrent** | | Direct benefit of enhanced internal market | | Direct benefit of enhanced internal market | | | | |

[77] There is clear evidence that the directives have contributed to both: increased safety and the functioning of the internal market. However, these effects cannot be quantified due to the lack of credible data on safety incidents and the impossibility of analysing the saved costs thanks to internal market harmonisation, at the level of so many diverse simple pressure vessels and pressure equipment. For this reason, the direct regulatory benefits are just mentioned in qualitative terms in this table.

The tables below provide an overview of relevant simplification and burden reduction potential and savings already achieved based on the information collected in the evaluation study:

| ***Simplification and burden reduction (savings already achieved)*** |
|---|
| **DIRECT COMPLIANCE COSTS, ENFORCEMENT COST SAVINGS AND INDIRECT COMPLIANCE COSTS** |
| There are no already realised cost savings from simplification as the Directives have only been amended twice: The first time in 2014 when being aligned to the NLF, and the second time by Directive (EU) 2024/2749 of the European Parliament and of the Council of 9 October 2024 amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU as regards emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance due to an internal market emergency (OJ L 2024/2749, 8.11.2024, ELI: http://data.europa.eu/eli/dir/2024/2749/oj). The alignment to the NLF brought limited changes focussed on this alignment, whereas the Directive on internal market emergency procedures is not focussed on simplification. The benefits provided by the initial and current iterations of the Directives such as giving access to a harmonised internal market, replacing diverging national rule sets are already covered in the table on costs and benefits – these effects can be seen as already achieved simplification. |

| ***Part II: Potential simplification and burden reduction (savings)*** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Citizens/Consumers | | Businesses | | Administrations | | Conformity assessment bodies | |
| | | | Quantitative [78] | Comment | Quantitative | Comment | Quantitative | Comment | Quantitative | Comment |
| **DIRECT COMPLIANCE COSTS** | | | | | | | | | | |
| **Adjustment** | **Restructuring or reducing conformity assessment modules** | **Recurrent** | - | | - | Reducing the number of modules or their structure could lead to cutting procedural costs for businesses. | - | | - | Reducing the number of modules or their structure could lead to cutting procedural costs for conformity assessment bodies. While a horizontal topic, this would have to be achieved for PED and SPVD individually, due to special adaptions to their conformity assessment modules, which are necessary to ensure the safety of welded products. |

[78] Quantitative information is systematically missing from this table. The evaluation study report could not quantify potential savings due to missing concrete evidence from stakeholders. Compare *Evaluation study of Directive 2014/68/EU on pressure equipment and Directive 2014/29/EU on simple pressure vessels – Final report, p. 43.*

| *Part II: <u>Potential</u> simplification and burden reduction (savings)* | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Administrative** | **Possibility to provide compliance documentation digitally** | **Recurrent** | - | | - | A clear legally certain possibility to provide compliance documentation digitally would cut down costs for printing and logistics. | - | | - | |
| **Direct, administrative** | **Accreditation** | **One-off/Recurrent** | - | | - | | - | | - | Clear harmonised rules for accreditation which are harmonised across Member States would lead to a decrease in administrative costs for conformity assessment bodies. |
| **Direct, administrative** | **Streamlining notification process, particularly on audits** | **One-Off/Recurrent** | - | | - | | - | | - | Clear harmonised horizontal rules on the notification process and the kind and frequency of audits would cut down the cost of administrative processes for conformity assessment bodies. |
| **ENFORCEMENT COST SAVINGS** | | | | | | | | | | |

| *Part II: <u>Potential</u> simplification and burden reduction (savings)* | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Abjudication/litigation** | **Central complaint system on notified bodies** | **Recurrent** | - | | | | - | For administrations, introducing such a system to centrally manage errors in the conduct of Notified Bodies would simplify and cut costs in enforcement procedures. | - | Such a complaint system would create new administrative burdens for conformity assessment bodies. |
| **Inspection** | **Standardised testing specifications for the analysis of products** | **Recurrent** | - | | | | - | This would cut costs by reducing procedural burdens and allowing authorities to acquire testing equipment more cost effectively for targeted needs. It is unclear if such testing specifications could be included in the legislation. | - | |

| *Part II: <u>Potential</u> simplification and burden reduction (savings)* | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Monitoring** | **Increased coordination of market surveillance authorities and data sharing** | **Recurrent** | - | | - | | - | This measure could reduce redundancies and create synergistic effects between the areas of expertise and efforts of different national market surveillance authorities. | - | |
| **Enforcement, monitoring** | **Harmonised rules for compliance documentation content, e.g. templates** | **Recurrent** | - | | - | | - | Mandatory templates or more detailed binding rules for compliance documents would cut down enforcement costs by making such documents more comparable and easier to scan for non-compliances. | - | |

| *Part II: <u>Potential</u> simplification and burden reduction (savings)* | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **INDIRECT COMPLIANCE COSTS** | | | | | | | | | | |
| **Indirect** | **Faster development of harmonised standards** | **Recurrent** | - | | - | Faster availability of relevant harmonised standards could cut down costs by allowing businesses to benefit from the presumption of conformity, speeding up processes and freeing up FTE. | - | | - | |
| **Indirect** | **Clearer criteria for assemblies of pressure equipment** | **Recurrent** | - | | - | Establishing clearer criteria for the assessment of assemblies could reduce costs by cutting down time needed for compliance processes. | - | Establishing clearer criteria for the assessment of assemblies could reduce costs by increasing legal certainty for enforcement and monitoring. | - | |

| *Part II: <u>Potential</u> simplification and burden reduction (savings)* | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Indirect** | **Clearer criteria for categorisation of pressure equipment** | **Recurrent** | - | | - | Establishing clearer criteria for the determination of categories of pressure equipment could lead to indirect compliance cost savings by cutting down time needed for compliance processes and avoiding overclassifications into more stringent categories. | - | Establishing clearer criteria for the determination of categories of pressure equipment could reduce costs by increasing legal certainty for enforcement and monitoring. | - | |

## ANNEX V. STAKEHOLDERS CONSULTATION - SYNOPSIS REPORT

The synopsis report is a summary of the stakeholder consultations conducted as part of the 'Study supporting the evaluation of the Directive 2014/68/EU on Pressure Equipment and Directive 2014/29/EU on Simple Pressure Vessels'. The evaluation covered the period of the last 10 years following the alignment of both directives to the New Legislative Framework in 2014.

The stakeholder consultation strategy included the following tools:

- Call for Evidence
- Target surveys
- Targeted interviews, including case study interviews
- Expert Panel (for case studies)
- Validation workshop

Consultations in the scope of this study were implemented between May 2024 and June 2025. A short description of the targeted stakeholder per each activity and the number of participants is included below:

**Overview of consultation activities**

| Activity | Stakeholder targeted | Timing | Stakeholder engagement |
|---|---|---|---|
| Call for Evidence | | The Call for evidence[79] was published on the *'Have your say'* portal and was open between 23 May and 20 June 2024. | 44 contributions |
| Targeted surveys | Three surveys tailored to three stakeholder groups:<br>- Businesses, including business associations at the national and EU level;<br>- Conformity assessment bodies (CABs);<br>- National authorities (including relevant Ministries implementing the directives, Market surveillance authorities, Accreditation bodies and Notifying authorities) | Between 18 September and 1 November 2024 (for CABs it was extended until 8 November 2024) | 304 replies:<br>200 businesses (including 66 SMEs)<br>60 Conformity assessment bodies<br>42 national authorities |

([79]) European Commission, Have your say - Pressure Equipment Directive & Simple Pressure Vessels Directive – evaluation, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14072-Pressure-Equipment-Directive-Simple-Pressure-Vessels-Directive-evaluation_en.

| Overview of consultation activities | | | |
|---|---|---|---|
| Targeted interviews | - National authorities;<br>- Conformity assessment bodies (CABs);<br>- Standardisation organisations;<br>- Businesses, including business associations at the national and EU level;<br>- Experts;<br>- EU Institution. | From December 2024 to June 2025 | 56 interviews |
| | Case studies interviews to manufacturers, users and conformity assessment bodies of products under scope | From December 2024 to April 2025 | 44 interviews |
| Expert Panel | - Manufacturers and users of products in scope;<br>- EU/national product associations;<br>- Conformity assessment bodies. | Online on 16 April 2025 | 55 participants |
| Validation workshop | - National authorities (relevant Ministries implementing the directives and Market surveillance authorities)<br>- CABF representatives<br>- Business associations<br>- Standardisation representatives | Online on 25 June 2025 | 32 participants |

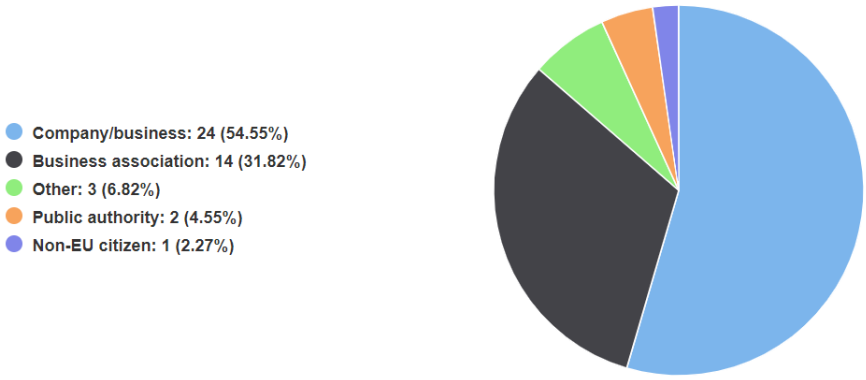
At the end of each consultation activity, the study team collected, cleaned and analysed the inputs and data received in line with Better Regulations Guidelines and Toolbox (#54).

Results of the consultation activities - Call for Evidence

The Call for evidence[80] was published on the 'Have your say' portal, where the public could submit their contributions in an open format regarding the evaluation of the Pressure Equipment Directive (PED) and Simple Pressure Vessel Directive (SPVD) between 23 May and 20 June 2024.

In total, 44 contributions were received, the majority from companies (54.55%), and business associations (31.82%).

**Distribution of contributions received under the Call for evidence by stakeholder group.**




Most contributions came from stakeholders based in Germany (36%), followed by France (23%), and Italy (9%).

The Call for evidence revealed a series of aspects identified by multiple respondents as potential areas for improvement for the PED and SPVD. Most contributions focused on PED, while six (13.6%) also explicitly mentioned aspects related to SPVD, and seven touched on the merger of the two directive (15.9%)

The most frequently cited concern relates to the classification and conformity assessment of assemblies under PED. Stakeholders reported confusion around the notion of assembly. This ambiguity leads to frequently mentioned issues such as the understanding and application of the PED assembly concept which warrant a more detailed description of requirements and process for assessing the conformity of assemblies as well as whether conformity assessment bodies need to be involved in the final verification of assemblies. In particular, the reliance on recital 7 PED allows assembled systems to be marketed under an 'installation' regime at times.

Material definitions under PED were also flagged as outdated. Stakeholders called for updates to accommodate composite and additive materials, and for revisions to essential safety requirements such as those on calculation methods, fire resistance, non-destructive testing, and traceability.

([80]) European Commission, Have your say - Pressure Equipment Directive & Simple Pressure Vessels Directive – evaluation, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14072-Pressure-Equipment-Directive-Simple-Pressure-Vessels-Directive-evaluation_en.

Another common issue is the absence of provisions for digital instructions for use and safety manuals. Unlike the Machinery Regulation, PED and SPVD do not yet allow digital formats, which stakeholders argue would improve consistency and accessibility.

PED and SPVD Guidelines were widely appreciated but seen as insufficiently binding. Respondents advocated for incorporating key elements of the guidelines into the legal text of the directives to ensure harmonised application across Member States. There was also a call to streamline and reduce the number of PED Guidelines.

Additional concerns included the need for better alignment between PED and the New Legislative Framework, improved coordination among notified bodies, and enhanced mechanisms for mutual recognition of welder qualifications and welding methods. While SPVD-specific feedback was more limited, it pointed to its narrow scope and outdated relevance considering that the PED could also be modified and include in its scope simple pressure vessels. Some stakeholders suggested expanding SPVD to include hydrogen-containing vessels or merging SPVD with PED to streamline the regulations.

Results of the consultation activities – Targeted surveys for businesses and business associations

***Profile of respondents***

The questionnaire for businesses and business associations received 200 replies. The vast majority of respondents (171; 85%), are businesses. National business associations (15; 7.5%) and EU business associations (4; 2%) account for approximately 10% of respondents. The most common types of businesses represented by respondents are manufacturers of pressure equipment (123; 42%), users of pressure equipment (55; 19%), and installers of pressure equipment (plant design or service providers: 48; 17%). As for size, the majority of respondents (60%) are from large enterprises (≥250 employees), making them the most represented group in the survey. Medium enterprises follow with 27% (47 replies), while small and micro-enterprises together account for 11% (17 and 2 replies, respectively).

***Effectiveness***

Around half of the respondents among businesses generally view the PED as either highly **effective** or effective in ensuring safety and facilitating the free movement of pressure equipment (71%, 61 replies out of 86), while 35% (30 respondents out of 86) rated its contribution to safety standards as very high and 34% (21 out of 62) as high. Views on the SPVD were more cautious, with just over half of the respondents indicating ‘to a very / to a large extent (56%, 35 out of 62) uncertainty about its safety impact but with a notable portion of respondents indicating uncertainty (14, 23%). Similarly, most respondents (56%, 35 out of 62) indicated that the SPVD made a significant contribution to the internal market. While essential safety requirements under PED are widely considered effective where nearly all respondents expressed agreement (39 out of 42, 93%), concerns persist about inconsistent enforcement across Member States and the

limited effectiveness of customs and market surveillance authorities. Only 9 respondents agreed with their effectiveness (22%), while 27% disagreed (11) and notably, 13 respondents indicated uncertainty (32%). Harmonised standards are widely used under PED according to half of the respondents (99 out 199 50%) reported that more than 80% of the pressure equipment they produce or work with complies with European harmonised product standards. Another 26% indicated compliance between 40% and 80%, while 16% reported lower levels. For materials, 49% (97 out of 199) said more than 80% comply with harmonised material standards. Less than half (43%, 86 out of 199) indicated that there are no hEN for all pressure equipment. For the majority of businesses, sufficient guidance is available to understand and apply the rules under the directives, as indicated by 130 respondents (77%). Among the aspects where further guidance is needed, the most commonly mentioned were information on conformity assessment procedures (20 respondents, 21%) and available standards (16 respondents, 17%).

***Efficiency***

Businesses report that compliance with the PED and SPVD involves substantial costs, with third-party conformity assessments being the most expensive element according to 137 respondents, 25%. Internal testing and assessment also contribute significantly (95, 18%), alongside the effort required to prepare technical documentation and declarations of conformity (88, 16%). Purchasing harmonised standards is another recurring cost, especially under the PED, where their use is widespread. However, the use of hEN is widely seen as an efficient way to comply with EU market legal requirements according to 82% of businesses (164 out of 199). Administrative burdens, including reporting obligations and interactions with market surveillance authorities, further contribute to costs. While not the largest cost category, these tasks are seen as time-intensive and often duplicative, especially for companies operating across multiple Member States. Digitalisation emerges as a key area for potential efficiency gains (86 replies out of 172, 50%), as well as simplification of documentation requirements (83 replies out of 172, 48%) and streamlining the process for certification of compliance (56 replies out of 172, 33%).

***Relevance***

Most businesses consider the directives broadly **relevant** to facilitate the movement of pressure vessels and equipment (81%, 157 out of 195 responses), to guaranteeing the safety (81%, 159 out of 196 responses) and to encourage the use of hEN (63%, 124 out of 196 responses) but note that they do not fully reflect technological and market developments. There is interest in using new manufacturing methods and materials, such as additive manufacturing and non-metallic components, but legal constraints (24%, 38 put of 159 responses) and the lack of harmonised standards (28%, 45 out of 196 responses) hinder adoption. Many respondents also wish to digitalise technical documentation (45%, 74 out of 163 responses), but current rules limit this possibility. The SPVD, in particular, is seen as outdated and less adaptable to innovation, with a high share of respondents expressing uncertainty about its applicability to modern practices

(64%, 23 out of 36 replied 'I don't know'; while 31%, 11 out of 36 neither agrees or disagrees).Most respondents (47%, 75 out of 160) disagree that safety requirements are outdated, and 29% (44 out of 158) neither agree or disagree on the use of digital tools by market surveillance authorities.

***Coherence***

Views on the **coherence** of the regulatory framework are mixed. While most businesses agree that the division between PED and SPVD is justified (38%, 71 out of 189 responses), some express disagreement (16%, 40 out of 189). The perception of overlaps between PED and SPVD shows a lack of consensus, with most respondents either unsure or neutral (137 out of 187, 83%), and only a small fraction strongly agreeing that there are no overlaps (36, 19%). On the clarity of product coverage under legal requirements, a majority agree that it is clear (61%, 116 out of 189 responses). Many highlight overlaps and unclear product coverage, especially when pressure equipment is integrated into machinery. This creates confusion and increases the administrative burden. Respondents also report inconsistencies between the PED/SPVD and other EU legislation, such as the Machinery Directive (mentioned 34 times) and the Transportable Pressure Equipment Directive (mentioned 19 times). These overlaps often lead to duplicate conformity assessments and uncertainty about which rules apply, reinforcing calls for clearer definitions and better alignment across directives.

***EU added value***

Businesses view the directives as critical tools for ensuring safety (40%, 16 out of 40 responses), and maintaining a level playing field across the EU (74%, 28 out of 38 responses). They strongly support the EU-level harmonisation provided by the PED and SPVD (46%, 18 out of 39). Most respondents (63%, 124 out of 196) believe that repealing the directives would negatively affect their business. Only a minority consider national legislation alone sufficient to maintain current standards or avoid trade barriers (26%, 10 out of 39). The PED, in particular, is seen as essential for reducing compliance complexity and enabling cross-border trade. It provides a common framework that supports legal certainty and fair competition.

Results of the consultation activities – Targeted survey for national authorities

***Profile of respondents***

Out of the total 44 replies, the largest share of respondents representing Authorities is from Germany (12; 27%), followed by Norway (3; 7%). Slovakia, Switzerland, Belgium, Latvia, Poland, Netherlands, Estonia, Italy, Türkiye, and Spain were all represented by two respondents each, making up 5% of respondents each. Among their responsibilities, the majority of respondents are responsible for market surveillance related to PED and SPVD (this is influenced by replies from Germany, where market surveillance is a regional responsibility). Accreditation of conformity assessment bodies under the

PED and SPVD (28; 22%) and implementation and coordination of the PED and SPVD (26; 20%) are other tasks related to the work of respondents.

***Effectiveness***

Authorities generally view the PED as moderately effective in ensuring safety with 66% (27 out 41 responses) rating it as contributing 'to a large' or 'very large extent' to safety and in ensuring market access (71%, 28 out of 40 responses). For the SPVD, 58% (22 out of 38 responses) considering it effective in ensuring safety of vessels and 66% of respondents (25 out of 38) consider it effective in ensuring the free movement of vessels, although with more neutral (24%, 9) or uncertain responses (18%, 7). A majority of authorities expressed confidence in the safety-related provisions: 55% (15 out of 27) agreed or strongly agreed that the testing and inspection procedures are comprehensive and adequate for ensuring safety; 65% (17 out of 26) agreed that the requirements for technical documentation are clearly specified and 77% (20 out 26) agreed or strongly agreed that the essential safety requirements are effective in ensuring a high level of safety. On conformity assessment, views are mixed with 31% disagreeing (8 out of 26 responses) and 27% (7 out 26) agreeing that they are carried out consistently across countries.

Regarding enforcement of the directives, 38% (10 out 26) authorities find the current procedures and national programmes for market surveillance effective for both the PED and SPVD. An equal proportion, however, expressed a neutral stance. In the frequent cases of non-compliance reported, the main issues are usually inadequate labelling (10 out 73), incomplete technical documentation (9 out of 73), missing instructions/technical documentation (9 out of 73), missing EU declaration of conformity (8 out of 73) and incorrect conformity assessment procedures (8 out 73). These issues were reported as being more prevalent in equipment imported from third countries by 71% of respondents (17 out of 24). On the issues faced by market surveillance the most common answers were limited staff (32%, 8 out of 25), insufficient financial resources to purchase samples (27%, 7 out of 26) and related testing capacity (19%, 5 out of 26), and lack of dissuasive penalties in national legislation (16%, 4 out 26). Authorities emphasise enforcement gaps and uneven application across Member States. Respondents expressed limited confidence in the sufficiency of customs controls with 33% of neutral responses (7 out of 24) and 29% (8 out of 24) indicating concerns about the effectiveness of current controls. In contrast, views on cooperation with customs authorities were more positive with 67% of respondents (16 out of 24) who found cooperation fast and effective in case of non-compliance.

Coordination groups at the EU level were viewed positively. Authorities found them particularly effective in addressing emerging issues (83%, 20 out of 24) and in harmonising the application of directives across countries (71%, 16 out of 24) and exchanging best practices (71%, 17 out of 24). These groups were also seen as valuable for supporting joint actions (67%) and fostering cooperation across countries (67%).

***Efficiency***

The most significant cost drivers for authorities in implementing the PED and SPVD were training of personnel (21%), carrying out inspections and controls (19%), and laboratory testing (15%). Administrative tasks such as reporting and documentation also represented a notable burden (13%).

Authorities identified several areas where digitalisation could improve efficiency. Data collection and analysis (30%, 28 responses) and reporting and documentation (29%, 27 responses) were the top priorities for digital transformation. Communication and coordination with customs authorities (22%) and personnel training (17%) were also highlighted as areas that could benefit from further digitalisation. However, IT systems and legal actions were less frequently cited as cost factors.

***Relevance***

Authorities generally affirmed the relevance of the PED and the SPVD in supporting regulatory goals such as market integration (73%, 32 out of 44 responses) and product safety (82%, 36 out of 44 responses). However, concerns emerged regarding the adaptability of the directives to technological developments. A significant share of respondents expressed uncertainty about whether the directives adequately support digitalisation (33%, 14 out of 43 per the PED and 26%, 11 out of 43 for the SPVD). The directives are seen to moderately accommodate innovations such as new materials (33%, 14 out of 43 for the PED) and manufacturing methods (32%, 14 out of 44 for the PED and 26%, 11 out of 43 for the SPVD). This uncertainty extends to the Essential Safety Requirements (ESRs) which are seen by 37% (16 out of 44) for the PED and 35% (15 out of 43) for the SPVD as adequately up to date to reflect market and technological changes. While some authorities agreed that the ESRs are sufficiently up to date, others disagreed or were unsure, suggesting that the regulatory framework may not fully reflect recent advancements in areas like additive manufacturing or the use of non-metallic materials.

Additionally, the clarity of definitions within the directives was questioned. Although a great portion of respondents found them adequate (43%, 19 out of 44 for the PED and 53%, 23 out of 43), others highlighted ambiguities that complicate enforcement, particularly in cross-border contexts where interpretation may vary.

***Coherence***

Authorities expressed mixed views on the coherence of the regulatory framework. While 20% (9 out 44) agreed that the division between the PED and the SPVD is justified, share either disagreed or were unsure (25%, 11 out of 44). However, the clarity of product coverage was more widely accepted, with 60% (25 out of 42) stating it is clear which products fall under the directives.

The alignment of PED and SPVD with the New Legislative Framework was generally seen as beneficial. More than half of the respondents agreed that it facilitates more efficient market surveillance (53%, 23 out of 43 responses) and conformity assessment (51%, 22 out of 43) by enabling authorities and notified bodies to operate across product

categories under a harmonised approach. Nevertheless, coherence issues with the NLF were identified by 17% (9 respondents).

Despite this, several inconsistencies were noted with other EU legislation. The most frequently cited overlaps were with the Transportable Pressure Equipment Directive (15%, 8 responses), the Machinery Directive/Regulation (12%, 6 responses), and the Gas Appliances Regulation (6%, 3 responses). These inconsistencies often stem from divergent scopes or definitions, complicating enforcement and increasing administrative burden. It is worth nothing that 35% of authorities did not identify any inconsistencies (18 responses).

***EU added value***

Authorities strongly affirm the added value of EU-level harmonisation. If the PED and SPVD were repealed, 74% of respondents (32 out of 43) believed it would have a negative/very negative impact on product safety, and 64% said it would harm the internal market (27 out of 43). Product quality and innovation were also expected to suffer for 70% and 21% of respondents, respectively. When asked whether national legislation alone could ensure safety and prevent trade barriers, the majority disagreed, with 49% (21 out of 43 responses) and 81% (34 out of 42), respectively. Only a minority of authorities believed that national rules could provide the same level of regulatory certainty (23%, 10 out of 43) or cost efficiency as the harmonised EU framework (10%, 12 out of 43). In contrast, 58% of respondents (25 out of 43) agreed that harmonisation lowers costs for European businesses and improves regulatory certainty.

Results of the consultation activities – Targeted survey for conformity assessment bodies (CABs)

***Profile of respondents***

60 responses were received by conformity assessment bodies. The majority of respondents (54, 83%) represent notified bodies, while the presence of recognised third-party organisations and user inspectorates indicates other types of organisations represented in the survey. Most organisations (50, 87%) operate with accreditation, whereas a small number of organisations work without accreditation (7, 12%). The spread of respondents across different European countries reflects a good geographical distribution, with a concentration in key countries like the Netherlands (8, 13%) and Germany (8, 13%), followed by Portugal and Italy (6 each, jointly accounting for 20% of total respondents). Most organisations focus on the PED (42, 70%). While some handle both directives (28, 30%), no respondent is notified for the SPVD only.

***Effectiveness***

CABs generally consider the PED effective in achieving its core objectives. A majority believe it contributes significantly to both the free movement of pressure equipment (89%, 50 out of 56 responses) and the assurance of safety 76% (42 out of 55 responses). Views on the SPVD are more limited, nevertheless consider the Directive effective in

ensuring free movement of vessels (94%, 16 out of 17) and to assuring safety (75%, 12 out of 16), though slightly more neutral particularly in relation to safety (19%, 3 out of 16).

Respondents shared their views on various aspects of conformity assessment and safety procedures: guidance materials (PED/SPVD Guidelines and CABF recommendations) are seen as helpful by 51% of CABs (30 out of 59), though 22% (13 out of 59) were neutral and 27% (16 out of 59) disagreed. Clarity of conformity assessment procedures was viewed positively by 68% of respondents (41 out of 60); while effectiveness of ESR was strongly endorsed by 80% of respondents (48 out of 50) and the comprehensiveness of testing and inspection procedures was also generally well-rated by 65% (39 out of 60). Clarity of technical documentation showed moderate support with 56% (33 out of 59) agreeing or strongly agreeing and 32% (19 out of 59) of respondents indicated a neutral stance. Respondents largely opposed reducing safety requirements and conformity assessment procedures: 92% (55 out of 60) disagreed or strongly disagreed with the idea that essential safety requirements could be reduced without compromising equipment safety, while for conformity assessment procedures, 67% (40 out of 60) disagreed or strongly disagreed with reducing them, while 20% (12 out of 60) agreed or strongly agreed, and 13% (8 out of 60) were neutral.

CABs frequently encounter differences in how the directives are interpreted across countries especially for the PED according to 51% of CABs (28 out of 55), while less for the SPVD (19%, 3 out of 16). Variations in how manufacturers apply harmonised standards are also noted by 31% of respondents for the PED (17 out of 55) and equally for the SPVD (31%, 5 out of 16). Many CABs rely heavily on PED/SPVD Guidelines and CABF recommendations, but some note that these are not legally binding and can lead to inconsistent interpretation. There are also notable discrepancies in how conformity assessment procedures are carried out by competing CABs for 37% of CABs for the PED (20 out of 54) and 19% for SPVD (3 out of 16), which can undermine consistency and trust in the system. However, the number of CABs in the market are generally seen sufficient for most of CABs for the PED (95%, 57 out of 60) and less for the SPVD (38%, 28 out of 60), with more unsure views (43%, 26 out of 60).

CABs engage in CABF coordination group in varies ways: 36% (39 out of 126) participate as a member of the CIRCABC interest group, 33% (42 out of 126) are part of the national coordination group and 31% (39 out of 126) attend CABF meetings. The CABF is generally seen effective across several key activities, mainly to provide recommendations (60%, 35 out of 59 responses), followed by to exchange information with other CABs (55%, 33 out of 59), address technical issues (53%, 31 out of 59), address harmonisation issues across CABs (44%, 26 out of 59).

***Efficiency***

Regarding costs incurred by CABs stemming from the directives, most respondents highlighted accreditation as the main driving costs (30%, 48 out of 161), followed by continued compliance (20%, 33 out of 161), and training (19%, 31 out 161).

Administrative costs are also mentioned by 17% of CABs (28 out of 161). Initial notification costs vary widely. Annual maintenance costs for notification can also be substantial, particularly when staff time and system upkeep are included.

82% of CABs (47 out of 57) are typically subject to annual controls by notifying authorities and are required to report regularly on their activities. The average number of full-time equivalent (FTE) staff dedicated to PED-related activities varies. Service delivery times also vary, but design examination and approval typically take between one and five days, while quality system certification can take up to ten days or more, depending on complexity. Digitalisation was seen as a key area for reducing administrative burden, with 36% (29 out 80) supporting increased use of digital tools and 19% (15 out of 80) favouring streamlined notification processes. 18% (14 out of 80) noted that other areas would help reduce administrative burden, namely simplifying accreditation activities and the related accreditation standards according to EA 2/17.

***Relevance***

CABs broadly affirm the relevance of the directives in supporting safety (76%, 43 out of 57) and market integration (88%, 52 out of 59). Views are more mixed on the directives' role in contributing to the use of harmonised standards: only 39% (23 out of 59) rated them as highly relevant, while 37% (22 out of 59) saw moderate relevance and 24% (14 out of 59) minimal relevance.

CABs generally support the PED's scope and its accommodation of new materials (54%, 29 out of 54) and methods (48%, 25 out 53), though some disagreement remains (26%, 14 out of 53). However, concerns persist about the adaptability of the PED and SPVD to new technologies. Many CABs question whether the ESRs are sufficiently up to date to reflect current market and technological developments. There is also uncertainty about the directives' support for digitalisation and the use of new materials and manufacturing methods, such as additive manufacturing and composite materials for 37% of CABs for the PED (20 out 53) and 50% of CABs for the SPVD (8 out 16). PED definitions are considered clear by over half of respondents, specifically, 54% (29 out of 54).

In contrast, SPVD definitions show greater uncertainty, with 44% of CABs (7 out of 16) indicating ambiguity. Survey responses indicate that digitalisation is moderately supported under both the SPVD and PED. For the SPVD, only 19% of respondents (3 out of 16) agreed that it allows for digitalisation of processes where appropriate, while a majority of 56% (9 out of 16) remained neutral and 19% disagreed (3 out of 16). Similarly, under the PED, 30% of respondents (16 out of 53) agreed or strongly agreed with its support for digitalisation, 43% were neutral (23 out of 53), and 21% disagreed (11 out of 53). In both cases, 6% of respondents were unsure.

***Coherence***

The division between the PED and SPVD is contested. While some CABs (22%, 13 out of 60) support the current structure, many argue (53%, 32 out of 60) that the SPVD could be integrated into the PED to simplify the regulatory landscape. This would likely solve

overlaps between the two directives which are frequently cited (44%, 26 out 59), and several respondents note that the SPVD does not adequately cover assemblies or cyclic conditions. Clarity regarding the scope of products under each Directive is clear for over half of respondents (64%, 37 out of 58).

Inconsistencies with other EU legislation, particularly the Machinery Directive/Regulation (18%, 17 out 96), TPED (16%, 15 out 96), and ATEX (6%, 6 out of 96), are also a recurring concern. These overlaps often result in confusion over scope and requirements, especially for products that fall under multiple directives. Issues with the NLF have also been mentioned by 8% of CABs (8 out 96).

***EU added value***

CABs strongly support the harmonisation achieved through the PED and SPVD. Most believe that repealing the directives would significantly negatively impact their organisation (81%, 48 out of 59). There is widespread agreement that national legislation alone could not ensure the same level of safety (51%, 30 out of 59) or facilitate the free movement of goods within the internal market (81%, 48 out of 59). A majority of respondents (76%, 44 out of 58) agree or strongly agree that harmonisation lowers costs for European businesses.

Results of the consultation activities – Targeted interviews

Targeted interviews were conducted with 56 stakeholders across six main categories:

- 26 interviews with national authorities, representing the largest share of stakeholders (44.1%). These included 5 interviews with WGP members, 5 with notifying authorities, 2 with accreditation bodies, 1 with an EU-level accreditation body, 10 with market surveillance authorities and 3 with customs authorities.
- 10 interviews with conformity assessment bodies, including 2 representatives of the Conformity Assessment Bodies Forum.
- 10 interviews with the industry, including business associations (7) and 3 individual businesses.
- 6 interviews with the standardisation sectors, including 2 HAS consultants.
- interviews with experts and academia.
- 1 interview with EU institutions.

Within the case studies, a total of 44 interviews were carried out with manufacturers and users, CABs, business associations and experts.

***Effectiveness***

The PED and SPVD are generally perceived as effective in ensuring safety and compliance across the EU across all stakeholder groups. Authorities and business associations alike acknowledge that the directives have contributed to a high level of protection for users and operators of pressure equipment. However, their effectiveness is

often undermined by inconsistent enforcement and interpretation across Member States. Authorities and CABs confirm that the conformity assessment procedures are generally robust, especially when supported by harmonised standards. However, several limitations were noted. Authorities pointed to weak and uneven market surveillance across Member States due to lack of resources, which undermines the directives' ability to ensure a level playing field. Business associations and CABs highlighted inconsistencies in how notified bodies interpret and apply the rules, leading to divergent outcomes for similar products. A major and recurring concern relates to the classification and conformity assessment of assemblies under the PED. Interviewees from the expert, standardisation and CABs communities highlighted the lack of clarity in distinguishing between an 'assembly' and an 'installation.' This ambiguity creates a grey zone in terms of responsibility, particularly for SMEs that manufacture components later integrated into larger systems and uncertainty over whether CABs must be involved in the final verification of the PED assembly. The absence of clear guidance on this issue was seen as a significant gap in the current framework.

Harmonised standards, while essential to demonstrating compliance with the ESRs, were another area of concern. Experts involved in standardisation work described the development process as slow, underfunded, and overly conservative, particularly in relation to emerging technologies like additive manufacturing. The lack of timely and flexible standards leaves manufacturers in a difficult position, often forced to rely on ISO standards that are not recognised as conferring presumption of conformity. This results in additional testing requirements and higher costs, especially for SMEs. Moreover, the limited involvement of technical experts in the standardisation process, due to lack of funding and institutional support, was seen as a barrier to innovation and responsiveness. In addition, the legacy national codes in some Member States continue to influence conformity assessments, creating additional complexity for manufacturers operating across border.

There was also concern that the directives do not adequately address the integration of new equipment into existing installations, particularly when documentation for older systems is lacking. In such cases, ensuring compliance with essential safety requirements becomes burdensome and uncertain.

***Efficiency***

Stakeholders generally acknowledge that the PED and SPVD have brought economic benefits by harmonising requirements across the EU, reducing the need for country-specific certifications, and enabling smoother cross-border trade. For example, one expert noted that companies no longer need to hire foreign inspectors to export to other Member States, as NBs based in their own country can now perform the necessary conformity assessments, leading to cost savings and improved market access.

However, several efficiency-related challenges were raised, particularly regarding the cost of compliance, administrative burden, and stakeholder engagement in the regulatory process.

Efficiency is a major concern across all stakeholder groups. A recurring theme was the high cost of conformity assessment, especially for SMEs. Experts pointed out that while the directives are technology-neutral, the lack of harmonised standards for emerging technologies (e.g. additive manufacturing) forces manufacturers to rely on ISO standards, which are not recognised for presumption of conformity. As a result, manufacturers must undergo extensive additional testing to satisfy notified bodies, significantly increasing costs. Authorities reported that the notification process for conformity assessment bodies is not always transparent, especially when accreditation is not used. The lack of formal EU-level guidance on these procedures leads to administrative delays and legal uncertainty. CABs and business associations criticised the complexity of the module system under the PED, noting that some modules (e.g. E and E1) are rarely used and that the wide range of combinations creates confusion rather than flexibility. The PED and SPVD Guidelines, while helpful, are not legally binding, and their interpretation varies across jurisdictions. This lack of harmonisation increases compliance costs, particularly for SMEs operating in multiple Member States.

Several interviewees highlighted the potential for digitalisation to improve efficiency. Remote inspections, which became more common during the COVID-19 pandemic, were cited as a promising practice that could reduce costs and increase flexibility. However, the directives currently lack provisions to support or regulate such practices. Experts called for the integration of digital tools, including AI and automated documentation systems, into the regulatory framework to simplify compliance and enforcement. There was also strong support for allowing digital formats for user manuals and technical documentation. While this would reduce printing and distribution costs, it would also improve accessibility and consistency. However, stakeholders cautioned that digitalisation should not impose additional burdens on SMEs, and hybrid systems may be needed during the transition.

Experts also pointed to inefficiencies in the standardisation process, describing it as overly formalistic and slow to adapt to industry needs. The mechanisms for stakeholder engagement in standardisation were criticised. Experts noted that while technical expertise exists, many professionals cannot afford to participate due to lack of funding. This limits the diversity of input and slows progress. The role of HAS consultants was also seen as a bottleneck, adding delays without clear added value according to some stakeholders actively participation in CEN technical committees. It should be noted that the role of HAS consultants is to support the Commission services in the process of checking compliance of the standards with the legislation to enable citation of references of harmonised standards in the Official Journal of the European Union.

***Relevance***

The directives are still considered relevant to the core needs of the pressure equipment sector, with most considering the directives structurally sound and adaptable to evolving industry needs. Standardisation experts consistently highlighted the flexibility of the directives, particularly the PED, in accommodating technological developments such as additive manufacturing and hydrogen applications. While the directives are seen as well-

written and conceptually robust, there is a recurring concern about the clarity and accessibility of harmonised standards. The legal status of these standards and their alignment with essential safety requirements (ESRs) are often misunderstood, leading to inconsistent application across Member States. Some stakeholders agree that they are not fully aligned with technological and market developments. Emerging technologies such as hydrogen systems, additive manufacturing, and digital conformity assessment tools are not adequately addressed. Several interviewees called for updates to reflect these trends and to ensure that the directives remain future proof. The SPVD was seen by many as outdated and potentially redundant, with suggestions to merge it into the PED to streamline the regulatory framework.

Business associations pointed out that certain sectors, particularly those dealing with composite materials and complex installations, face challenges due to the directive's current scope. For example, the growing use of composite pressure vessels in hydrogen transport is not adequately addressed, and integrated systems such as cryogenic installations often fall into regulatory grey zones. These associations generally support maintaining the directive's core structure but advocate for targeted updates that reflect sector-specific innovations without expanding the scope unnecessarily.

Authorities generally support the relevance of PED and SPVD but emphasise the need for clearer definitions and better integration with national regulations. Several authorities noted that inspection and testing procedures for hydrogen and methane systems are not sufficiently covered, posing potential safety risks. Others highlighted the ambiguity surrounding legacy equipment and digital documentation formats, such as the use of QR codes for CE marking. On their hand, conformity assessment bodies affirmed the relevance of PED but expressed concerns about practical implementation. The interpretation of harmonised standards varies widely, and the lack of clarity around modules H and H1 creates difficulties, especially for manufacturers operating globally.

Experts and standardisation bodies also noted that the current approach does not sufficiently support innovation, as the development and revision of standards is slow and often disconnected from real-world industrial timelines.

***Coherence***

Across stakeholder groups, there is general agreement that the PED and SPVD are conceptually coherent within the EU regulatory framework. However, several stakeholders noted that practical inconsistencies arise when these directives intersect with others, particularly in areas involving complex installations. Standardisation and business association emphasised that the interaction with the Machinery Directive can be problematic. Equipment that falls under both directives may be subject to conflicting requirements, especially when pressure components are integrated into broader machinery systems. This overlap creates uncertainty about which directive takes precedence and how essential safety requirements should be applied. The lack of harmonised guidance on these intersections was identified as a barrier to consistent implementation. The widespread use of PED Guidelines helps mitigate some of this

confusion, but their non-binding nature and inconsistent interpretation limit their effectiveness.

Conformity assessment bodies also highlighted operational inconsistencies that arise from divergent interpretations of harmonised standards and overlapping directives. They noted that the lack of uniform guidance across Member States leads to variable enforcement and confusion among manufacturers. CABs also reported that the integration of PED with newer EU regulations, such as the Cyber Resilience Act and digital product passports, is still underdeveloped. This creates uncertainty about how to assess compliance for equipment that incorporates digital components or AI-driven functionalities.

Authorities offered mixed views on coherence. Some considered the directives well-aligned with national legislation and other EU instruments, while others pointed to gaps in integration. For example, the treatment of legacy equipment and modified installations was cited as an area where PED lacks clarity, particularly when such equipment is subject to other directives. Additionally, the emergence of horizontal regulations, such as those addressing digitalisation, cybersecurity, and sustainability, was seen as a challenge to maintaining coherence. Authorities stressed the need for PED and SPVD to remain focused on essential safety requirements and avoid duplicating provisions already covered by other legislation.

Stakeholders also highlighted the need for better alignment between EU-level rules and national practices, particularly in areas like hydrogen inspection and the treatment of assemblies.

***EU added value***

Despite the challenges, stakeholders unanimously recognise the EU added value of the PED and SPVD. The directives have harmonised safety standards across the EU, facilitated cross-border trade, and provided a common legal framework for manufacturers and regulators. However, the full benefits of EU legislation are not being realised due to national-level divergence in enforcement and interpretation. There is strong support for enhanced EU-level coordination, including more binding guidance, streamlined procedures, and a more agile standardisation process. Some stakeholders proposed merging the PED and SPVD to reduce fragmentation and improve coherence, while others called for a more integrated approach to emerging risks and technologies.

Results of the consultation activities – expert panels

The expert panel focused on the case studies related to the evaluation of the PED and SPVD. The two-hour meeting took place online on 16 April 2025 and included participants from notified bodies, market surveillance authorities, manufacturers, and associations across Europe for the products under scope. Four of the case studies cover products under the PED, namely industrial steam boilers, hydrogen refuelling stations, portable fire extinguishers, reactors and heat exchangers, while one focuses exclusively

on simple pressure vessels. The discussions revolved around the findings for the effectiveness, efficiency, relevance, and coherence of the directives.

***Effectiveness and efficiency concerns***

Participants raised persistent concerns about the clarity of the SPVD's scope, particularly regarding the definition of simple pressure vessels and the classification of oil separators. Diverging interpretations persist across Member States, with some authorities excluding oil separators due to design features (e.g. bolted flanges), while others argue they fall within the SPVD based on fluid type and construction. This lack of alignment continues to create legal uncertainty and enforcement challenges.

The rising costs of accreditation were also highlighted, especially in light of upcoming ISO 17020 revisions. Notified bodies expressed concern that these changes will further increase the financial burden, particularly for smaller organisations.

***Divergent conformity assessment***

The assessment of PED assemblies remains a complex and inconsistent area. Participants noted that notified bodies apply different approaches to evaluating assemblies, with some relying on documentation and others requiring physical testing. This inconsistency is compounded by the absence of a shared understanding of what constitutes a complete assembly and the lack of harmonised qualification requirements for notified body personnel.

***Manufacturer perspectives***

Manufacturers reported that conformity assessment costs are often underestimated. One participant estimated that compliance with the PED accounts for up to 30% of total manufacturing costs, particularly when including testing, materials, and inspections. Concerns were also raised about competition from third-country manufacturers who may not be held to equivalent standards, creating an uneven playing field. The flexibility allowed under the quality assurance Module H was seen as a potential loophole that could undermine compliance.

***Market surveillance issues***

Market surveillance authorities emphasised the overlap between the PED and other EU legislation, particularly the Machinery Directive. They clarified that no single directive dominates; rather, manufacturers must apply all relevant directives based on the technical characteristics of their products.

***Merging directives***

The potential merger of the PED and SPVD sparked debate. Some participants supported consolidation, arguing it would streamline processes, eliminate duplication, and resolve classification ambiguities. Others opposed the idea, citing the SPVD's specific technical focus and the risk of increased costs or reduced safety in high-volume serial production.

Market surveillance authorities generally favoured a merger, while some industry representatives called for maintaining the current structure unless clear benefits could be demonstrated.

| Results of the consultation activities – validation workshop |
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The validation workshop was organised online on 25 June 2025. The session brought together 32 stakeholders, including national competent authorities, market surveillance, conformity assessment bodies, and business and industry associations. The workshop focused on discussing the evaluation's findings, structured around the five evaluation criteria: effectiveness, efficiency, relevance, coherence, and EU added value.

### *Effectiveness*

Several persistent challenges were identified. Diverging interpretations of the directives, particularly around the definition and scope of 'assemblies' under PED, lead to inconsistent enforcement and legal uncertainty across Member States. Authorities also noted significant variation in notified bodies practices, with differing national oversight and inconsistent application of EA 2/17. Access to guidance also remains uneven: many economic operators are unaware of official resources, and the inactivity of the Working Party Guidelines has created a backlog of unresolved questions. The ICSMS platform is underutilised due to duplication with national systems, lack of training, and unclear reporting rules. Concerns were raised about non-compliant imports from third countries, especially via e-commerce, despite CE marking. Finally, the slow adoption of harmonised standards was seen as a barrier to effective conformity assessment and legal clarity, particularly for SPVD, where no harmonised product standard currently exists.

### ***Efficiency***

Digitalisation was seen as a key opportunity to reduce burdens, with proposals for an EU-wide certificate database and better integration of digital documentation. However, stakeholders advised waiting for horizontal EU initiatives before embedding digitalisation in the directives. Coordination mechanisms like the CABF and WGP were viewed as essential and in need of reinforcement. On costs, manufacturers noted that third-party assessment costs vary widely by product and risk category, but standard purchase costs were often overestimated. CABs reported underestimated training costs and burdens from multiple accreditation standards, which led to redundant and sometimes conflicting requirements. Product compliance costs can be high (up to 30% of product value in extreme cases) especially for first-time manufacturers. Administrative burdens were also noted, particularly the obligation to report all withdrawn certificates, even when unrelated to safety.

### ***Relevance***

The PED remains broadly relevant, particularly for established sectors. However, stakeholders stressed the need for updated harmonised standards to keep pace with

emerging technologies such as additive manufacturing and hydrogen applications. While the PED's essential safety requirements are generally adaptable, they are not always suited to new production methods. The SPVD was seen as less flexible and less able to accommodate innovation.

***Coherence***

Internal coherence issues were raised regarding the treatment of assemblies assembled by users, which are excluded in Recital 7 but not clearly addressed in the operative articles of the PED. In terms of external coherence, the overlap of the PED with the Machinery Directive continues to cause confusion. Authorities and conformity assessment bodies confirmed that there are conflicting interpretations on the conformity assessment of certain products that fall under both the Machinery Directive and under the PED. Authorities also discussed sustainability-related gaps, such as the reuse of components. On the question of merging the PED and SPVD, many authorities supported consolidation to eliminate duplication and classification issues, while some industry representatives defended the SPVD's technical specificity and warned against unnecessary disruption.

***EU added value***

There was unanimous agreement that the directives have delivered significant EU added value by ensuring high safety standards and supporting the Internal Market. Further harmonisation, particularly in notified body oversight, enforcement, and standardisation, were identified as an area for increased added value.