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Assessing merits and bottlenecks in Europe's standardisation system

Executive summary

The Standardisation Regulation provides a clear and stable legal framework that fosters the development of standards in line with the European standardisation principles of openness, inclusiveness, transparency and consensus.¹

The Regulation's existing provisions fulfil its objectives and remain future proof to deliver standards supporting a green, digital and resilient single market. We therefore believe the Regulation's principles and content do not require any change.

However, EU efforts should be focused on resolving issues related to the current implementation of the European standardisation system, particularly the timely citation of harmonised standards supporting EU policies.

Since 2016, the European Commission's procedures for developing and citing harmonised standards have introduced unjustified pressures and critical bottlenecks. These issues have severely affected the system's efficiency. The current implementation process needs to be improved without destabilising the solid legal framework established by the Standardisation Regulation.

Key areas of concern include:

- ▶▶ **Implementation challenges:** The procedures initiated by the Commission following the James Elliott court case and the guidelines outlined in the Vademecum have created significant delays and obstacles in the citation of harmonised standards.² These procedures have undermined the leading role of the European standardisation system.

¹ Regulation (EU) No 1025/2012. This paper expands on DIGITALEUROPE's response to the online questionnaire on the evaluation of the Standardisation Regulation. It provides context and clarifications for our overall position. It also provides recommendations on the current implementation of the Regulation. See https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13446-European-standardisation-evaluation/public-consultation_en.

² C-613/14 and SWD(2015) 205 final, respectively.

- ▶▶ **Bottlenecks in citation:** The Commission's prescriptive approach has resulted in stringent timelines and detailed work programmes that put undue pressure on experts, limiting their ability to develop high-quality standards. This approach has also led to frequent challenges and refusals of consensual support for deliverables that meet the standardisation request requirements.
- ▶▶ **Divergence from international standards:** The Commission's approach has required European-specific modifications to international standards. This divergence increases development time, costs and technical barriers to trade, putting European industry at a competitive disadvantage.
- ▶▶ **Consequences for economic operators:** The current lists of harmonised standards are often obsolete, incomplete or delayed, causing confusion and uncertainty among manufacturers, importers, SMEs, customs officers and market surveillance authorities. This loss of certainty has degraded the implementation of EU policy objectives and weakened the CE marking.

To address these challenges, trust between the ESOs and the Commission must be restored. Clearer roles and responsibilities need to be reinforced. The assessment process should focus on compliance with the standardisation request without subjective criteria that contradict the consensus-making process. Additionally, improving the timeline for preparing and citing harmonised standards is essential.

Whilst the principles and content of the Standardisation Regulation are sound and do not require change, the implementation process needs significant improvement. By addressing these implementation issues, the European standardisation system can continue to support a robust single market and maintain Europe's global leadership in standardisation.

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Merits of the Standardisation Regulation

The intention of the ‘New Approach,’ rationalised by the New Legislative Framework (NLF), was to harmonise product legislation.³ Its goal was to define EU policy objectives and requirements in legislation, and to rely on European harmonised standards for defining technical specifications that support these objectives and laws.

Harmonised standards are developed by private standards development organisations designated as European standardisation organisations (ESOs: CEN, CENELEC and ETSI) through established public-private partnerships, involving all relevant stakeholders. These organisations synthesise policy objectives with market needs and technological advancements. National standardisation bodies (NSBs) must adopt these standards as national standards and withdraw any conflicting national standards within defined timelines. The Standardisation Regulation has successfully supported the harmonisation of standards within Europe, allowing broader and faster market access and significantly reducing inherent costs. These harmonised standards enable the free movement of products within the European Economic Area.

Industry and other stakeholders, including societal stakeholders, can contribute to the development of such standards, emphasising the Regulation’s focus on a market-driven approach. The Regulation allows stakeholders to share best practices and knowledge through standards. The involvement of diverse stakeholders, ranging from large global companies and SMEs to societal groups and public entities, ensures a balanced specification that reflects various views and interests. The standards’ content, acknowledged through a final vote approval by NSBs, represents a consensus and reflects the state of the art in science and technology.

The timing for developing harmonised standards – excluding the citation process – is generally satisfactory. When industry identifies a market need for a standard, companies allocate the necessary resources to address that need promptly. As a result, experts typically reach a consensus within the predetermined timeline, provided that the timeline is realistic. This process includes addressing market needs whilst complying with regulatory requirements.

Forming consensus amongst a diverse group of stakeholders takes time, but considering diverse perspectives and jointly assessing contributions is crucial for achieving high-quality, balanced standards that are useful for all. For especially urgent market needs, ESOs have processes that allow for fast-track development when consensus can be quickly achieved. Additionally, when consensus is more difficult to reach but an urgent need exists, ESOs permit the

³ COM(85)19 final.

publication of deliverables other than European standards to provide interim solutions for industry.

European standardisation system players are already very active in most of the emerging new policy areas listed in the questionnaire. We believe that the current level of engagement is appropriate and does not require further stimulation.

Implementation challenges

The European Commission initiates the process for the creation of harmonised standards by requesting ESOs to develop and publish the necessary deliverables. Once the ESOs publish these standards, the Commission cites them in the Official Journal of the European Union (OJEU). Manufacturers can then refer to these harmonised standards for presumption of conformity.

Clear communication of recognised harmonised standards is crucial for supporting market access, especially in the context of CE marking and the NLF. It is essential to align the Regulation's current implementation with the guidelines outlined in the Vademecum on European standardisation.

However, there have been challenges in adapting the process to the Court of Justice of the European Union's (CJEU) legal findings. Current approaches have caused delays in the delivery and citation of harmonised standards, and previous improvement actions have not resolved these issues. These approaches have also led to unnecessary deviations from international standards, hindering access to the single market and threatening the leading role of the European standardisation system.

To address these challenges, it is crucial to streamline the process and ensure timely delivery and citation of harmonised standards, maintaining alignment with international standards to facilitate market access and uphold the European standardisation system's leadership.

Improving citation of harmonised standards

Since 2016, following the James Elliott court case and the implementing rules defined in the Vademecum, the Commission has been implementing processes not originally foreseen in the Regulation. As we previously argued, these processes create bottlenecks for citing harmonised standards in the OJEU.⁴ So far, we have not noted any significant progress towards resolving this situation.⁵

⁴ See DIGITALEUROPE's response to the standardisation strategy, available at <https://cdn.digitaleurope.org/uploads/2022/04/DE-Response-to-the-Standardisation-Strategy-April-2022.pdf>.

⁵ See 'Status of standardisation in support of EU legislation' section.

It is crucial to emphasise that these issues are entirely independent of the Regulation itself.

Over the years, the Commission services have increasingly used standardisation requests more prescriptively, tightening timelines or detailing work programmes. This approach pressures experts to develop standards within an excessively short timeframe, a problem that adding more experts to committees cannot resolve. It also limits flexibility in finding higher-quality solutions for standards users.

In parallel, by highlighting the legislative aspects of harmonised standards, the Commission has been introducing new obstacles that prevent the citation of offered standards. At times, the Commission has challenged or refused consensual support even when deliverables cover the requirements described in the standardisation request.

These practices exceed, or even contradict, the Regulation's original aim. Although the Commission has claimed these practices are based on the conclusions of court cases, these conclusions should be read considering the NLF Decision,⁶ whereby if evidence emerges that a cited harmonised standard fails to meet the legal objectives, the presumption of conformity can be withdrawn. Additional pressure on the citation process is therefore unwarranted.

The visible consequences are that the current lists of harmonised standards can be characterised as follows:⁷

- ▶▶ **Obsolete:** They often reference standards that were withdrawn by NSBs several years ago.
- ▶▶ **Incomplete:** Many European standards that reflect the state of the art regarding essential legislative requirements are missing.
- ▶▶ **Delayed:** There are significant delays, especially when new requirements need to be considered.

Whilst the list of cited harmonised standards was once an essential tool supporting the NLF, the current situation has become very confusing, and at times incomprehensible, for most economic operators. Manufacturers, importers, SMEs, customs officers and market surveillance authorities are left uncertain about which standards to apply without clear guidance. This is especially problematic when listings refer to obsolete standards, are cited with restrictions or are incomplete.

⁶ Decision 768/2008.

⁷ See 'Status of standardisation in support of EU legislation' section.

This loss of certainty has led to a degraded implementation of EU policy objectives and a weakening of CE marking.

Divergence with international standards

The Commission's prescriptive approach makes proper implementation of the Vienna and Frankfurt agreements nearly impossible when adopting international standards as European harmonised standards,⁸ necessitating European-specific modifications. This is despite the EU's commitment to the World Trade Organisation's (WTO) Technical Barriers to Trade (TBT) Agreement and other bilateral trade agreements aimed at aligning European and international standards. Consequently, industry experts and stakeholders on European Technical Committees are overburdened, tasked with resolving these issues, leading to delays in adopting international standards in Europe.

Aligning European standards with international ones provides a competitive edge for Europe's industry. Deviations from international standards or the creation of separate European standards, on the other hand, merely generate additional costs and barriers to global market access.

Proposed solutions

Trust between the ESOs and the European Commission must be quickly restored. The main problem lies in the unclear roles and responsibilities of each actor involved in the process, despite their being defined in the Regulation's Art. 10.

The following proposals aim to better define the main actors' roles and responsibilities, thereby improving trust. This would enable the rapid restoration of the system, and reallocate expert time currently dedicated to resolving obstacles towards developing international standards supporting innovations in the EU.

Reassessing the risk of the 'presumption of conformity' principle

Legislation under the NLF, supported by the Blue Guide,⁹ clarifies that risk assessment about state-of-the-art requirements is the basis of conformity in Europe. The NLF has clarified that harmonised standards are a means to demonstrate compliance. Yet, the presumption of conformity is dependent on a proper risk assessment by the manufacturer, ensuring that all risks associated with the product in relation to EU policy objectives and requirements are adequately covered by the applied standards. This principle is reinforced

⁸ Agreement on technical cooperation between ISO and CEN ('Vienna agreement') and IEC-CENELEC agreement on common planning of new work and parallel voting ('Frankfurt agreement').

⁹ 2022/C 247/01.

by Art. 7(3) of the General Product Safety Regulation (GPSR).¹⁰ Even if a cited harmonised standard is part of EU law, respect for the essential requirements defined in EU legal acts takes precedence.

Facilitating market access and free movement through cited harmonised standards does not conflict with enforcing EU policies and legislation. The NLF Decision, the Market Surveillance Regulation¹¹ and the GPSR provide the necessary tools and authority for proper enforcement. Additionally, there is a formal objection procedure in the Standardisation Regulation, allowing Member States or the European Parliament to raise concerns about a standard's content.

Harmonised standards play a crucial role in ensuring proper enforcement. They define the level of protection to be considered within their scope. Even when standards are not applied in testing, they are usually considered in the manufacturer's risk assessment and by notified bodies as reference documents. If necessary, the Blue Guide's clause 4.1 could be refined by referring to Art. 7(3) of the GPSR.

Roles and responsibilities in assessing deliverables

The roles and responsibilities of the ESOs, NSOs and the Commission in reviewing deliverables need realignment, achievable within the Standardisation Regulation's framework. DIGITALEUROPE recognises the importance of ESOs' quality checks to ensure compliance with their internal regulations and standardisation requests before being submitted for a vote. This practice should be encouraged in international standardisation bodies as well.

The following points should be clarified, for example in the Vademecum:

- ▶▶ **NSB voting support:** A positive NSB vote, based on procedures in Art. 10(2a), should indicate NSB support that the ESO deliverable satisfactorily covers EU policy objectives and other requirements defined in the Commission's standardisation request. The vote should also confirm compliance with the ESO's internal regulations. The Commission should presume that the content of the deliverable adequately addresses the essential requirements of EU legislation and the ESO's internal regulations.
- ▶▶ **Scope and editorial checks:** The Commission should regularly verify that the standard's scope matches the standardisation request and ensure compliance with other editorial elements specified clearly in the

¹⁰ Regulation (EU) 2023/988.

¹¹ Regulation (EU) 2019/1020.

request for the deliverable, such as relevant annexes linking to EU legislation and title translations.

- ▶▶ **Respect of consensus:** The Commission should avoid contradicting the content of a deliverable stemming from a consensus-building process. If issues with the content are identified, the Commission should report its concerns to the relevant sectorial Expert Groups and the European Parliament. If no formal objection is raised within three months after submission, the deliverable should be deemed compliant and cited without delay.
- ▶▶ **Periodic oversight and monitoring:** Instead of checking every single deliverable, the Commission could audit the operations of the ESOs and NSOs (e.g. yearly) to ensure compliance with standardisation policy objectives as defined in the Standardisation Regulation. The Commission might publish a report identifying necessary improvements, and the ESOs should implement corrective measures and report back. This process would address the root causes of potential issues, rather than patching single deliverables.
- ▶▶ Regarding the roles and responsibilities in a standardisation request, a clear decision is needed on the role of the HAS consultants delegated by the Commission. These consultants should either participate in the consensus-making process by offering expertise and recommendations or limit their assessments purely to compliance with the standardisation request without applying subjective criteria. For instance, subjective criteria such as whether 'the deliverable sufficiently covers the requirement' can contradict the consensus-making process and should be eliminated. This approach ensures clarity and consistency, supporting a more objective standardisation process.

Timeline for preparing harmonised standards

Industry faces challenging timelines for implementing new EU policies and requirements. However, there is a lack of clear deadlines for concluding some tasks. We recommend the following points for the Vademecum:

- ▶▶ **Consideration of development time:** Legislators should consider that three years is the usual time required for preparing and adopting a standard. This ensures the Regulation's principles of openness, inclusiveness, transparency and consensus are observed. ESOs should be consulted during the development of regulations to align deadlines and ensure standards are available by the time requirements are enforced.
- ▶▶ **Finalisation of standardisation request:** Standardisation requests trigger the development of harmonised standards. Legislators must

understand that delays in finalising these requests directly lead to delays in standard adoption. Standardisation requests should be finalised within three months of the publication of any new legislation at the latest.

- ▶▶ **Response to ESO questions:** During the development process, ESOs may seek clarification from the Commission regarding the standardisation request or deliverable. We encourage the Commission to respond to ESO queries within one month. In specific situations requiring input from sectorial expert groups or national consultations, this period can be extended by up to three months. Both parties should be promptly informed if an extension is necessary.
- ▶▶ **Deliverable submission:** The time for ESOs to submit deliverables to the European Commission is excessively long.¹² ESOs should promptly submit deliverables responding to standardisation requests immediately upon their availability.¹³
- ▶▶ **Citation:** Although the Regulation's Art. 10(6) stipulates that citation should occur 'without delay,' the current average time for citation is excessively long. We recommend that citations be completed within three months from when the standard is offered for citation by the ESO, ensuring alignment with the date of publication.¹⁴
- ▶▶ **Formal objections:** Conclusions on formal objections should be reached within three months of raising the objection, based on procedures defined in the Regulation's Arts 10(4)-(5).

Awareness of the standardisation process

Officials assessing the standardisation system and deliverables, as well as new experts involved in developing harmonised standards, should be fully aware of the Regulation's provisions, the Vademecum, ESO internal regulations, the ESO approval stages, and the national implementation of standards. This understanding is crucial to prevent counterproductive decisions stemming from

¹² COM(2022) 30 final.

¹³ In the CEN-CENELEC process, the 'date of availability' (DAV) refers to the date when a standard or deliverable is formally approved and made available by CEN or CENELEC. This is the point at which the standard is considered complete and ready for publication and distribution. The DAV signifies that the standard has passed all necessary approvals, including technical committee reviews and national member votes, and is now ready for implementation and citation by the Commission.

¹⁴ In the CEN-CENELEC process, the 'date of publication' (DOP) refers to the date when a standard is officially published and made publicly available by CEN or CENELEC. This follows the DAV, marking the point at which the standard is distributed to the NSBs and made accessible to the public, industry stakeholders and other interested parties. The DOP signifies that the standard is fully approved, endorsed and ready for use across Europe.

misunderstandings of existing processes and regulations, thereby ensuring greater efficiency during the development phase.

This can be achieved by implementing a comprehensive onboarding training programme for newcomers. This programme should be jointly defined by ESOs, the Commission and industry representatives.

One standard, one date of withdrawal

The date of cessation of presumption of conformity should match the standard's withdrawal date.¹⁵ When a standard supports different acts, this date should be identical for all acts. Management of the withdrawal date should remain under the ESO's decision unless the formal objection procedure is applied.

Alignment with international standards

DIGITALEUROPE reiterates the goal of aligning European standards with international standards, consistent with the WTO TBT Agreement and bilateral agreements. This principle, fundamental for European industry's competitiveness in a global market, should receive greater emphasis in the Vademecum, and be considered when assessing a harmonised standard developed in parallel with an international standardisation body.

Inclusiveness in European standardisation

DIGITALEUROPE emphasises the fundamental principle of inclusiveness to ensure that citizens are not discriminated against based on their employer's origin throughout the European standardisation process. This includes ESOs, NSOs and sectorial expert groups. If an exclusion mechanism is necessary to prevent undue influence incompatible with EU principles, a transparent mechanism based on concrete evidence of policy violations should be established, rather than targeting individuals' nationalities or companies' headquarters.

Non-exhaustive list of hurdles

In this section, we outline initiatives that have distorted some core principles of the Standardisation Regulation over the years:

- ▶▶ **Role of consultants:** The Commission's HAS consultants are now prohibited from providing drafting recommendations. They conduct

¹⁵ In the CEN-CENELEC process, the 'date of withdrawal' (DOW) is the date by which any conflicting national standards must be withdrawn, ensuring that the European standard is adopted uniformly across all member countries. This date is set to ensure that there are no overlapping or conflicting standards within the European standards system. The DOW is typically specified when the new standard is published and is a critical part of maintaining consistency and harmonisation within the European standards framework.

stringent reviews of deliverables for citation in the OJEU without suggesting changes. These reviews are often subjective, and despite efforts to establish objective criteria, inconsistencies persist amongst assessors.

- ▶▶ **Non-consensus-based assessments:** The Commission's assessments are not consensus-based, as noted in the Vademecum. This results in unilateral decisions impacting the enforcement of collective agreements, which contradicts the Regulation's principles.
- ▶▶ **Focus on weaknesses:** Reviews excessively highlight standards' alleged weaknesses, disregarding the added value of citation for Europe's industry and the proper enforcement of EU policy and legislative objectives. Citation of a standard is an essential tool in the context of NLF legislation.¹⁶
- ▶▶ **Irrelevant comments and questions:** Reviews often include comments and questions unrelated to the initial standardisation request, leading to delays. This contradicts the Regulation's mandate.
- ▶▶ **Lack of transparency:** Comments and questions on published standards from HAS consultants or Commission services are not publicly available. This prevents stakeholders from understanding citation refusals and considering the Commission's or consultants' opinions.
- ▶▶ **Absence of formal objection procedures:** There are no formal objection procedures for comments or questions from Commission services raised in reviews. This means such comments are not subject to advisory or examination procedures, and Expert Groups are often not consulted or vaguely informed about the reasons for obstacles and delays in citation.
- ▶▶ **Inconsistent legal interpretations:** There are inconsistencies in the legal interpretation of essential requirements amongst assessors. We have experienced different officials involved in specific Directives or Regulations having divergent opinions.
- ▶▶ **Contradictions with consensus-based deliverables:** Reviews often contradict the content of deliverables adopted based on a consensus approach following a vote by NSBs, as per the Regulation.
- ▶▶ **Citation refusals and delays:** Citation refusals, delays or misalignments with standardisation requests have become common. The average time for citation now extends well beyond three months

¹⁶ See Opinion of Advocate General Medina in C-588/21 P.

and can take years after publication by the ESOs, deviating from Art. 10(6)'s objective of achieving citation 'without delay.'

- ▶▶ **Inconsistent withdrawal dates:** Non-citation and delays have led the Commission to define its own withdrawal dates from the OJEU, which are often inconsistent with the ESOs' prescribed dates. For standards linked with multiple acts, withdrawal dates can vary across listings, despite similar or identical EU policy objectives.
- ▶▶ **Deviations from international standards:** Deviations from international standards require extra development time for the European standard, taking no less than 12 months. These deviations create a competitive disadvantage for Europe, pose technical barriers to trade and make consensus challenging at EU level.
- ▶▶ **Issues in European Technical Committees:** European Technical Committees are either stuck resolving citation issues, whilst international experts develop innovative solutions, or have resigned from resolving issues, meaning standards may never be offered for citation in the OJEU despite covering EU policy requirements. An example is the rejection of citation for harmonised standards that refer to non-ESO standards, such as IEEE standards, posing significant barriers to developing European standards in the global context and hindering collaboration with other standardisation entities.

Status of standardisation in support of EU legislation

This section provides the status of standards cited in the OJEU supporting three key Directives relevant to the digital industry: the Electromagnetic Compatibility Directive (EMCD);¹⁷ the Low Voltage Directive (LVD);¹⁸ and the Radio Equipment Directive (RED).¹⁹

A comparison with the results of a previous DIGITALEUROPE analysis in September 2023 shows that the situation has continued to deteriorate.²⁰

Methodology

¹⁷ Directive 2014/53/EU.

¹⁸ Directive 2014/35/EU.

¹⁹ Directive 2014/53/EU.

²⁰ See DIGITALEUROPE, *Position on call for evidence for the evaluation/fitness check 'European standardisation – evaluation,'* available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13446-European-standardisation-evaluation/F3437127_en.

The aim of this section is to define a KPI reflecting how up to date the referencing of standards cited in the OJEU is with respect to the acknowledged state of the art. Due to the lack of automated tools, the status of each standard reference cited in the OJEU was checked manually. The study was limited to the three major directives (EMCD, LVD and RED) due to time constraints.

The statuses of standards cited were defined as follows: current (the reference of the standard cited in the OJEU is up to date and is the latest edition published by the ESO); current with new version in development (the reference of the standard cited in the OJEU is up to date, but an ongoing project is active on updating the standard;²¹ superseded (the reference of the standard cited in the OJEU is not the latest edition/version, but the date of withdrawal of any conflicting national standard as defined by the ESO has not passed yet); or superseded and withdrawn (the reference of the standard cited in the OJEU is not the latest edition/version, and the date of withdrawal of any conflicting national standards as defined by the ESO has passed).

The lists were obtained from Excel files generated and made available by the Commission.²² The dates of withdrawal for conflicting national standards were checked using: the CEN/CENELEC search engine,²³ supplemented by the database for a few withdrawn standards to get the effective date of withdrawal;²⁴ and the ETSI search engine,²⁵ supplemented by the foreword page of the superseding standard defining the effective date of withdrawal.

Limitations

The method used cannot identify references of harmonised standards for which an older version is not already cited, e.g. a standard covering a new product category. Therefore, the KPI result is likely more optimistic than reality. Additionally, the method cannot identify delays in adopting ISO/IEC standards as European standards by the ESO or other delays in adoption due to obstacles in citation. A separate KPI would be needed for such purposes. Other KPIs, such as the rate of the Commission's rejection and the mean time for citation after publication by the ESO, would also be useful.

Only references of standards adopted by the ESO were considered. Drafts and corrigenda were disregarded. When there is an amendment (e.g. A1) with its own date of withdrawal defined by the ESO, it was considered as superseding/withdrawing the non-amended reference.

²¹ Checked for EMCD and LVD only.

²² https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en.

²³ <https://standards.cencenelec.eu/>.

²⁴ <https://projex.cencenelec.eu/>.

²⁵ <https://www.etsi.org/standards/>.

EMCD²⁶

When the latest EMCD entered into force, the listing of harmonised standards from the previous directive was adopted, with some exceptions for products newly falling within the scope of the RED. A total of 126 references were cited, including 10 with a defined date of cessation of presumption of conformity, aligned with the ESO's date:

- ▶▶ 37 references were withdrawn or updated in the OJEU during the 2016-2024 period;
- ▶▶ 138 references remain cited, none with a later date of cessation of presumption of conformity; and
- ▶▶ 4 out of the 138 remaining cited standards include restriction notices.

The evolution of the status of cited standards, as tracked by the ESOs, provides a better indicator for monitoring the standardisation system's progress post-Elliott case. Considering the full list of standards cited in the official records (see Figure 1):

- ▶▶ 64 (46%) of the standards cited in the OJEU are superseded by a newer version and withdrawn by all NSBs, based on the ESO's instruction;
- ▶▶ 20 (14%) of the standards cited in the OJEU are superseded by a newer version and will soon be withdrawn by all NSBs, per the ESO's instruction; and
- ▶▶ 54 (40%) of the remaining standards are up to date, with 22 of those having active projects for updates.

²⁶ The latest Commission file, dated 19 September 2022, was used for this analysis. Data was consolidated based on available information as of 8 July 2024.

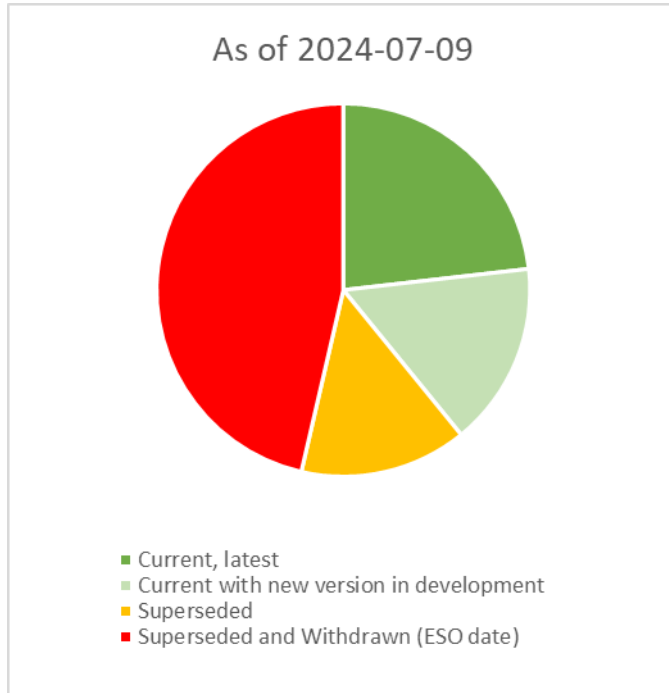


Figure 1 – ESO status of standards referenced in OJEU for EMCD

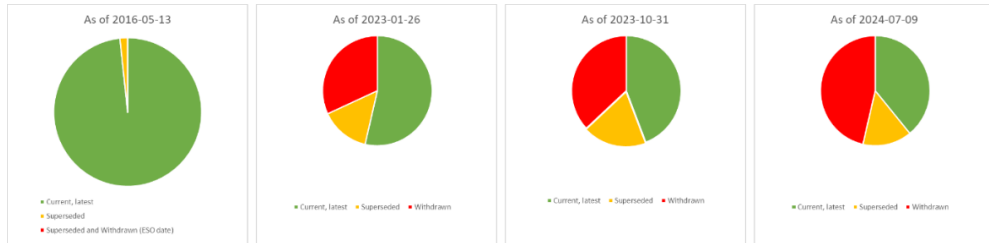


Figure 2 – Evolution of status of standards referenced in OJEU for EMCD

Despite efforts to update standards, the OJEU increasingly fails to reflect the latest versions. For 60% of product categories:

- ▶▶ The listing encourages the use of outdated standards;
- ▶▶ The relevance of withdrawn standards concerning essential requirements needs reassessment, whilst the most efficient solution would be to cite the latest versions without delay; and
- ▶▶ The ESOs continue to develop state-of-the-art standards approved by NSBs, but most of these newly created standards are not yet cited in the OJEU.

LVD²⁷

²⁷ The latest Commission file, dated 23 April 2024, was used for this analysis. Data was consolidated based on available information as of 10 July 2024.

When the latest LVD entered into force, the listing of harmonised standards from the former Directive was adopted. A total of 734 references were cited, including 78 with a defined date of cessation of presumption of conformity, aligned with the ESO's date:

- ▶▶ 250 references were withdrawn or updated in the OJEU during the 2016-2024 period;
- ▶▶ 663 references remain cited, with 90 having a later date of cessation of presumption of conformity; and
- ▶▶ 1 of the 573 remaining references of cited standards contains restriction notices.

For the full list of standards cited in the OJEU (see Figure 2):

- ▶▶ 126 (22%) of the standards cited in the OJEU are superseded by a newer version and withdrawn by all NSBs, based on the ESO's instruction;
- ▶▶ 81 (14%) of the standards cited in the OJEU are superseded by a newer version, and all NSBs will be withdrawing the standard based on the ESO's instruction; and
- ▶▶ 336 (64%) of the remaining standards are up to date, with 143 of those having active projects for updates.

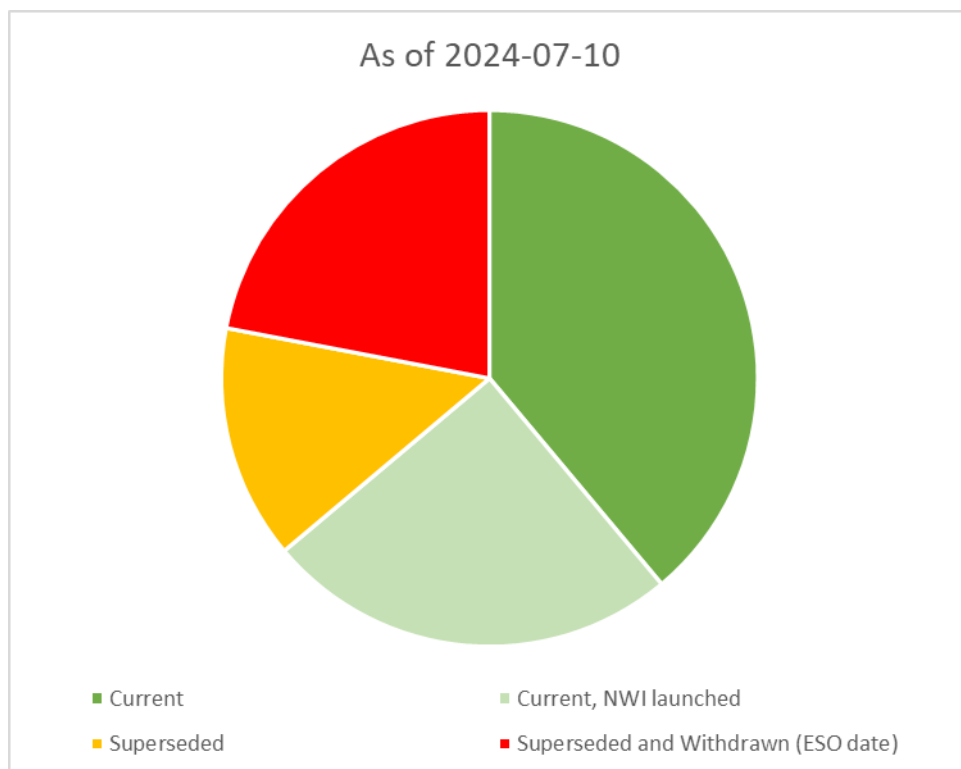


Figure 3 – ESO status of standards referenced in OJEU for LVD

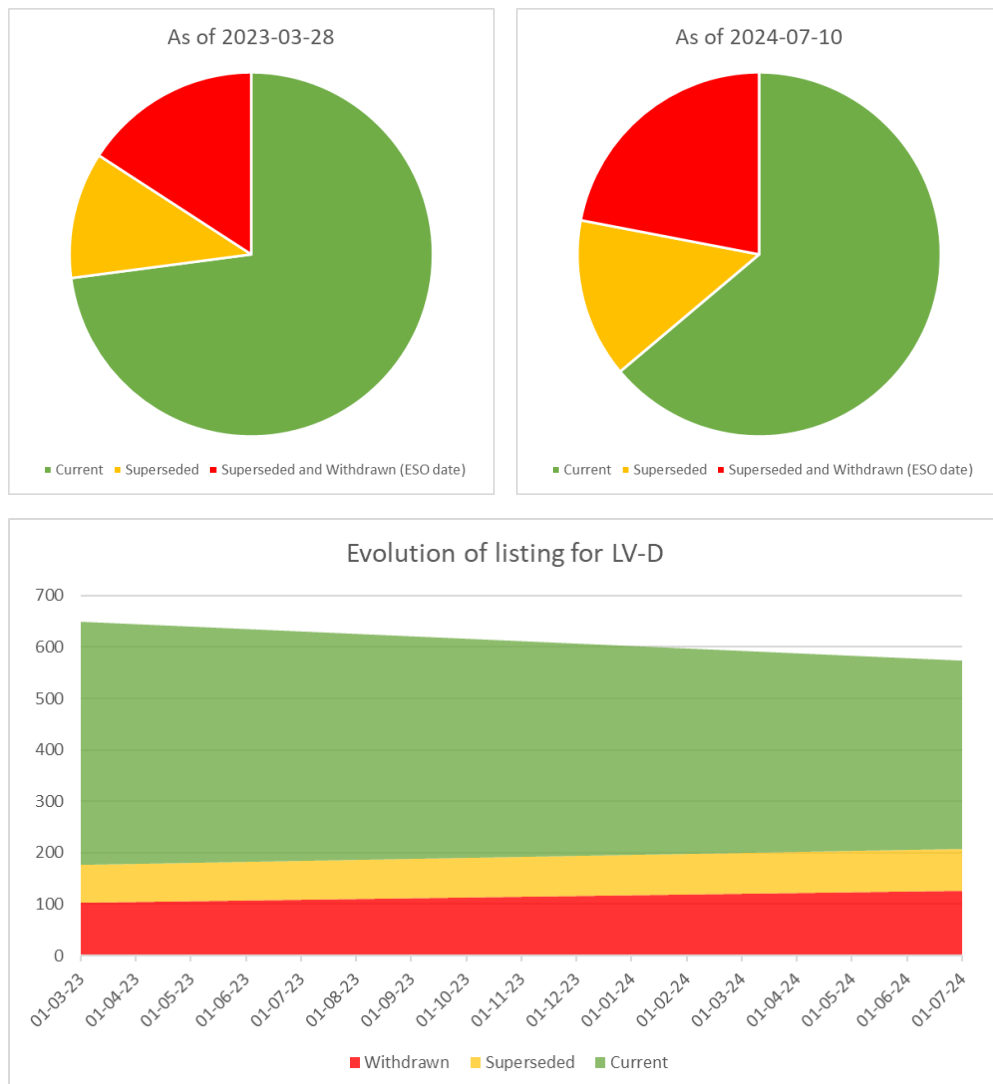


Figure 4 – Evolution of status of standards referenced in OJEU for LVD²⁸

The trend for the LVD indicates a reduction in the number of standards cited. Despite efforts to update the standards, the OJEU increasingly fails to reflect the latest versions.

For 36% of product categories:

- ▶▶ The listing encourages the use of outdated standards;
- ▶▶ The relevance of withdrawn standards concerning essential requirements needs reassessment, whilst the most efficient approach would be to cite the latest versions without delay; and

²⁸ Standards with a defined date of cessation of presumption of conformity are excluded from the above graphs.

- ▶▶ The ESOs continue to develop state-of-the-art standards approved by NSBs, but these are not being cited in the OJEU.

RED²⁹

In 2016, the Commission opted to start anew since the scope and essential requirements of Art. 3(2) RED had changed compared to the former R&TTE Directive.³⁰ Consequently, the initial list of standards cited in the OJEU contained only four references, all for Art. 3(2). By June 2017, marking the end of the transition from R&TTE to RED, 117 standards were available, many of which had been developed and cited under the R&TTE regime.

Additionally, whilst the R&TTE listing indicated that harmonised standards cited under the EMCD or LVD provided presumption of conformity for Arts 3(1)(a)-(b), respectively, the RED listing does not make such statements. Therefore, additional specific listing requests are necessary for each standard covering a category of equipment that might include a radio functionality aligning with the RED's definition of radio equipment.

Cited standards for Art. 3(1)(a)

For clarity, two categories of standards are considered separately:

- ▶▶ Standards for exposure to electromagnetic fields (EMF, such as specific absorption rate); and
- ▶▶ Other standards for safety (such as electrical shock, burn, fire hazard or injuries).

For standards relating to exposure to EMF, four standards are cited, all of which have active projects for updating.

For other safety standards, no reference standards are cited. This situation is puzzling, especially when compared to the 573 remaining standards cited under the LVD, to which the Art. 3(1)(a) essential requirement refers. Outside of EMF exposure, incorporating radio functionality in a product generally has minimal impact on product safety.

Cited standards for Art. 3(1)(b)

²⁹ The latest Commission file, dated 1 December 2023, was used for this analysis. Data was consolidated based on available information as of 11 July 2024. The following assessment of the cited standards is categorised by essential requirement, although the OJEU listing does not specify which essential requirements each cited standard covers.

³⁰ Directive 1999/5/EC.

Four standards are cited. This should be compared to the 138 standards cited for the EMCD and the numerous standards prepared by ETSI specifically for radio functionalities.

Notably, three of these EMCD standards, cited in 2022, include restrictions that do not allow the use of tolerances for measuring equipment, which goes beyond the scope of the RED requirements for conferring presumption of conformity. Without allowing such tolerances, measurement is not feasible, rendering the citation ineffective. The remaining standard was withdrawn by an amendment (A11) In July 2022, even though this amendment has no practical effect on measurement results.

Cited standards for Art. 3(2)

All 155 referenced standards covering Article 3.2 were prepared by ETSI:

- ▶▶ 5 standards are superseded by a newer standard but have not yet reached the ESO's date of withdrawal;
- ▶▶ 17 standards have reached the ESO's date of withdrawal; and
- ▶▶ 37 standards are cited with a restriction, making it impossible to use the Module A self-declaration, which is the primary intent of harmonised standards.

Cited standards for Art. 3(3)

Three standards for Art. 3(3)(g) are cited, also covering Art. 3(2).

Harmonised standards for Arts 3(3)(d)–(f) (cybersecurity) are under development. Despite the exceptional efforts of CEN-CENELEC JTC 13 in developing these standards within a challenging timeline, the HAS consultant concluded with a negative assessment result, even after a 100% positive outcome of the formal vote. This demonstrates how the HAS consultant's opinion can undermine the consensus achieved through extensive standardisation work over two years.

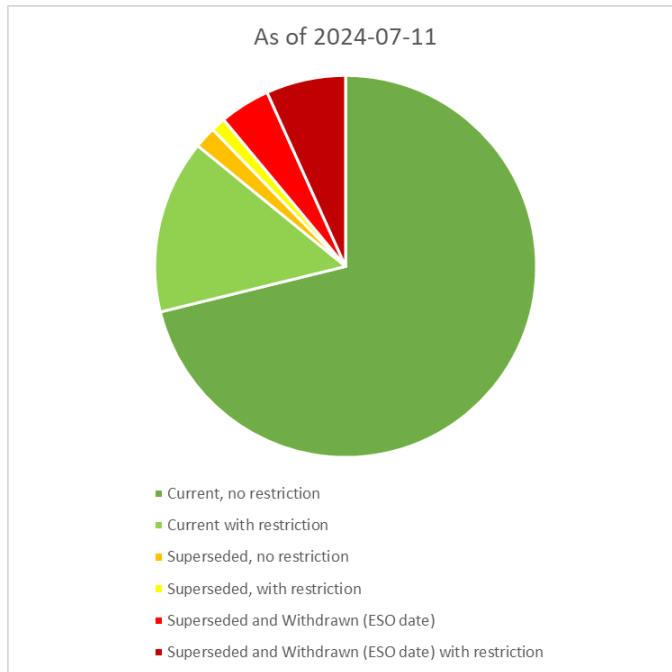
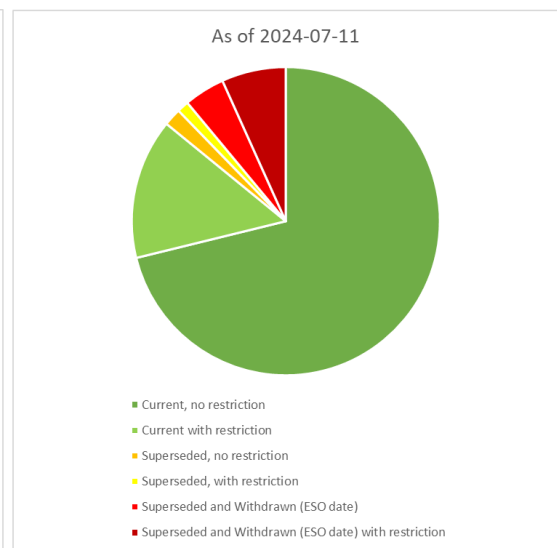
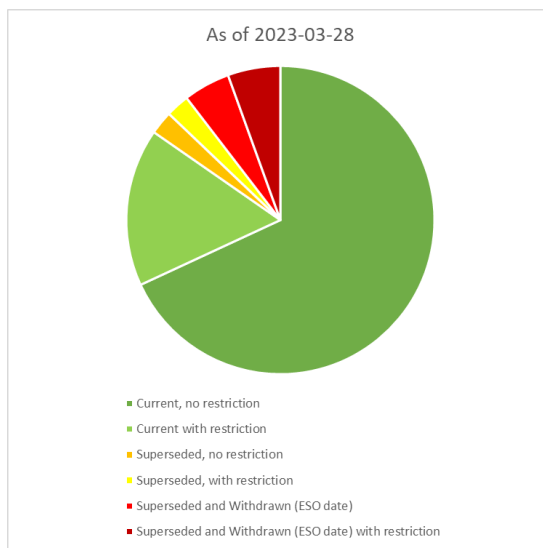


Figure 5 – ESO status of standards referenced in OJEU for RED



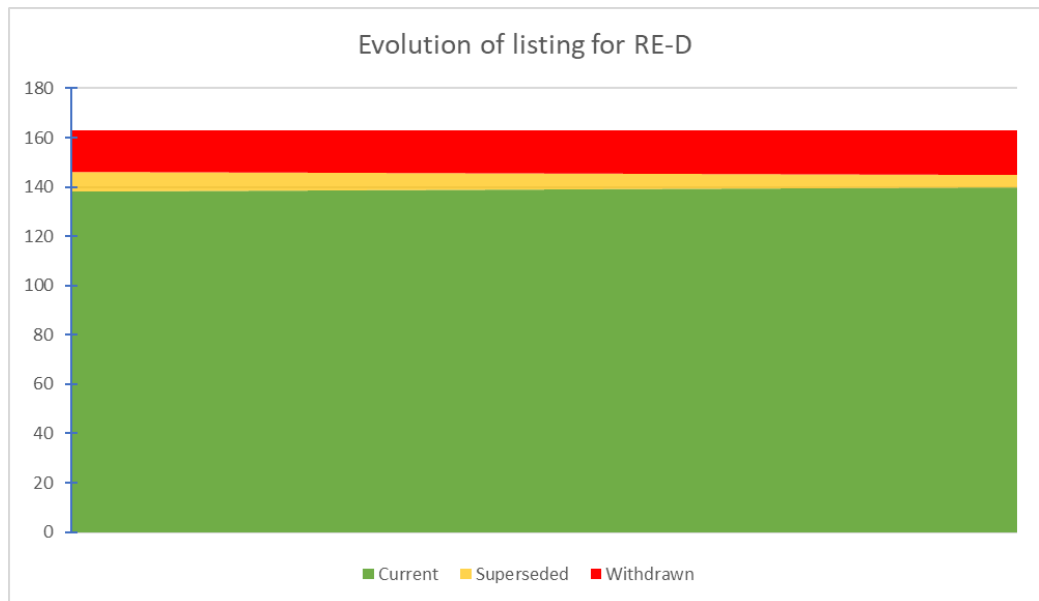




Figure 6 – Evolution of status of standards referenced in OJEU for RED


The situation for the RED appears stable, with standards for Art. 3(2) cited, though nearly a quarter of these have restrictions. Additionally, there is a persistent lack of standards for Art. 3(1).


This highlights the difficulty in obtaining citations for internationally developed standards. ETSI predominantly develops European-based standards for Art. 3(2), whereas CEN-CENELEC standards covering Art. 3(1) are primarily internationally developed.

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