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Foreword

This Technical Report (TR) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

Modal verbs terminology

In the present document "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

Executive summary

The present document examines the background to the citation of harmonised standards and identifies issues that do now, and might in the future, impact on ETSI's ability to deliver standards to a specification that is deemed acceptable to the EC. Issues are explored and recommendations made to alter ETSI working practices to address these issues.

After consideration by the EC, EESC and ETSI a group should be set up between the three organizations to consider these issues and recommendations as a matter of urgency.

Once the issues have been resolved, Master Documentation setting out the requirements for harmonised standards should be agreed.

Delays in citations

The availability of harmonised standards is critical to the smooth and efficient design and development of products to be placed on the European market. The absence of harmonised standards leads to delays in products coming to market and additional - sometimes significant - costs. Delays to the citations of such standards, therefore, are highly unsatisfactory and both the ESOs and the EC have to recognize that they have a role to play.

It is recommended, therefore:

- ETSI should seek greater involvement in the drafting of SRs, warning that failure to heed such a request will lead to more rejected requests and, ultimately, bigger delays to standards becoming available.
- The EC and ESOs should, jointly, develop an understanding of the scope of the associated SRs before setting timescales associated with delegated acts.
- The Impact assessment should clearly set out the assumed scope of the Delegated Act so that the true cost of the demanded legislation can be calculated.
- ESOs should be allowed to partially accept SRs if disagreements are encountered or, if deemed inappropriate, for a particular ESO to respond to a part of an SR.
- ESOs should be allowed staged implementation dates, whereby tranches of standardisation activity can be delivered by an initial deadline and the entire work packages completed by a later date(s).

Functional requirements

Prior to the RED delegated act, tests contained in Harmonised Standards were primarily based on physical attributes and the laws of physics which where well understood with tests being appropriate to the type of device. With the scope of radio standards being expanded to include functional requirements (in particular software), however, defining requirements and drafting corresponding tests becomes ever more challenging, when the way in which the requirements are achieved is implemented differently from product to product. Documenting a procedure, therefore, that satisfies the EC's interpretation of legal certainty will become ever more challenging.

It is recommended, therefore:

- When writing new types of standards, the EC or HAS need to be involved from the start of the work. If, when developing a new framework, the work proceeds in a direction counter to the EC's visions, there is a risk that much time will be lost.
- TCs should note that industry would be reluctant for manufacturers to have to deliver source code, manuals etc., as this is undesirable and risky.
- ETSI needs to develop a way in which testing is feasible without revealing products' inner workings.
- ETSI might consider merging TC AI and/or TC Cyber into ERM to better connect the expertise within the organization.
- When subjective testing is involved, the complexity and time it takes for the ESOs to conduct the risk analysis supposed to be captured in the HEN increases exponentially with the scope of the expected legislation (e.g. addressing consumers/B2B as well as industrial/B2C products). This should be considered by regulators when setting the scope and timeframe of legislations such as the RED cybersecurity articles, the CRA, or the AI Act. NLF based.

The EC should not use NLF based legislation such as the RED to introduce such functional requirements involving subjective testing if it is going to insist on such a high level of legal certainty:

- A clarificatory discussion should be held between the EC and standards bodies with clear outcomes on how to addresses functional requirements.
- ETSI should continue to highlight the gap between what can be achieved with NLF standards (used at the point of placing products onto the European market) and what stakeholders require in order to keep products secure through their lifetime. A lifetime commitment would be a challenging ask raising fundamental questions over the liability of products managed by consumers and would be best addressed using more targeted legislation such as the Cyber Security Act or Cyber Resilience Act.

Horizontal issues

Experience from a great many TCs and reported at OCG RED has revealed that there are a large number of issues being raised by the EC desk officer and the HASCs that are common across TCs, or are receiving inconsistent assessments. Many of these have been collated into a single document to be presented to the EC, and ultimately turned into a FAQ document. It is likely that this treatment of similarly common issues will continue on an ongoing basis within OCG RED.

It is recommended, therefore:

- ETSI OCG RED should continue to collate and maintain a database of detailed technical/ legal issues that have been raised by the EC and/or the HASC in order to avoid repetitive discussion of topics and inform rapporteurs.
- The EC should allow in situ testing/standards to be written in case it is impractical to carry out such testing in a test laboratory or factory setting.

Relationship with the EC

In a report from the Commission to the European on its Standardization Strategy [i.28] in February 2022, the EC claimed that the high number of failed reviews of standards was, 'mainly due to inadequacy with EU law, showing that more work is to be invested in the development process of standards - e.g. within the technical committees - so that the work is more aligned with the policy and legal requirements". Experience of ETSI & CENELEC TC leads, however, challenges this narrative suggesting that, although in many cases this might have been fair criticism, there have been other factors that have led to unfavourable reviews.

Widespread concern was also expressed by TC chairs over the consistency of decisions and inflexibility of the EC in assessing candidate harmonised standards, and there was frustration at the growing number of standards that are rejected or cited with restrictions.

Many examples of inconsistency of decisions from standard to standard were cited, leading to frustration and delays in the publication of standards. Such delays cost standards writers time, and hence money, but also leave the EU market with incomplete documentation, thereby adding further costs to industry and leading to uncertainty in the quality of products being placed on the market.

The EC is empowered to introduce delegated acts on existing legislation, such as the RED, providing it carries out a thorough impact assessment. Recent experience demonstrates that, even after the (sometimes controversial) public debate and publication of such an impact assessment, the corresponding actions, such as the publication a delegated act or the issuance of a Standardisation request, the actual impact on industry (both cost and time to make changes) and the market more widely is often wildly underestimated.

It is recommended, therefore:

- All meetings and decisions by the HASC and EC staff should be documented.
- All meetings with the EC discussing matters pertaining to the citation of standards should be minuted - at least on the ETSI side - so that all discussions are captured.
- Highlight the cost (to industry, MSAs and Europe) of onerous compliance requests and missing or out-of-date standards.
- Better education up to politicians (on mandates) so that all understand the implications of mandates, especially the way in which they might be converted to SRs.
- When drafting standards, all issues should be collected and faced directly without trying to hope that the problems will go away.
- Rapporteurs should not take the attitude that 'if the EC has not complained ETSI should not make any changes' - all issues should be addressed to avoid future problems, even extending to other standards.
- Affected rapporteurs should not reject issues simply because they were only reported for other standards.
- Cross-standard references might, where practical and applicable, be encoded into ETSI processes to ensure that they are pursued.

- The EC should draft a clear set of rapporteurs'/HASC guidelines, because the current guidelines are confusing and go into insufficient detail when compared to the issues being raised by the HASCs and the EC itself.
- In anticipation of formal documentation from the EC, ETSI should generate a set of 'Master Documentation', setting out its understanding of what is expected and what is required in harmonised standard. This might be founded on the horizontals issues FAQs that are being generated by TC ERM.
- ETSI should put a process in place to ensure that the Master Documentation set is updated appropriately as new information comes to light, or an earlier understanding is altered or clarified.
- The EC has suggested there should be training for rapporteurs and ETSI officers but conversely, it may prove useful for EC legal services group to have experience of everyday life in test labs e.g. with accreditation services.
- The EC should publish Impact Assessments for all mandates, and update those assessments in the light of developments that significantly impact on the cost of their implementation.
- The reinstatement of generic standards, which are necessary in the European market.
- As paperwork causes the majority of issues, in particular the technical file, the master documentation should set out a clear understanding as to what is required.
- ETSI and the EC need to find a balance as to what properties of equipment can be declared.
- However, the handling of measurement uncertainty is understood globally and ETSI should continue to use the same approach.

Relationship between ERM and other TCs & ESOs

The relationship between ETSI and the other ESOs (CEN and CENELEC) is excellent and the formal channels for exchanging information and collaborating works well. Nevertheless, collaborative preparatory work for the RED 3(3) articles revealed that in order to achieve the tight timescales involved, progress could only be made through a loose, informal way of working between ETSI TC Cyber and CEN/CENELEC JTC13. This cross ESO working was brought about by the necessarily broad scope associated with the RED 3(3) articles requirements. In future, more and more products will involve cross boundary working (e.g. White goods) and so more collaboration will be needed - both between and within ESOs (i.e. between TCs).

It is recommended, therefore:

- Existing OCG groups which have been used as an interim solution to cross-cutting Standardisation Request are unable to prepare and agree standards and so TC Cyber and whichever group takes over the OCG AI work should join ERM for the purpose of ensuring members are kept up to date, or another structure might be considered.
- Given it currently it takes many months to set up joint groups with much political discussion, a permanent, informal inter-ETSI-CEN/CENELEC liaison group might be set up with a changing membership dependent on subject.
- More widely, a matrix structure might be set up between ETSI/CEN/CENELEC identifying who can immediately speak to whom, which might help with the limited interconnectivity within CENELEC, where individuals are present only on specific committees.
- Permanent Hybrid meeting facilities should be set up to encourage members to participate in this cross-ESO work.
- Governments should be encouraged to better fund standardisation activities including membership of ETSI.

Legal certainty

The EC's interpretation of legal certainty, influenced by their interpretation of the Elliott case, has led to the delay of many harmonised standards since the transition from the R&TTE to the RED, where statements within new (and existing) standards have been deemed to be insufficiently certain. The EC has made it clear that it considers harmonised standards to be legal documents, the implication being that they should be sufficiently legally certain, even though they are, essentially, technical documents with different demands on the quality of their scope and content.

It is recommended, therefore:

- A discussion is needed to ensure that all parties have the same understanding of this matter.
- The exact implications for HS need to be agreed. Does it require minor changes to the text in HS, or will it require major changes and lead to HS for use with a DoC becoming different to HS for use in type approval?
- The cost versus benefit of requirements and procedures should be used by ETSI to establish a sufficient level of testing detail, the principle of which the EC should accept.
- ESOs should always take the safest approach to handle uncertainties related to risk analysis, until criteria to overcome this uncertainty are identified and agreed with EC.
- If the EC feels that requirements demanding subjective testing should be included in NLF legislation, there should be an acknowledgement of, acceptance and description as to how such requirements should be documented and tested by the EC, which would be captured in the master documentation.

Reputational damage

ETSI has a global reputation, both with regulators and industry and has long since prided itself on writing clear and easy to follow standards and procedures. Demands that are being made recently of TCs by the EC and HASCs - both demanding unrealistically onerous procedures and also the removal of instructive text - however, is damaging the quality of standards in the eyes of our customers and thereby damaging the reputation of ETSI itself.

It is recommended, therefore:

- ETSI should recognize that there is a bigger picture (than ETSI standards becoming very EU-specific) in that Europe is mandating more and more European Common Modifications to globally-accepted International standards (developed by domain experts over many years, only for EC lawyers to find legal fault), leading to fragmentation of standards, which can only lead to higher costs for consumers, and the disadvantaging of European industry.
- ETSI, ultimately, perhaps, has a choice: write global standards only or adapt them to EU-specific requirements, perhaps by way of an addendum. This would allow ETSI standards to continue to be consumed in its traditional global markets.
- Two-part standards might be considered, thereby satisfying the needs of the EC whilst not compromising standards' global relevance, where detail (such as measurement procedures) that has been excluded by the EC (but which infrequent users of the standards need, such as details of measurement tolerances) might be returned.
- Else suites of documents could be written: one part for the engineers and/or technicians who are involved in the (planning and execution of) testing and one part having legal significance.
- ETSI should continue to vocally defend industrial participation in standards writing.
- Both ETSI and the EC should understand the implications of detailed assessment procedures that are currently being demanded, which lead to long and costly testing sessions, the cost of which to European industry (and, ultimately, consumers) should be highlighted.
- In diverging from international standards, Europe risks isolation, which ETSI believes runs counter to the interests of Europe. Deviations should be a last resort, and so the EC should be encouraged to approach third-party SDOs and make their points, else uncertainty will continue to haunt European standards.

Availability and variability of HAS consultants

In 2018 the European Commission introduced the concept of Harmonised Standards Consultants (HASC) to independently review the standards produced by the ESOs in response to Standardisation Requests. The reviews are intended mainly to ensure that harmonised standards are legally sound and accurately reflect the intentions of the Standardisation requests. A standard checklist of criteria is used by the consultants.

From late 2019, however, TC ERM, started to experience problems with the availability of HAS consultants to attend ETSI meetings. The result of this is increased misunderstanding by both parties on the intent of each other and an over reliance on the final review by the RED Desk Officer which takes place after the standard has been published by ETSI and the work item closed, making revision of the standard time consuming.

TC ERM has also experienced different approaches and comments from different individual consultants. This undermines the entire process because a TC might receive a "green light" from one during a review and then a subsequent review by a different consultant might raise concerns that were not there in the first review. This lack of consistency makes drafting extremely frustrating.

It is recommended, therefore:

- HASC's should be given clearer guidance as to the scope of their activities and detail of where they should intervene, with emphasis on intervention only in case of clear breaches of a standard's content.
- HAS consultants should be present in resolution meetings as well as engaging them at early stage in the standard's genesis.
- A process should be put in place to avoid or resolve contradictory opinions by different HAS Consultants on similar issues, before such opinions are validated and transmitted to the ESOs for action. In case an approved new opinion contradicts a previously expressed one, the ESOs should not be held responsible for delays resulting from aligning the standards with the new opinion.

Challenges of the EC's new standardisation strategy

When a request for standardisation is made by the Commission, the European standardisation organizations are the only bodies that can issue standards and standardisation deliverables. They do so in line with specific procedures set out in Article 10 of Regulation (EU) No 1025/2012 of the "Standardisation Regulation". The Standardisation Regulation also provides that the European Union may support the European standardisation organizations financially.

In its foreword, the EC contends that, *"the strategic importance of standards has not been adequately recognized at the cost of EU leadership in standards-setting. This must change"*. ETSI does not recognize the issues raised in this paragraph and would appreciate more explanation.

It is recommended, therefore:

- The intention of the call to the ESOs to "facilitate access to standards" should be clarified, e.g. does it means facilitate access to the standards development process to certain types of stakeholders, or facilitate access to published standards (ETSI standards are freely available via the ETSI website) by all stakeholders, or both? The current ESOs landscape supports different financing models affecting either access to the development of standards or access to the text of approved standards. This diversity of models has successfully proven its ability to efficiently address a variety of issues, so the impact of enforcing a single model should be carefully analysed.
- It should be acknowledged that European standards and legislation may serve different purposes, which may be better served by different processes in the way to develop and disseminate European standards. While Member States appointed representatives may be best placed to contribute when it comes to defining requirements for protecting consumers in already existing markets, the pace of innovation in Information and Communication Technologies requires anticipation to ensure timely availability of mature interoperability standards as an enabler to the development of new market segments. This requires active involvement of scarcely available experts in the innovative ecosystems. The ability of national committee based representation to address such cases has to be assessed, while the ETSI industry-based participation model enabled the success of the EU initiated GSM standards in the 1990s, which set the basis to global cellular communication systems worldwide for the following decades.
- In judging the performance of the ESOs, there needs to be a clearly stated and agreed upon performance/speed objectives is necessary.
- The EC and the ESOs need to work together to anticipate regulation that may be required in the future for new and fast-evolving sectors.
- Many ambiguities could be avoided if the Commission would agree, as a Best Practice principle, to atomize its SR to the extent possible, i.e. one SR per HEN, or at least if the Standardisation Request could set specific timeline for each HEN it covers while the ESOs would be allowed to individually Accept or Reject the development of each HEN under such a combined SR.

- The Standardisation Request should define the scope affected and the overall goal to achieve, i.e. the "WHAT", without entering into technical details on "HOW" this goal has to be achieved. Frequently, the Commission has a tendency to enter far into ESO's territory when drafting its SRs (e.g. converting high level objectives into detailed technical requirements).

- Change process to allow partial acceptance of SRs and/or dialogue or ensure that SRs are split into appropriate and specific individual requests (with separate requests for separate deliverables whenever possible), with realistic timescales.

Process issues

With the EC's new assertiveness in judging standards for citation it has become apparent that the ENAP process itself creates problems that lead to delays and frustration within TCs.

The main problem encountered so far with the Standardisation Request process stems from the fact that the ESOs can only fully accept or fully reject an issued SR within one month, with neither comments nor conditions admitted.

It is recommended, therefore:

- Many ambiguities could be avoided if the Commission would agree, as a Best Practice principle, to atomize its SR to the extent possible, i.e. one SR per HEN, or at least if the Standardisation Request could set specific timeline for each HEN it covers while the ESOs would be allowed to individually Accept or Reject the development of each HEN under such a combined SR.

- The Standardisation Request should define the scope affected and the overall goal to achieve, i.e. the "WHAT", without entering into technical details on "HOW" this goal has to be achieved. Frequently, the Commission has a tendency to enter far into ESO's territory when drafting its SRs (e.g. converting high level objectives into detailed technical requirements).

- Change process to allow partial acceptance of SRs and/or dialogue.

- EC comments should be submitted at a stage where they could be debated and acted upon in the normal process of standards production. This means as early in the process as possible and whilst this may place a burden upon the RED desk and others, submission of comments during the ENAP process should be seen as the appropriate place, thus making the act of citation a more straight forward step that does not get bogged down in revision of the standard when the work item is closed and the standard published. Furthermore submission of EC comments here also means that the EC comments along with everyone else's are subject to full public scrutiny as part of the established process for standards.

- The EC's right to fail/restrict citations comes at the end of the process - no time to remedy - Update ENAP process, therefore, the ENAP process could be revised in such a way that:

    - an additional NSO/NSB assessment (in parallel to first HASTAC assessment) could be established to increase the NSO/NSB involvement during the EN preparation and not only NSO/NSB commenting possibility during the ENAP official public enquiry step (including vote);

    - the second HASTAC assessment may take place during the public enquiry;

    - at the final stage (ETSI publication) the EC assessment may be prepared before ETSI would "final" publish the EN. This "freeze" of the EN could provide ETSI the possibility to consider editorial changes (requested by EC) to improve clarification in the EN.

Relationship with National Standardization Organisations/Bodies (NSOs/NSBs)

The Standardisation Strategy makes clear the EC's desire to ensure that NSOs/NSBs play a major role in the response of ESOs to SRs. As a minimum, NSOs/NSBs will be responsible for rubber stamping ESOs' response to SRs and the final deliverable. NSOs/NSBs, however, do not, typically, currently engage with these processes, which is left to industry participants.

It is recommended, therefore:

- The EC should clarify the process that it sees for enabling the 41 NSOs/NSBs of Europe to make decisions on responses to SRs and publication of the resulting standards.

- ETSI should work with the NSOs/NSBs to educate them as to their roles and responsibilities to ensure timely production of harmonised standards.
- National Governments should be encouraged to fund their NSOs/NSBs' access to ETSI in order to allow them to better engage with the standardisation process.

Introduction

The European Commission, in launching its Standardisation Strategy in February 2022, highlighted the pivotal role that standards have to play in supporting the EU's single market, delivering *"great benefits for companies and consumers, creating a level-playing field in the single market for businesses and increasing consumer confidence"*. Whilst acknowledging Europe's success in standardisation, the Commission contends that, *"the strategic importance of standards has not been adequately recognized at the cost of EU leadership in standards-setting. This must change"*.

ETSI plays a key role in supporting regulation and legislation with technical standards and specifications, and is recognized by the European Union (EU) as one of the three official European Standards Organizations (ESO) under Regulation 1025/2012. It supports the policies of the EU and the European Free Trade Association (EFTA), in particular producing standards to support European regulation and legislation as defined in Regulations, Directives and Decisions developed by the EU, most importantly in the form of Harmonised Standards (European Standards (ENs) with a special status). By adhering to these standards, manufacturers and service providers can claim 'presumption of conformity' with the essential requirements of a directive (by self-declaration), thereby saving them from having to go through costly type approval processes in different member states.

Over the past five years there has been some disagreement between the ESOs and the EC over the content of harmonised standards and efforts have been made on both sides to improve understanding. As a result of the Elliott case [i.11], the EC sees harmonised standards as being legal documents in and of themselves, and this interpretation has led to particular difficulties, in that demands are being made for there to be legal certainty in both the language and the methodologies used. This, coupled with other recent developments, has led to difficulties in writing and having standards cited.

It is necessary, therefore to examine the nature of the concerns from all parties and understand the underlying issues before setting out a way in which the current system maybe improved.

1 Scope

The present document examines the background to the citation of harmonised standards and identifies issues that do now, and might in the future, impact on ETSI's ability to deliver standards to a specification that is deemed acceptable to the EC. Issues are explored and recommendations made to alter ETSI working practices to address these issues.

Clause 4 provides background to the establishment of the RED in the context of the NLF. It sets out recent developments that have affected the citation of standards put forward by the ESOs and describes the detailed process by which related secondary legislation come into being and how the EC requests the ESOs write candidate standards.

Clause 5 examines the issues that have been faced by both the EC and the ESOs in recent years, and makes recommendations as to how ETSI can alter its procedures to best address these issues and suggests changes that might be made to the relationship between the EC and the ESOs to further streamline this process.

2 References

2.1 Normative references

Normative references are not applicable in the present document.

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] CEPT T/R 20-06 (15 September 1988): "Transmitters and receivers for low power cordless microphone".

[i.2] European Commission: The Electromagnetic Compatibility (Amendment) Regulations 1994.

[i.3] Radio and Telecommunications Terminal Equipment (RTTE) Directive 1999/5/EC.

[i.4] 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 and repealing Directive 1999/5/EC Text with EEA relevance.

[i.5] Regulation (EC) 765/2008 of the European Parliament and of the Council.

[i.6] Decision 768/2008 of the European Parliament and of the Council.

[i.7] Regulation (EU) 2019/1020 of the European Parliament and of the Council.

[i.8] Commission notice - The 'Blue Guide' on the implementation of EU product rules 2022.

[i.9] 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 Text with EEA relevance.

[i.10] M/536 Commission implementing decision C(2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.

[i.11] Judgment of the Court (Third Chamber) of 27 October 2016, James Elliott Construction Limited v Irish Asphalt Limited.

NOTE: Available at https://curia.europa.eu/juris/liste.jsf?language=en&num=C-613/14.

[i.12] Judgment of the General Court (Fifth Chamber) of 8 November 2018, Dyson Ltd v European Commission.

[i.13] Cyber Resilience Act - new cybersecurity rules for digital products and ancillary services.

NOTE: Available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13410-Cyber-resilience-act-new-cybersecurity-rules-for-digital-products-and-ancillary-services_en.

[i.14] A European approach to artificial intelligence.

NOTE: Available at https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence.

[i.15] Industrial products - evaluation of the new legislative framework.

NOTE: Available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12654-Industrial-products-evaluation-of-the-new-legislative-framework/public-consultation_en.

[i.16] Standardisation requests - mandates.

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NOTE: Available from https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF.

[i.38] TC210: "Committee responsible for Electromagnetic Compatibility" (produced by CENELEC).

[i.39] IEC TC77: "Committee responsible for Electromagnetic compatibility".

3 Definition of terms, symbols and abbreviations

3.1 Terms

Void.

3.2 Symbols

Void.

3.3 Abbreviations

For the purposes of the present document, the following abbreviations apply:

3GPP	3G (mobile) Partnership Project
5G	5nd Generation (mobile networks)
AI	Artificial Intelligence
B2B	Business to Business
B2C	Business to Customer
CE	Conformité Européene
CEN	The European Committee for Standardisation
CENELEC	The European Committee for Electrotechnical Standardisation
CEPT	European Conference of Postal and Telecommunications Administrations
CIA	Confidentiality, Integrity, Availability
CISPR	Comité International Spécial des Perturbations Radioélectriques
CNCT	Connect (the name of the DG)
COST	Cooperation in Science and Technology (a name)
COVID-19	Coronavirus
CRA	Cyber Resilience Act
CSA	Cyber Security Act
DA	Delegated Act
DDoS	Distributed Denial of Service
DECT	Digit Enhanced Cordless Telecommunications
DG	Directorate-General
DoC	Declaration of Conformity
EC	European Commission
ECC	Electronic Communications Committee
EEA	European Economic Area
EESC	European Economic and Social Committee
EG	Expert Group
eIDAS	electronic IDentification, Authentication and trust Services
EMC	Electromagnetic Compatibility
EMCD	ElectroMagnetic Compatibility Directive
EN	European Norm

ENAP	EN Approval Procedure
ENISA	European Network and Information Security Agency
EP	European Parliament
ERA	European Research Area
ESO	European Standards Organization
ESS	European standardisation system
EU	European Union
FAQ	Frequently Asked Questions
GNSS	Global Navigation Satellite System
GROW	Growth (the name of the DG))
GSM	Global System for Mobile communication
HASC	Harmonised Standards Consultant
HASTAC	Harmonised Standards Technical Advisory Consultants
HS	Harmonised Standard
ICT	Information & Communication Technology
IEC	International Electrotechnical Commission
IoT	Internet of Things
ISG	Industry Specification Group
ISO	International Organization for Standardization
IT	Information Technology
JTC	Joint Technical Committee
LI	Lawful Interception
ME	Middle Easy
MHz	Mega Hertz
MS	Member Sates
MSA	Market Surveillance Authority
MSG	Mobile Standards Group
MU	Measurement Uncertainty
NB	Notified Body
NDICI- GE	Neighbourhood, Development and International Cooperation Instrument - Global Europe
NLF	New Legislative Framework
NSO/NSB	National Standardisation Organization/National Standardisation Body
OCG	Operational Coordination Group
Q2	Quarter 2
Q3	Quarter 3
R&TTE	Radio Equipment & Telecommunications Terminal Equipment
RED	Radio Equipment Directive
RES	Radio Equipment & Systems
RSA	Rivest-Shamir-Adleman
SA	South Africa
SAI	Securing Artificial Intelligence
SDO	Standards Development Organization
SME	Small- or Medium-sized Enterprise
SR	Standardisation Request
SRD	Short Range Devices
TETRA	Terrestrial Trunked Radio
TFEU	Treaty on the Functioning of the European Union
TV	Television
UK	United Kingdom
UWB	Ultra Wideband
WG	Working Group

4 Background

4.1 History of ETSI in European regulation

4.1.0 General Introduction

Around 80 % of spectrum use was by national Governments in the 1950s: Military Telecommunications, Emergency Services and Broadcast. International use was limited in the main to aeronautical, Marine and Radio Amateur. Regulation was primarily via ITU Radio Regulations [i.34] for allocations and some parameters such as Emissions in the Spurious Domain via Resolutions and Reports. Which is still true today.

The introduction of transistors in the mid-50s was a major game changer. Prior to this, equipment was valve driven, bulky and power hungry. One of the first products was a broadcast radio receiver: dry battery powered and just 10 x 7 x 4 cm in size, it started a revolution in commercial and domestic devices which accelerated as transistors turned into chips and power consumption fell.

The proliferation of devices generated national standards and "Type Approval" testing initially by Government labs only then expanded to commercial labs, some of which supported multiple country accreditation. In order to place a device on all 40+ CEPT Countries' markets, therefore, 40+ tests where needed.

A second complication was the nature of spectrum allocation and licensing. Spectrum allocations were not necessarily harmonised throughout CEPT and most devices were stand alone and therefore channel allocations could be a linear progression, but devices such as radio microphones, which where used simultaneously in close proximity, could not use linear progressive allocations due to intermodulation products. These problems have now mainly been solved, greatly helped by the single market.

By the mid-1980s this situation received another "Game Changer": mobile phones. Evolving first as national systems (in some cases groups of three or four countries), by the mid-1980s it was recognized that a "common" European phone system was needed.

CEPT recognized that its ability to produce such a complex set of standards in a timely manner (coupled with the ever growing commercial/domestic device market) was not realistic and the concept of ETSI was born with a view of involving industry.

NOTE: CEPT consisted primarily of Administrations at this time that had neither the knowledge nor the experience in writing standards, and took some years to produce a radio microphone standard (CEPT T/R 20-06 [i.1] consisting of a single page.

ETSI was set up in 1988 by the European Conference of Postal and Telecommunications Administrations (CEPT) in response to proposals from the European Commission. There have been many significant events and achievements since ETSI was created - and many of them have had a global impact:

- Establishment of the most successful 2nd generation technology, GSM.
- ETSI EN 300 220 [i.33] and other SRD standards set the scene for producing SRDs throughout the world.
- Satellite standards.
- ETSI standards used as the foundation of local type approval around the world (ME, SA, Australia).
- DECT (Digital Enhanced Cordless Telecommunications).
- TETRA (Trans-European Trunk Radio).

ETSI standards were accepted by all CEPT administrations, however, mutual acceptance of test results by accredited labs outside of a few countries was not achieved. In order ease the situation, the European Commission developed the EMC directive in 1994 [i.2], which generated a new definition of "EMC parameters for radio equipment", identifying a common set of parameters to be used by all countries.

Prior to the EMC directive, Type Approval by Administrations for radio devices required measurement of all applicable parameters, the EMC directive generated a new definition of "EMC" parameters for radio equipment. Inclusion or exclusion of parameters for EMC standards was a long and interesting discussion/argument and from a measurement perspective is a totally artificial construct.

A second major change was allowing the manufacturer to select his own lab throughout the EC and beyond and then self-declare by means of a Declaration of Conformity rather than go to each EU Administration, this was soon followed by most CEPT Administrations. The NLF formalized the manufacturers' position when showing compliance to directives.

Radio aspects, however, remained unaddressed in a common framework, and so the Radio & Telecommunication Terminal Directive (R&TTE) [i.3], enacted in 1999, brought in all aspects of "type approval", now referred to as "compliance to the Directives", under manufacturers' control providing they use a harmonised standard or a notified body.

All receiver parameters (other than spurious emissions) were excluded from the R&TTE, the thinking being that the "user would decide" on the quality of receiver they wanted. Unfortunately this did not work because consumers were unable to discern the role of embedded radios, and the Radio Equipment Directive (RED) [i.4] was created in 2014 to correct this and other minor issues.

4.1.1 ETSI Structure

In 1988, ETSI had two main areas of work: mobile radio standards; and radio devices. The work of the two groups was not coordinated, however, and so a horizontal group - initially known as Radio Equipment & Systems (RES) - was formed, which met three or four times a year to discuss and agree standards and work items.

Mobile expanded to spawn the 3rd Generation Partnership Project (3GPP), which was initially formed in December 1998 when the European Telecommunications Standards Institute (ETSI) partnered with other telecom Standard Development Organizations (SDOs) from around the world to develop new technologies (or more specifically, technology specifications) for world wide networks and equipment.

Following the introduction of the R&TTE directive a number of devices such as TV and Radio transmitters - previously governed by National specifications - were included in the R&TTE, and RES was reformed to become TC ERM (EMC & Radio matters). ERM has the role of co-ordination of ETSI positions for the use of radio spectrum among radio groups and this has worked well, because much legislation from the EC was specific to radio devices and their physical parameters.

ETSI is an accessible place to develop standards for many industries, as there is no need to seek permission from an NSD/NSO to participate (as is the case in CEN/CENELEC and ISO). This has enabled it to develop ground breaking work in new areas, such as CYBER and LI (Lawful Interception), thereby establishing itself in many niche domains that would have been much more difficult in the other ESOs.

4.2 The RED in the context of the NLF

The NLF was adopted in 2008 to improve the internal market for goods and strengthen the conditions for placing a wide range of products on the EU market Aimed at improving market surveillance and the quality of conformity assessments it also clarifies the use of CE marking as well as creating a toolbox of measures for use in product legislation.

The NLF is implemented through regulations setting out the requirements for product accreditation and the market surveillance [i.5], a common framework for the marketing of products [i.6] and compliance of products [i.7].

The NLF is intended to bring product harmonisation legislation across a variety of sectors, including Medical Devices, Personal Protective Equipment and construction products, in line with the legislation.

In order to help Member States and others who need to be informed, to better understand the NLF, the EC has published the Blue Guide [i.8]. First published in 2000 and updated as recently as 2022 (the EC proposed changes to the Blue Guide in 2021, but these were rolled back after concern from industry; and further updated the guide in mid 2022), it has since become one of the main reference documents explaining how to implement the legislation based on the New Legislative Framework. The guide sets out, inter alia, when legislation applies to products, the actors involved in placing products on the market, product requirements, conformity assessment, accreditation and market surveillance. It is intended purely as a guidance document - only the text of the Union harmonisation act itself has legal force - and in certain cases, there may be differences between the provisions of a Union harmonisation act and the contents of this Guide.

The Radio Equipment Directive and Low Voltage Directive [i.9] are both governed by the NLF, the former having replaced the R&TTE and coming into force in 2016. Most of the harmonised standards associated with the legislations needed to be updated to comply with both the new requirements of the RED as well as the additional scrutiny that the EC applied to the standards in the light of the recent legal cases (see below). One of the complications was the extension of the legislation to include the performance of radio receivers, because it was not clear against which criteria designs would be judged, and given that some aspects of radio receiver performance was already covered by the EMC directive, specifically (radio receiver) spurious emissions & immunity.

The migration process was protracted, caused by the issues above, and as a consequence there was a period in 2017 when many products had no corresponding harmonised standard. The deadline for making these standards available was relaxed by one year.

In common with other Directives under the NLF, the RED demands various Essential Requirements to be satisfied in order for the product to be placed on the market. The Essential Requirements are contained in section 3 of the RED, but each need to be activated by separate Delegated Acts - legislation written by the EC setting out the detail of each Essential Requirement, and these are brought into being as the result of public consultation and the execution of an Impact Assessment, to determine the likely effect of such bringing into force on the industry.

Manufacturers placing equipment on the European market can demonstrate compliance either through a process of self-certification, whereby compliance to harmonised standards can determine compliance with the legislation; or the equipment can be presented to a Notified Body (NB) appointed by the EC to make their own judgment as to whether the product satisfied the Essential Requirements. The RED places an obligation on manufacturers to carry out a conformance assessment on their products to determine exactly which harmonised standards, if any, can be applied in order to demonstrate conformance with the Essential Requirements of the RED. Furthermore, all products require a risk assessment to be carried out demonstrating that the Essential Requirements of the product are safeguarded under all foreseen intended uses.

ESOs are responsible for writing harmonised Standards and do so at the request of the EC associated with various European Mandates. The main Mandate by which such standards are requested is M/536 [i.10], the main Implementing Decision associated with the RED.

Until recently, only articles 2.1 - health and safety as well as Electromagnetic Compatibility (EMC) - and 2.2 - 'effective and efficient use of spectrum' - of the RED had been activated, and a large number of standards written (most of which had been adapted to standards applicable under the old R&TTE Directive), using which manufacturers could prove compliance with those Essential Requirements. As and when further Essential Requirements items are activated, either associated with RED, or other, future, Directives, the process summarized in section 4.2 is pursued.

In 2016, in reviewing standards previously associated with the R&TTE Directive that were adapted by the ESOs to conform to the requirements of the new RED, the EC set out concerns with the transcribed standards, which drastically delayed the publication of the standards and their citation in the OJEU (thereby designating them as harmonised standards). Many of the concerns related to the EC's interpretation of the legal status of the standards, and were in turn derived from the EC's interpretation of the implication of the 'Elliott' [1.11] and 'Dyson™' cases [i.12], in which the EC was found liable for the consequences of the apparent short comings of a harmonised standard used in the construction industry. In the period, 2015-2019, the Commission issued 35 SRs, with an additional nine in 2020. Out of these 44 SRs, six were rejected (13,6 %), of which ETSI was responsible for only one.

Through 2018, the ESOs and the EC struggled to agree the details on many standards, and although the EC retains the right for desk officers to be the final arbiters of the suitability of each standard, Ernst and Young was awarded a contract to manage the appointment of a cadre of technical staff, known as Harmonised Standards Consultants (HASCs) to carry out interim reviews of standards during their drafting.

In 2020, the EC initiated the process for introducing Essential Requirements from section 3.3 (Subclauses d (safeguarding of networks), e (protection of personal data) and f (fraud)) of the RED ('Cyber') and these represented a new class of requirements: functional requirements, and preparing to draft standards that satisfy the stringent legal constraints demanded by the EC for such requirements proved extremely challenging. In parallel with this, the EC investigated the activation of further articles of the RED 3.3 i and 4, corresponding to software updates and radio/software combination testing requirements, respectively, but this has been put on hold pending the development of the Cyber Resilience Act [i.13], a cross cutting piece of legislation that will affect both wired and radio-connected devices.

In 2021, the EC commenced the implementation of the AI Directive [i.14] which focuses on two areas: excellence in AI and trustworthy AI. The European approach aims to ensure that any AI improvements are based on rules that safeguard the functioning of markets and the public sector, and people's safety and fundamental rights.

The EC chose to award the Standardisation Request for the RED 'Cyber' standards to CEN/CENELEC alone for perceived security concerns, but had it been awarded jointly to all three ESOs, issues would have been encountered in defining the boundary between the organizations. It remains to be seen how a similar division of work will be requested by the EC for the standards associated with the AI Directive,

In 2021, the EC launched an initiative seeking to evaluate whether the NLF remains fit for purpose in a digital and circular economy and a consultation [i.15] was closed in March 2022; 'Commission Adoption' is planned for Q2 2022, although it is not clear at this point exactly what would be adopted.

4.3 The activation process

4.3.1 Procedures establishing secondary legislation

Much of the EU's regulatory work involves secondary legislation. Primary legal acts establish which of the procedures for secondary legislation is to be used. Firm guidelines and rules govern that choice.

Many of the legal acts that are adopted in the European Union are of a general nature. The practical details of these legal acts are dealt with through secondary legislation. Secondary legislation cannot exceed the framework established in the general act. However, specific measures can still yield significant effect. The procedure for adopting secondary legislation depends on which procedure is used. One of these procedures is for delegated acts, detailed in Annex B.

4.3.2 Standardisation requests - mandates

According to the EC website [i.16]:

"Standardisation results from voluntary cooperation between industry, businesses, public authorities, and other stakeholders. About a fifth of all European standards are developed following a standardisation request (mandate) from the European Commission to the European Standardisation Organisations (ESOs). This is a request to draw up and adopt European standards or European standardisation deliverables in support of European policies and legislation. European standards and European standardisation deliverables, even though developed under a Commission request and for European legislation, usually remain voluntary. However, when European standards are adopted, National Standardisation Bodies (NSBs) should transpose them into identical national standards and withdraw any conflicting national standards.

How does it work?

Draft requests are drawn up by the Commission through a process of consultation with a wide group of interested parties including social partners, consumers, small and medium-sized enterprises (SMEs), industry associations and EU countries. Before being formally sent to the ESOs, they are submitted to the Committee on Standards of the Regulation (EU) 1025/2012 for a vote. If this vote is positive, the Commission adopts the request as a Commission Implementing Decision.

The objective of standardisation requests is to develop and adopt European standards or European standardisation deliverables within a given time. This is the only type of request under Regulation (EU) 1025/2012; The ESOs, which are independent organisations, have the right to refuse a mandate if they do not think that standards can be produced in a particular area. Due to the preceding consultation process, standardisation requests are rarely refused."

4.4 Recent developments

4.4.1 The HASC process

In 2018 the European Commission introduced the concept of Harmonised Standards Consultants (HASC) to independently review the standards produced by the ESOs in response to Standardisation Requests. The reviews are intended mainly to ensure that harmonised standards are legally sound and accurately reflect the intentions of the Standardisation requests. A standard checklist of criteria is used by the consultants.

Funding was in place through 2021 to offer up to three reviews of each standard, although from the perspective of the European Commission the acceptance of the review is voluntary on behalf of the ESOs, whilst the final review by European Commission staff will be the ultimate arbiter of whether the standard can be cited in the European Journal and hence enter into legal force. Nevertheless, ETSI has adapted its procedures to require any standard being put forward as a harmonised standard to undergo at least one such review.

According to the EC, 'As of 9 December 2021, the Commissions' contractor managing the HAS consultants, had received 3 312 requests for assessments of draft HENs from the ESOs, under 21 pieces of EU legislation, of which 2 944 have been processed and 368 were non-eligible. Across all sectors, only 27,58 % of the HAS assessments came out as positive, mainly due to inadequacy with EU law, showing that more work is to be invested in the development process of standards - e.g. within the technical committees - so that the work is more aligned with the policy and legal requirements'

Three separate checklists of standards exist, one drafted by the EC for use by the HASCs; a checklist compiled by the ETSI Secretariat to aid rapporteurs; and a similar document has been drawn up by CEN/CENELEC. Furthermore, TC ERM is working on developing a set of FAQs derived from resolution to issues common to two or more TCs.

4.4.2 ESO/EC Task Force

In November 2021 the EC, along with the three ESOs, launched a task force entitled, 'Timely European standards for a Green and Digital, Single and Global Market', intended to streamline and improve the delivery of harmonised standards. The work is divided into two workstreams: Strategic Alignment and Operational Improvement, leading to a proposed Action Plan to be delivered later in 2022 where there is likely to be a range of outcomes.

At an interim workshop [i.17] in March 2022, agreement was reached on the preliminary stages & SR drafting, but topics that were still under discussion were:

- ESOs' ownership of SR execution and the extent of the EC's support.

And the next items to discuss will be:

- other aspects of standards development process and HAS assessment;
- possible ESOs fast track procedures to address shortcomings that would block or delay the citation, identified at a later stage;
- the citation process;
- maintenance of all processes;
- periodic review of cited standards;
- amending SRs;
- better alignment and improvement of IT tools.

4.4.3 Activation of RED articles of 3.3/4

Several members states had expressed concerns at the vulnerability of some 'Consumer IoT' devices available on the European market, first to address of their threat to privacy and personal data as well as fraud, before being enlarged to threat that poorly protected devices might pose to the wider Internet, not least through their recruitment into DDoS botnets.

In 2018, the European Commission announced plans to activate Articles 3.3 d) (harm to network), e) (personal data and privacy of the user), f) (fraud) and i) (upgradable software) as well as 4 (compliance of combinations of radio equipment and software). Pursuant to this, two Impact Assessment studies were carried out, reporting in April 2020 [i.18] for Art. 3. e) and f) and July 2021 for reconfigurable radio systems [i.19], respectively. Unfortunately, impact Assessment regarding 3.3 d), which is technically the most impacting in terms of scope and implications, was never performed as the initial intention of MSs was to focus on Art. 3.3 e) and f) only, before it was finally decided to include the Network protection issues as well. The second report reflected the widespread concern in industry over potential regulatory overreach and further plans for the activation of Articles 3.3 i) and 4 are on hold.

Industry highlighted at the time the inappropriateness of using the RED for cyber requirements, firstly because they should apply equally to wired products (e.g. webcams), and secondly because the level of legal certainty being applied (by the EC) to both the writing of the harmonised standards and their application was inappropriate for these types of requirements (see section 5.3). It became clear, however, that the RED was chosen because it was a convenient statute to which these requirements could be appended quickly, this despite the fact that the Cyber Security Directive would soon be in place which could have adopted these requirements.

The Delegated Act activating Articles 3.3 d), e) and f) was published in December 2021 with a 30-month transition period. As of early July, 2022, the Associated Standardisation Request of which a draft was refined with CEN/CENELEC and ETSI was issued to CEN/CENELEC alone, after concerns were raised over the make up of ETSI in what was considered by the EC to be, '*critical policy aspects*'. It is not clear what the definition of this term might be and whether similar (such as the AI-Act) SRs will be directed away from ETSI in future.

The final SR draft was submitted in mid-June by the Commission to the Committee on Standards of the Regulation (EU) 1025/2012 [i.37] (see clause 4.2.7), a process which requires 4 to 8 weeks for approval after submission. Since the transition period set forth in the delegated act is not affected, this delay directly impacts the period allocated to the ESOs to develop the required HENs, which was already very tight. Seeing the delays in the publication of the Standardisation Request, it is interesting to remember that speed of implementation was the key argument advanced more than 2 years ago by the Commission to address observed IoT security deficiencies by means of a DA on RED Articles d), e) and f), which limits the scope only to those products that qualify as Radio Equipment. Furthermore, discussions have already started around an upcoming much wider security related legislation, the Cyber Resilience Act, which intends to supersede the essential requirements addressed in the above DA while generalizing them to the much wider range of ICT products, tangible or intangible (i.e. software), that do not qualify as Radio Equipment. It can be hoped, however, that the lessons learned while elaborating the RED 3(3) d/e/f DA and SR will be leveraged for the elaboration of the CRA.

4.4.4 EC Report on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020

The latest version of the EC 5-yearly report [i.20] on its assessment of the effectiveness of the standardisation process was issued in February 2022. The report was scathing about the ESOs' performance, noting that there is *'...room for improvement in different areas ... in particular to aspects of inclusiveness and the role of NSBs in the ESS'*.

On Research bodies they conclude that: *'...the reports of the ESOs highlight that there were different activities involving research organisations. However, the reports are not fully clear on the effectiveness of the activities, e.g. on its effects on the adoption of specific standards or increased participation'*.

Cooperation between NSBs (National Standardisation Bodies) and ESOs was noted to be deficient: 'In late 2021, some NSBs voiced concerns about their role within ETSI. There are ongoing discussions between ETSI and some European NSBs about their recognition as strategic partners to standardisation'.

Regarding transparency between standardization bodies: 'As regards NSBs, in 2019, approximately 70 % had online tools facilitating access to draft national standards to relevant stakeholders. Nevertheless, based on the reporting from civil society organizations and Small And Medium Enterprises (SMEs), access to NSB activities remains a challenge.'

Finally, with respect to access of SMEs to standards: 'NSBs in CEN and CENELEC *"have been granting more and more special rates to SMEs for participating in standardisation activities between 2015 and 2019, while ETSI NSBs faced a decreasing trend in such special rates provided"*. On this matter, the 2019 ETSI report also reads: *"ETSI does not operate under the national delegation principle so their [SMEs] participation in ETSI's technical organization and work is direct through their membership of ETSI […]. Only during the public approval process do these stakeholders need to submit their comments via the ETSI NSBs"*.

4.4.5 The Standardisation strategy

The new standardisation strategy [i.21] was adopted on 2 Feb 2022. In it the EC noted that *'the strategic importance of standards has not been adequately recognized at the cost of EU leadership in standards-setting. This must change.'*, although it is not clear on what evidence this observation is made.

"[The] strategy proposes a set of actions to put standards back at the core of a resilient, green and digital EU single market and to strengthen the global role of the European standardisation system. By:

- *Leveraging the European standardisation system - to deliver on the twin green and digital transition and support the resilience of the single market.*
- *Upholding the integrity, inclusiveness and accessibility of the European standardisation system - putting good governance principles in place.*
- *Global standards-setting: supporting the EU's leading position as a forerunner in key technologies and promoting EU core values.*
- *Cutting-edge innovation that fosters timely standards.*
- *Ensuring future standardisation expertise - the need for education and skills.*
- *The way ahead - future of the European standardisation system."*

Under each of these bullet headings there is a set of actions on the EC, the details of which are shown in annex A.

Highlights from the Strategy includes an update to Regulation (EU) No 1025/2012 as regards the decisions of European standardisation organizations concerning European standards and European standardisation deliverables, but this includes no impact assessment.

Under bullet 2 a separate consultation [i.22] was held in February 2022 and various other changes are required of ESOs.

On a related note, in July 2022, 'the Internal Market Committee adopted its position for the updated Regulation governing the European standardisation system, which aims to enhance its governance structure and reinforce the role of national representatives of EU Member States. The changes proposed to existing rules aim to improve all ESO's governance structure to require decisions concerning European standards following mandates from the Commission to be taken by national delegates (the national standardisations bodies) from the EU and EEA member states. This way the decision-making process would be protected from undue influence of foreign actors during the development of standards for key areas, like cybersecurity or hydrogen standards. The internal governance of European standardisation organizations would also have to take into account the views of all European stakeholders (including SMEs and civil society organizations)' [i.23].

The EC has emphasized that 'European standardisation [needs to] to become more agile, flexible and focused to anticipate the standardisation needs' 'more functional and agile', with no justifying metrics apparent.

The strategy document also sets out the responsibilities of standardisation bodies, the list of which was updated in May 2022 [i.24].

4.4.6 Cyber Resilience Act

The EC launched a Call for evidence for Impact Assessment on the CRA in 2022 [i.25], and has suggested that it will publish a draft in Q3 2022 with the aim of establishing common standards for cybersecurity products. Therefore, while the act is still in draft and far from certain in terms of exact wording, it will cut across cyber security of all product and services sold in Europe along with threat sharing, etc. This will impact nearly all manufacturers and operators. The exact impact is unknown, but ETSI will be watching the developments closely, assuming that it will be excluded from the writing of the HENs themselves.

5 Issues analysis

5.1 Introduction

This clause identifies the issues that have been faced by ETSI in writing standards for citation in the official journal, examines their root cause and suggests remedies for resolution.

5.2 Delays in citations

5.2.0 Discussion

The availability of harmonised standards is critical to the smooth and efficient design and development of products to be placed on the European market. The absence of harmonised standards leads to delays in products coming to market and additional - sometimes significant- costs. Even the Notified Body route cannot proceed without some form of a base standard against which judgements can be made. Delays to the citations of such standards, therefore, are highly unsatisfactory and both the ESOs and the EC have to recognize that they have a role to play.

In the EC's review of the performance of the ESOs for RED standards over the period 2016-2020 [i.20] the EC commented that, for the period 2018-2020 '*the median time between the adoption of a HEN by CEN, CENELEC or ETSI, and the formal delivery to the Commission for citation in the OJEU is 100 days. This means that the ESOs may take over three months to submit, to the Commission, a standard after it was made publicly available, before the Commission can start assessing and processing the HEN for citation in the OJEU*'.

Closer examination of these statistics shows that the figure for ETSI over the period is 28 days (the worst year being 2019 at 49), which seems perfectly reasonable, but nevertheless, ETSI should continue to strive to develop standards as quickly as possible, noting that delays incurred by the wider ENAP process, such as the time for the EC's desk officers to review RED standards (which, for the period, 2021, on average these were cited 304 days after publication; and in 2020, averaged 324 days [i.26]), are out of its control.

NOTE: The present document makes no attempt to comment on the performance of fellow ESOs, CEN & CENELEC, but our understanding is that, as well as a greater need to allow CEN/CENELEC members to review submissions, CEN & CENELEC often chose not to submit standards immediately and so this is an unfair metric to cite.

It should be noted that for new legislation and delegated acts there are many more steps that lead from a political decision to legislate to the citation of ESOs' standards. Recently, for example, by far the most significant delay to the availability of harmonised standards for the 'Cyber' requirements of the RED has been the agreement of the Delegated Act and the publication of the associated SR. The table below highlights the timelines that would apply were ETSI to be writing the standard (and noting that CEN/CENELEC's internal timescales are somewhat extended associated with the time to consult NSOs/NSBs).

Table 1

Milestone	Date	Time from previous milestone
Launch of impact Assessment	September 2018	-
Closure of Impact Assessment	December 2020	16 months
Publication of Delegated Act	December 2021	12 months
Publication of SR	July 2022?	7 months
Standards drafting begins	September 2022	1 month
ENAP process begins	December 2022	2 months (see note 2)
Harmonised standard available	October 2023	10 months
Act goes live	August 2024	10 months (see note 1)
NOTE 1: To allow industry implementation. NOTE 2: An unrealistically short period of time to draft such a complex standard.		

As a consequence, the quality of the standards is likely to be degraded - if indeed they are accepted at all by the EC and the HASCs - leading to a period in 2024 when all radio products will need to be presented to NBs (with or without a base standard at that time, and despite the inevitable shortage of capacity at that time).

Several members felt that the milestones associated with the Delegated Act were driven more by political concerns than a realistic assessment of the time needed for the scope of the work to be completed. This was exacerbated by a perception that the scope of the DA was far greater than that assumed (implicitly) by the Impact Assessment.

It is worth noting that the increased role that the EC seeks for NSO/NSBs in the development of ETSI are likely to extend the standard publication process further as more time will be required for NSO/NSBs to engage with the core of the TCs' drafting process.

A further criticism made by the EC is the rejection of SRs, *"The ESOs have often reported the following reasons for rejecting: disagreement on certain requested standards; disagreement on some requirements contained in the SR; disagreement that certain requested technical specifications are needed in support of a specific essential requirement; or disagreement with deadlines set for the delivery of requested standards."* However, TCs have complained of a lack of willingness on behalf of the EC to understand the impact of certain requirements on viable timescales, particularly if the requirements are ill formed or even not yet defined at the time of publication of the Standardisation Request. TCs also complained of the need for a take-it-or-leave-it situation, where it is not possible for an ESO to partially reject an SR, if it is not deemed entirely feasible.

5.2.1 Recommendations

The following recommendations are made to resolve many of these issues:

- ETSI should seek greater involvement in the drafting of SRs, warning that failure to heed such a request will lead to more rejected requests and, ultimately, bigger delays to standards becoming available.
- The EC and ESOs should, jointly, develop an understanding of the scope of the associated SRs before setting timescales associated with delegated acts.
- The Impact assessment should clearly set out the assumed scope of the Delegated Act so that the true cost of the demanded legislation can be calculated.
- ESOs should be allowed to partially accept SRs if disagreements are encountered or, if deemed inappropriate, for a particular ESO to respond to a part of an SR.
- ESOs should be allowed staged implementation dates, whereby tranches of standardisation activity can be delivered by an initial deadline and the entire work packages completed by a later date(s).

5.3 Functional requirements

5.3.0 Discussion

With the introduction of 3.3 of the RED delegated act and AI Directive, physical requirements have been replaced by "subjective" nonphysical/functional requirements which, whilst affecting the majority of ERM radio groups, are outside its current expertise. Expertise was resident in TC Cyber which had been mainly focused on network issues and legislation, plus ISG SAI which has been set up to handle AI security issues. An added complication was the fact that because CEN/CENELEC was best placed to carry out activities integrating radio devices into many white goods and previously non-radio devices such as farm machinery, that meant that because the same radio device might be used in multiple products, standards would need to be applicable without double testing.

Prior to the RED delegated act tests contained in Harmonised Standards where primarily based on physical attributes and the laws of physics which where well understood with tests being appropriate to the type of device. Most radios are able to be considered as 'black boxes', where the testers do not need to trouble themselves with the way in which certain behaviours are achieved. With the scope of radio standards being expanded to include functional requirements (in particular software), however, defining requirements and drafting corresponding tests becomes ever more challenging, when the way in which the requirements are achieved is implemented differently from product to product. Documenting a procedure, therefore, that satisfies the EC's interpretation of legal certainty will become ever more challenging.

Subjective testing will vary with each family of devices and individual discussion is needed as "one size will not fit all" and the only person who is in a position to fully understand the content of software is the original writer - manufacturer, therefore a certification of packages should be considered to avoid expensive time consuming tests and a manufacturers risk assessment used for the remaining software.

The RED 3.3 delegated act and other legislation such as the AI Act cannot have tests based on the physical attributes and the laws of physics, but will have to rely on subjective observation. In fact, once self-learning AI systems become available the situation will become even more complex.

In preparing standards, ESOs and manufacturers using those standards need to carry out a risk assessment on the products covered. Since the NLF applies at market placement, independently of particular use cases a product could have in the hands of customers, the view of the EC is that the HEN should not leave it up to the manufacturers to decide by themselves which risks need to be mitigated based on their own risk analysis, as this would open the door to legal uncertainty.

Instead, a generic risk analysis based on relevant features or characteristics of the products covered should be conducted by the ESOs, and the manufacturer would need to compare their products against the criteria set forth in the HEN, to determine which clause(s) apply. So, as long as legal certainty requires that harmonised standards need to be applicable in the same manner across products, and yield reproducible results for products meeting the same criteria, writing harmonised standards that have fair chances of being cited implies that all subjective factors are elaborated into lists of profile characteristics. (e.g. use case details, assumptions about adversary capabilities, interfaces of assets, bit entropy, etc.). Assessing all relevant combinations represents a substantial amount of the work that has to be conducted by the ESOs to elaborate HENs.

Whatever subjective factors are not elaborated into these lists of options, would have to fall under the "default" clause in the respective harmonised standards. The greater the variety of products that the harmonised standards covers, the more difficult it will be to write "default" clauses that accommodate these subjective factors in a way that is practically applicable for any product.

This means that the wider the scope of a legislation involving subjective testing, the more complex and time consuming it will be to develop HEN addressing it.

It can be expected that subjective testing will have an ever increasing impact in standardization, because as ICT pervades society more and more, people may be ever more looking into technology for solutions to problems that are societal in nature. The AI Act that seeks to address "*risk of adverse impact on fundamental rights*" is a prominent example of this trend.

Proving 'negative' behaviours is a related phenomenon. Proving that a device will ***never*** exploit some form of behaviour is both physically and philosophically fraught and, unless the approach to standards writing and certification of working allows activities such as code walk throughs or similar analysis, these requirements will prove impossible to police.

Security requirements

Security legislation can involve proof of negatives - that a system or device cannot be compromised - which is, in any case, impossible: such analysis can only demonstrate that the risks of threats have been addressed appropriately. To this end - in the context of the RED Cyber requirements - there would appear to be a contradiction between the level of legal certainty demanded by the EC and that deliverable with such technologies.

The testing of security features is further complicated for a number of reasons. The common question of "is it secure?" is not a reasonable one, in many respects it is so unreasonable that it ought never to be answered. The security domain has developed a simple paradigm: Confidentiality, Integrity, Availability (CIA).

The CIA paradigm works on at a level where specific mechanisms are used to address specific problems. In simple terms, an algorithm or a process will give absolute guarantees and a set of tests can prove it works - this will demonstrate an implementation conforms to the requirements for implementation. So for example if the requirement is to implement a hash function then assuming the standards are followed and the hash function is "good" then it will be resistant to attack (it prevents adversarial manipulation of data). However, if the system mandates (say) public key crypto using RSA, which relies for its security on the infeasibility of factoring large numbers, the security requires that no tools or techniques exist that makes the factoring trivial (a quantum computer will do this).

If the infeasibility constraint is broken, there is no security anymore - irrespective of all the conformance tests being passed. This is the distinguishing characteristic of security analysis: it has guarantees only if the rules that exist at the time of creation stay in place. This is different from classic radio requirements where what is sent out on the antenna today will the same in the future as the laws of physics do not change.

In practical terms, if a standard is developed to give protection against all of the attacks that are were known during its writing leading to a claim of conformance, but then a new attack is developed that destroys the protections the standard offers, who would be liable for shortfall in the time that it would take to update it to reinstate the protection? It would be unreasonable for manufacturers to be held liable for losses incurred for such a change of environment when using a proscribed standard, especially if the new attack was an unknown at the writing of the standard.

Furthermore, initial experiences in these areas do not bode well: preliminary work in TC Cyber to address a risk assessment methodology was not universally embraced. Therefore, without agreement between the EC and the ESOs on how to proceed here, there is a risk that much time will be lost and standards writers will have no direction in specifying testing of functional requirements.

Functional requirements are, by their nature - they often being associated with/applicable across many commercial applications - likely to have impacts across several current TCs, as has been demonstrated by the preliminary work that was carried out by TC Cyber in the context of the RED Cyber requirements, and as is being demonstrated in the analysis of the anticipated AI legislation.

An additional complication is that a devices software rarely relies in a single software writer but relies on "packages" such as Bluetooth® or specific software to control parts of a device, say power charging. A manufacturer combining a number of packages will not have access to the base code as this will have been complied and cannot be "uncompiled". Thus, for the majority of devices using software, the manufacturer will only write software to link such packages.

An additional issue are the collection of "personal data" such as blood pressure, heart rate and other data from sports and medical devices which may go through multiple links and also stored in the cloud.

5.3.1 Recommendations

The following recommendations are made to resolve many of these issues:

- When writing new types of standards, the EC or HAS need to be involved from the start of the work. If, when developing a new framework, the work proceeds in a direction counter to the EC's visions, there is a risk that much time will be lost.
- TCs should note that industry would be reluctant for manufacturers to have to deliver source code, manuals etc., as this is undesirable and risky.
- ETSI needs to develop a way in which testing is feasible without revealing products' inner workings.
- ETSI might consider merging TC AI and/or TC Cyber into ERM to better connect the expertise within the organization.
- When subjective testing is involved, the complexity and time it takes for the ESOs to conduct the risk analysis supposed to be captured in the HEN increases exponentially with the scope of the expected legislation (e.g. addressing consumers / B2B as well as industrial / B2C products). This should be considered by regulators when setting the scope and timeframe of legislations such as the RED cybersecurity articles, the CRA, or the AI Act. NLF based.
- The EC should not use NLF based legislation such as the RED to introduce such functional requirements involving subjective testing if it is going to insist on such a high level of legal certainty.
- A clarificatory discussion should be held between the EC and standards bodies with clear documented outcomes on how to address functional requirements.
- ETSI should continue to highlight the gap between what can be achieved with NLF standards (used at the point of placing products onto the European market) and what stakeholders require in order to keep products secure through their lifetime. A lifetime commitment would be a challenging ask raising fundamental questions over the liability of products managed by consumers and would be best addressed using more targeted legislation such as the Cyber Security Act or Cyber Resilience Act.

5.4 Horizontal issues

5.4.0 Discussion

Experience from a great many TCs and reported at OCG RED has revealed that there are a large number of issues being raised by the EC desk officer and the HASCs that are common across TCs, or are receiving inconsistent assessments. Many of these have been collated into a single document to be presented to the EC, and ultimately turned into a FAQ document. It is likely that this treatment of similarly common issues will continue on an ongoing basis within OCG RED.

NOTE: During discussions leading to the compilation of the present document it was noted that issues have been encountered associated with high power broadcast filters, which are not feasible to test in a laboratory (due to high powers) and so can only be tested in situ.

5.4.1 Recommendations

The following recommendations are made:

- ETSI OCG RED should continue to collate and maintain a database of detailed technical/legal issues that have been raised by the EC and/or the HASC in order to avoid repetitive discussion of topics and inform rapporteurs.
- The EC should allow in situ testing/standards to be written in case it is impractical to carry out such testing in a test laboratory or factory setting.

5.5 Relationship with the EC

5.5.0 Discussion

In a report from the Commission to the European on its Standardization Strategy [i.28] in February 2022, the EC claimed that the high number of failed reviews of standards was, 'mainly due to inadequacy with EU law, showing that more work is to be invested in the development process of standards - e.g. within the technical committees - so that the work is more aligned with the policy and legal requirements". Experience of ETSI & CENELEC TC leads, however, challenges this narrative suggesting that, although in many cases this might have been fair criticism, there have been other factors that have led to unfavourable reviews, including inconsistent reviews by the HASCs and the EC.

Widespread concern was expressed by TC chairs over the consistency of decisions and inflexibility of the EC in assessing candidate harmonised standards, and there was frustration at the growing number of standards that are rejected or cited with restrictions.

Citation process

Perceived weaknesses of the citation process are discussed in clause 5.12.

Consistency of decisions

Many examples of inconsistency of decisions from standard to standard were cited, leading to frustration and delays in the publication of standards. Such delays cost standards writers time, and hence money, but also leave the EU market with incomplete documentation, thereby adding further costs to industry and leading to uncertainty in the quality of products being placed on the market.

For example, the EC's Guide to the EMC Directive describes three layers of standards: Generic Standard; Product Family Standards; and Product Standards that have increasing levels of specificity and thus preference. However, when a Generic EMC standard was submitted that was to be used as a default or "fall-back" standard ETSI was told that Generic standards cannot be listed as, by definition, it is not "state of the art". It is very confusing when an EC-written and published guide says a different thing to what the EC will accept in the form of standards.

Furthermore, both the EMCD and the RED operate under the same legal framework, making it is reasonable to assume that if a standard is cited under the EMCD it can be normatively referenced under the RED article 3.1(b). However, ETSI has seen standards refused citation because the EC has "changed its mind" over the validity of some of the cited standards. Confusingly these standards remain cited for a presumption of conformity under the EMCD.

A number of standards have been unsuccessfully submitted for citation several times, the reason being that on each occasion the EC has found new issues in the same text.

Some members also felt the whole HASC process is undermined by the observation that the EC Desk officer is the ultimate arbiter of the suitability of standards for citation. Standards that have been given a clean bill of health by the HASC are rejected by the EC, leaving TCs to conclude that the HASC is practically useless and most effort should be put into getting standards in front of the EC, even If this does then require a second iteration of the standard.

TCs have furthermore complained of a lack clarity on the expectations of the EC for a harmonised standard, observing that the level of detail available in publicized guidance from the EC is inconsistent with the level of detailed comments being received on individual standards. For example, an issue with the specification of environment profiles has only recently appeared, whereas the initial text for HS skeleton given by EC did not mention this requirement. This creates a sense of global insecurity for members contributing to the writing. The EC's insistence that all tests have to be carried out under all conditions of the environmental profile would be hugely onerous to carry out and TG UWB has carried out significant work to resolve this issue, suggesting that there should be a differentiation between 'relative' tests and 'specific' tests - the latter being carried out at under nominal conditions.

WG EMC has also learned that the EC still has an issue with tolerances in test methods (e.g. radiated field measurements). Difficulties arise when an object is being rotated and the accuracy of the test varies (but never falls below the minimum). Suggested EC solutions are unrealistic and insist on products demonstrating conformance, which will lead to trade barriers.

Finally, standards allowing (or expecting) manufacturers' declarations of equipment properties are a further stumbling point, with interpretation from the EC and the HASCs varying from a full prohibition of the declaration of any parameters to a more pragmatic interpretation. The EC has said, *"All the parameters declared by the manufacturer shall correspond to the intended use of the equipment."* Alone, this makes sense, but how can this be handled when writing a harmonised standard? TGs are left to consider their own interpretation and may not come to the same conclusion as one another.

Scope of impact assessments

The EC is empowered to introduce delegated acts on existing legislation, such as the RED, providing it carries out a thorough impact assessment. Recent experience demonstrates that, even after the (sometimes controversial) public debate and publication of such an impact assessment, the corresponding actions, such as the publication a delegated act or the issuance of a Standardisation request, the actual impact on industry (both cost and time to make changes) and the market more widely is often wildly underestimated. In other examples, the impact assessment was simply not carried out, for example, in introducing the Article 3(3) d of the RED (network security), the scope of the networks was not clear, leading to impractical requirements for standards; and in the update to the Standardisation Directive (EU-1025/2021 [i.37]), no impact assessment was carried out at all despite the recent changes have potentially profound impact on the ESOs.

It is apparent that several of these initiatives - and the associated timelines - have been driven by political imperatives, leading unrealistically reduced timescales to write the corresponding standards. There is a danger that this will lead to rushed and so poor standards, in turn leading to a fragmented market and increased costs.

5.5.1 Recommendations

The following recommendations are made:

- All meetings and decisions by the HASC and EC staff should be documented.
- All meetings with the EC discussing matters pertaining to the citation of standards should be minuted - at least on the ETSI side - so that all discussions are captured.
- Highlight the cost (to industry, MSAs and Europe) of onerous compliance requests and missing or out-of-date standards.
- Better education up to politicians (on mandates) so that all understand the implications of mandates, especially the way in which they might be converted to SRs.

- When drafting standards, all issues should be collected and faced directly without trying to hope that the problems will go away.
- Rapporteurs should not take the attitude that, 'if the EC has not complained drafting groups should not make any changes' - all issues should be addressed to avoid future problems, even extending to other standards.
- Affected rapporteurs should not reject issues simply because they were only reported for other standards.
- Cross-standard references might, where practical and applicable, be encoded into ETSI processes to ensure that they are pursued.
- The EC should draft a clear set of rapporteurs'/HASC guidelines, because the current guidelines are confusing and go into insufficient detail when compared to the issues being raised by the HASCs and the EC itself.
- In anticipation of formal documentation from the EC, ETSI should generate a set of 'Master Documentation', setting out its understanding of what is expected and what is required in harmonised standard. This might be founded on the horizontals issues FAQs that are being generated by TC ERM.
- ETSI should put a process in place to ensure that the Master Documentation set is updated appropriately as new information comes to light, or an earlier understanding is altered or clarified.
- The EC has suggested there should be training for rapporteurs and ETSI officers but conversely, it may prove useful for EC legal services group to have experience of everyday life in test labs e.g. with accreditation services.
- The EC should publish Impact Assessments for all mandates and update those assessments in the light of developments that significantly impact on the cost of their implementation.
- The reinstatement of generic standards, which are necessary in the European market.
- As paperwork causes the majority of issues, in particular the technical file, the master documentation should set out a clear understanding as to what is required.
- ETSI and the EC need to find a balance as to what properties of equipment can be declared.
- However, the handling of measurement uncertainty is understood globally and ETSI should continue to use the same approach.

5.6 Relationship between ERM and other TCs & ESOs

5.6.0 Discussion

The relationship between ETSI and the other ESOs (CEN and CENELEC) is excellent and the formal channels for exchanging information and collaborating works well. Nevertheless, collaborative preparatory work for the RED 3(3) articles revealed that in order to achieve the tight timescales involved, progress could only be made through a loose, informal way of working between ETSI TC Cyber and CEN/CENELEC JTC13. This cross ESO working was brought about by the necessarily broad scope associated with the RED 3(3) articles requirements. In future, more and more products will involve cross boundary working (e.g. White goods) and so more collaboration will be needed - both between and within ESOs (i.e. between TCs).

TC ERM has long demonstrated the advantages of a horizontal group within ETSI, such as the exchange of information; enabling of cooperation between groups rather than multiple outputs on a single subject; and (accepting all groups are open to all ETSI members, except 3GPP, and ETSI is input driven) the exchange of information in the enlarged ETSI Family via a horizontal group. Similar cross-TC consensus would be beneficial in the new non radio regulation on Cyber and AI which will affect almost all radio groups in ERM. Regular exposure to progress and problems in these areas will both inform and encourage participation in the works.

5.6.1 Recommendations

The following recommendations are made:

- Existing OCG groups which have been used as an interim solution to cross-cutting Standardisation Request are unable to prepare and agree standards and so TC Cyber and whichever group takes over the OCG AI work should join ERM for the purpose of ensuring members are kept up to date, or another structure might be considered.
- Given it currently it takes many months to set up joint groups with much political discussion, a permanent, informal inter-ETSI-CEN/CENELEC liaison group might be set up with a changing membership dependent on subject.
- More widely, a matrix structure might be set up between ETSI/CEN/CENELEC identifying who can immediately speak to whom, which might help with the limited interconnectivity within CENELEC, where individuals are present only on specific committees.
- Permanent Hybrid meeting facilities should be set up to encourage members to participate in this cross-ESO work.
- Governments should be encouraged to better fund standardisation activities including membership of ETSI.

5.7 Legal certainty

5.7.0 Discussion

The EC's interpretation of legal certainty, influenced by their interpretation of the Elliott case, has led to the delay of many harmonised standards since the transition from the R&TTE to the RED, where statements within new (and existing) standards have been deemed to be insufficiently certain. The EC has made it clear that it considers harmonised standards to be legal documents, the implication being that they should be sufficiently legally certain, even though they are, essentially, technical documents with different demands on the quality of their scope and content.

Legal certainty is a well-established principle in liberal democracies. It is simply that the citizen would be expected to know what is required of him, before the event.

The European Court of justice has stated in its judgment between the European Parliament and The Council of Ministers that:

"*the principle of legal certainty requires that rules of law be clear and precise and predictable in their effect, so that interested parties can ascertain their position in situations and legal relationships governed by EU law" [i.27]*.

A similar description of the principle can be found in found in other reference sources, including Wikipedia.

From the point of view of a manufacturer wishing to place a product on the market, legal certainty means that what is required of the product is clear beforehand and is not, for instance, discovered later in a conversation with a Market Surveillance Authority (MSA).

The EC has stated that HS ought to provide legal certainty. Under a type approval system, this was less important as legal certainty could be seen as coming in the form of a document from an assessor or a test house.

Under a DoC system, however, a manufacturer looking for legal certainty will inevitably turn to the HS. The idea that the HS should provide it is therefore reasonable.

Nevertheless, among ETSI members, some serious implications have been debated.

Several common views are that legal certainty:

1) Means that everything (the standard itself, the outcome of a test) ought to stand up in court.
2) Requires exhaustive testing of every aspect of a product under all conditions.
3) Means that a question has to be resolved without doubt e.g. a test ought to yield an absolute yes/no answer.

Point 1) appears to be a misinterpretation of the matter.

Point 2) may also be a misinterpretation. It is as if the phrase *interested parties can ascertain their position (with reasonable accuracy)* has evolved into *interested parties ought to ascertain their position (with absolute accuracy).*

Point 3) may be a confusion with the matter of measurement uncertainty. There is, however, a link between legal certainty, as in "what is required of a manufacturer" and the result of the tests, which when all combined together answer the question "has the manufacturer taken the appropriate measures to conform to the security requirements?" This is where measurement uncertainty applies, since answering "it depends" as a test result is not going to be satisfactory.

Measurement Uncertainty (MU) is a physical fact of radio and EMC measurements and is recognized by Administrations in their registration of laboratories. Previously, the "shared risk" approach has been taken by Administrations, where an agreed level of MU was taken into account providing that the measurement met the required limit. ETSI and other standards bodies published these agreed limits. The recent removal of this approach, however - due to comments from the EC - has generated a situation where administration measurements - due to their better facilities - may disagree with a manufacturer's measurement, leading to a formal non-compliance that may not be important in the real world. It also conflicts with international use of ESOs standards.

With MU in mind, therefore, the legal certainty - as in, "what is required of a manufacturer" - is affected when considering compliance to a regulatory requirement. The MU issue is open to interpretation depending on whether the MU of the laboratories or manufacturer are taken into account.

It should also be noted that the principle of legal certainty works both ways. ETSI members and rapporteurs may expect that it is clear what they have to do in order to have HS accepted by the EC. At present they are operating without a specification or handbook. The system of trial and error with HAS Consultants followed by a separate opinion from a Desk Officer appears to violate the principle of legal certainty.

5.7.1 Recommendations

The following recommendations are made to resolve many of these issues:

- A discussion is needed to ensure that all parties have the same understanding of this matter.
- The exact implications for HS need to be agreed. Does it require minor changes to the text in HS, or will it require major changes and lead to HS for use with a DoC becoming different to HS for use in type approval?
- The cost vs benefit of requirements and procedures should be used by ETSI to establish a sufficient level of testing detail, the principle of which the EC should accept.
- ESOs should always take the safest approach to handle uncertainties related to risk analysis, until criteria to overcome this uncertainty are identified and agreed with EC.
- If the EC feels that requirements demanding subjective testing should be included in NLF legislation, there should be an acknowledgement of, acceptance and description as to how such requirements should be documented and tested by the EC, which would be captured in the master documentation.

5.8 Reputational damage

5.8.0 Discussion

ETSI has a global reputation, both with regulators and industry and has long since prided itself on writing clear and easy to follow standards and procedures. Demands that are being made recently of TCs by the EC and HASCs - both demanding unrealistically onerous procedures and also the removal of instructive text - however, is damaging the quality of standards in the eyes of our customers and thereby damaging the reputation of ETSI itself.

In addition, the original objectives of the EC were to ensure leadership in the field of standardisation. ETSI standards achieve, but increasing specialization on European legislation detracts from worldwide use.

The EC's continued refusal to accept citation of standards from globally recognized SDOs, such as IEC and CISPR leading to the need for Common European modifications (i.e. deliberate departures from globally accepted norms, as Europe unilaterally altering such standards is unrealistic, especially when the motivation is questionable from a technical perspective, and causes further delays) is having a similar effect. For example, one member commented that when working on IEC CISPR standards, where he is always trying to think ahead to what Europe might require, and yet still the standards are forbidden to be cited, whilst in TC210 [i.38] there is a working group (TC210 WG 18) that creates Common European Modifications modifying standards (from IEC CISPR and IEC TC77 [i.39]) to adapt them to European requirements.

ETSI is of the view that Europe should try to align with global standards whenever possible because the fundamental laws and techniques are universal and that otherwise it risks Europe having diminishing impact in the world, an important soft political power. Many of the changes, too, extend testing time, for example, from 4 hours to 4 days in IEC EN 61000-4-3 [i.28].

Many of the concerns that are raised by the EC in this regard appear to be legal in nature and do not take into account the practicalities of standard laboratory practice, and so the EC should be more prepared to understand the concerns raised in this regard, else there is a danger that, technical issues are being fudged and important decisions avoided.

Member disillusionment is another serious issue that should concern ETSI: evidence has emerged of a feeling from several members that rules are being applied arbitrarily leading to extended drafting times which has led some member companies to question the value of remaining ETSI members, reasoning that certification of products by notified body might be a more cost effective way of placing products on the market and therefore leaving/downgrading their membership.

One TC has abandoned even trying to cite standards, reasoning that its European users would feel better served entirely circumventing the whole process.

There is also an observation that industrial stakeholders are being more and more marginalized and that ETSI might, in the future, struggle to support their interests.

Two-part standards

Two-part standards might be a compromise solution to the requirements of the EC whilst maintaining ETSI's global reputation. Noting that the overlap of the content of harmonised standards is significant, ETSI might, as a matter of course, publish global standards, but also a second harmonised standard containing the additional mandatory elements demanded by the EC (as well as removal of content that is deemed to be inadmissible). This would pose some administrative challenges to TCs, but allow harmonised standards to be cited and ETSI's traditional global customers to be satisfied.

ETSI should continue to highlight, however, that where the implicit European requirements diverge from global norms - both specific standards and detailed technical points - the European market risks constructing barriers to trade both into and out of the union. This further risks Europe becoming a niche market making European products uncompetitive.

5.8.1 Recommendations

The following recommendations are made to resolve many of these issues:

- ETSI should recognize that there is a bigger picture (than ETSI standards becoming very EU-specific) in that Europe is mandating more and more European Common Modifications to globally-accepted International standards (developed by domain experts over many years, only for EC lawyers to find legal fault), leading to fragmentation of standards, which can only lead to higher costs for consumers, and the disadvantaging of European industry.

- ETSI, ultimately, perhaps, has a choice: write global standards only or adapt them to EU-specific requirements, perhaps by way of an addendum. This would allow ETSI standards to continue to be consumed in its traditional global markets.

- Two-part standards might be considered, thereby satisfying the needs of the EC whilst not compromising standards' global relevance, where detail (such as measurement procedures) that has been excluded by the EC (but which infrequent users of the standards need, such as details of measurement tolerances) might be returned.

- Else suites of documents could be written: one part for the engineers and/or technicians who are involved in the (planning and execution of) testing and one part having legal significance.

- ETSI should continue to vocally defend industrial participation in standards writing.
- Both ETSI and the EC should understand the implications of detailed assessment procedures that are currently being demanded, which lead to long and costly testing sessions, the cost of which to European industry (and, ultimately, consumers) should be highlighted.
- In diverging from international standards, Europe risks isolation, which ETSI believes runs counter to the interests of Europe. Deviations should be a last resort, and so the EC should be encouraged to approach third-party SDOs and make their points, else uncertainty will continue to haunt European standards.

5.9 Availability and variability of HAS consultants

5.9.0 Discussion

In a report from the Commission to the European on its Standardization Strategy [i.29] in February 2022, the EC claimed that the high number of failed reviews of standards was, *"mainly due to inadequacy with EU law, showing that more work is to be invested in the development process of standards - e.g. within the technical committees - so that the work is more aligned with the policy and legal requirements"*. Experience of ETSI & CENELEC TC leads, however, challenges this narrative suggesting that, although in many cases this might have been fair criticism, there have been other factors that have led to unfavourable reviews.

To exacerbate the situation, funding of the HASC programme was disrupted in early 2022 which consequently further delayed the preparation of all such standards.

From late 2019, TC ERM, started to experience problems with the availability of HAS consultants to attend ETSI meetings. Prior to this, TCs could (and did) request the presence of the HAS consultant in technical meetings where their input was deemed valuable to all present, keeping them on track and focussed during the drafting and resolution of both HAS review and Public Enquiry comments. Subsequently, this has since ceased, allegedly over funding issues. The result of this is increased misunderstanding by both parties on the intent of each other and an over reliance on the final review by the RED Desk Officer which takes place after the standard has been published by ETSI and the work item closed, making revision of the standard time consuming. The HAS Consultants contract was finally renewed in Summer 2022.

TC ERM has also experienced different approaches and comments from different individual consultants. This undermines the entire process because a TC might receive a "green light" from one during a review and then a subsequent review by a different consultant might raise concerns that were not there in the first review. This lack of consistency makes drafting extremely frustrating. Furthermore, when a different consultant gets involved TCs have found, on occasion, that they are expected to explain how/why it has arrived at certain decisions that would have been apparent to either the earlier consultant or the new one if they had followed the drafting process from early stages. As an example, ETSI EN 303 204 [i.30] (Fixed Short Range Devices (SRD) in data networks; Radio equipment to be used in the 870 MHz to 876 MHz), which went through the process of citation after three rounds of resolution assessments, only for an identical annex on measurements to be deemed to have several critical findings two months later by another HAS consultant.

Furthermore, with respect to Wanted Performance Criteria, comments have been received from the HASCs, whereas ETSI understands that ETSI is solely responsible for setting pass/fail criteria, with ultimately the ECC having the main say in their values, and that under the RED EG many decision makers come from national delegations and so much of this is driven by national communications policies. This has been repeatedly questioned by HAS consultants.

Finally, several TCs, as well as CENELEC, have reported experiences of contradictions between different HASCs, leading to confusion, delays and, ultimately, limitations of standards' citations.

5.9.1 Recommendations

The following recommendations are made to resolve many of these issues:

- HASC's should be given clearer guidance as to the scope of their activities and detail of where they should intervene, with emphasis on intervention only in case of clear breaches of a standard's content.
- HAS consultants should be present in resolution meetings as well as engaging them at early stage in the standard's genesis.

- A process should be put in place to avoid or resolve contradictory opinions by different HAS Consultants on similar issues, before such opinions are validated and transmitted to the ESOs for action. In case an approved new opinion contradicts a previously expressed one, the ESOs should not be held responsible for delays resulting from aligning the standards with the new opinion

5.10 Challenges of the EC's new standardisation strategy

5.10.0 Discussion

When a request for standardisation is made by the Commission, the European standardisation organizations (as defined in Regulation (EU) No 1025/2012 [i.22]) are the only bodies that can issue standards and standardisation deliverables. They do so in line with specific procedures set out in Article 10 of Regulation (EU) No 1025/2012 of the "Standardisation Regulation". The Standardisation Regulation also provides that the European Union may support the European standardisation organizations financially.

The European standardisation organizations are defined in Article 2, point 8 and Annex I to the Standardisation Regulation. There are three European standardisation organizations: CEN, CENELEC and ETSI. They have an exclusive role to carry out standardisation work requested by the Commission in support of EU legislation and policies.

In the view of the Commission, today, *"the ESOs' internal governance, decision-making procedures and their membership structure have gone through multiple changes" since the above mechanism was incepted.*

They consider that "The European standardisation organisations now cooperate with a wide range of stakeholders, including from third countries, and allow them to participate not only in the technical work but also in their internal policy- and decision-making. Such cooperation is welcome; however, when the European standardisation organisations should focus on supporting EU legislation and policies, safeguards are needed to ensure sound procedure and a balanced representation of stakeholders' interests, in line with the strategic priorities and legislative needs."

Therefore, they intend to ensure that "*when the European standardisation organisations support the application of EU legislation and develop standards that are crucial to the EU general public and to companies, the internal governance of the European standardisation organisations must duly take into account the views of all European stakeholders (including small and medium enterprises and civil society organisations)."* In a criticism directly targeting the role of ETSI as an ESO, they add that "*This is even more pertinent given that some European standardisation organisations are mainly composed by economic operators who have voting rights and the participation of civil society organisations and public authorities is limited in some cases"*.

In consequence, as part of the reform of the EU Standardization system announced by Commissioner Breton in early February, the Commission:

- Presented a legislative proposal amending Regulation (EU) No 1025/2012, in which it proposes basic criteria when handling European standardisation requests under Article 10 of Regulation (EU) No 1025/2012.
- Called on the European standardisation organizations to make proposals by the end of 2022 to modernize their governance to fully represent the public interest and interests of SMEs, civil society and users and to facilitate access to standards.
- Will launch the evaluation of Regulation (EU) 1025/2012 to assess whether it is still fit for purpose.
- Will launch a peer review process amongst Member States and national standardisation bodies by the end of 2022 to achieve better inclusiveness, including of civil society and users, and SME-friendly conditions for standardisation.
- Will develop a horizontal approach to the development of technical or common specifications through implementing acts under sectoral legislation.

The proposed amendment aims to ensure that "the decision-making bodies of European standardisation organizations concerning European standards and European standardisation deliverables requested by the Commission under Article 10(1) of Regulation (EU) No 1025/2012 be taken exclusively by representatives of national standardisations bodies" and "provide that the Commission may only make such requests to a European standardisation organization that complies with that requirement". This will pertain to:

a) decisions on the acceptance, refusal and execution of standardisation requests;

b) decisions on the acceptance of new work items;

c) decisions on the adoption, revision and withdrawal of European standards or European standardisation deliverables.

It would allow a transition period of 6 months to "enable the European Standardisation Organizations - where necessary - *to adapt their internal rules of procedure*". It should be noted, however, that during this interim period, despite the fact that ETSI has responsibility for radio devices and was an early mover in the Cyber requirements standardisation, the Commission already used the argument of non-compliance with the new rules to exclude ETSI from the RED 3.3 d/e/f standardization request, sending it only to CEN and CENELEC, even though ETSI was initially very active in the preparation of the Standardisation Request. Furthermore, this Standardisation Request involves the production of deliverables dealing with 5G Base Stations and eIDAS, which are not in the CEN/CENELEC areas of expertise. At the same time, it is worth highlighting that CEN/CENELEC JTC 13 recently created a working group to support ENISA in producing an EU 5G certification scheme under the CSA, while neither ETSI nor 3GPP considered similar initiatives.

Furthermore, the overall European standardization landscape will also be affected by the following actions from the Commission:

- Work with the ESOs, stakeholders and other partners to immediately address the identified standardisation urgencies, as regards e.g. chips certification and data standards.
- Set up a High-Level Forum to assist the Commission in anticipating upcoming standardisation priorities and engage with the European Parliament and Council to ensure political concertation on these priorities.
- Reflect the standardisation priorities in the Annual Union Work Programme on Standardisation from 2022 onwards.
- Review existing standards to identify needs for revisions or development of new standards to meet the objectives of the European Green Deal and Europe's Digital Decade and support the resilience of the EU single market.
- Set up an *EU excellence hub on standards* to bring together the standardisation expertise, and nominate a Chief Standardisation Officer, who will steer this network and ensure Commission oversight on the alignment of standardisation activities with EU policy objectives and strategic interests.
- Work with the ESOs on concrete solutions and targets to accelerate the development and adoption of standards, implementing concrete solutions to achieve higher consistency of standards offered for publication by reference in the *Official Journal of the European Union.*
- Set up a mechanism with EU Member States and national standardisation bodies to monitor, share information, coordinate and strengthen the European approach to international standardisation (ISO, IEC, ITU and other relevant international fora), supported by the *EU Excellence Hub on Standards.*
- Foster the development and deployment of international standards for a free, open, accessible and secure global internet and establish an EU internet standards monitoring website.

In its foreword, the EC contends that, *'the strategic importance of standards has not been adequately recognized at the cost of EU leadership in standards-setting. This must change'*. ETSI does not recognize the issues raised in this paragraph and would appreciate more explanation.

5.10.1 Recommendations

The following recommendations are made to resolve many of these issues:

- The intention of the call to the ESOs to "facilitate access to standards" should be clarified, e.g. does it means facilitate access to the standards development process to certain types of stakeholders, or facilitate access to published standards (ETSI standards are freely available via the ETSI website) by all stakeholders, or both? The current ESOs landscape supports different financing models affecting either access to the development of standards or access to the text of approved standards. This diversity of models has successfully proven its ability to efficiently address a variety of issues, so the impact of enforcing a single model should be carefully analysed.

- It should be acknowledged that European standards and legislation may serve different purposes, which may be better served by different processes in the way to develop and disseminate European standards. While Member States appointed representatives may be best placed to contribute when it comes to defining requirements for protecting consumers in already existing markets, the pace of innovation in Information and Communication Technologies requires anticipation to ensure timely availability of mature interoperability standards as an enabler to the development of new market segments. This requires active involvement of scarcely available experts in the innovative ecosystems. The ability of national committee based representation to address such cases has to be assessed, while the ETSI industry-based participation model enabled the success of the EU initiated GSM standards in the 1990s, which set the basis to global cellular communication systems worldwide for the following decades.

- In judging the performance of the ESOs, there needs to be a clearly stated and agreed upon performance/speed objectives is necessary.

- The EC and the ESOs need to work together to anticipate regulation that may be required in the future for new and fast-evolving sectors.

5.11 Process issues

5.11.0 Discussion

With the EC's new assertiveness in judging standards for citation it has become apparent that the ENAP process itself creates problems that lead to delays and frustration within TCs.

The main problem encountered so far with the Standardisation Request process stems from the fact that the ESOs can only fully accept or fully reject an issued SR within one month, with neither comments nor conditions admitted.

A good example of such issues is the E112 SR addressing Article 3(3)(g) of the RED that was rejected by ETSI in the autumn of 2020, and used by Commissioner Breton as an example of unacceptable behaviour from an ESO because he claimed that this stemmed from a refusal from non-EU headquartered companies to implement Galileo GNSS interoperability in their products. It has to be noted that the Standardisation Request contained the text *"ETSI should therefore promptly report to the Commission if it considers that more time is required to draft the standards than initially foreseen or that it is appropriate to adapt the scope of the request, in order to allow the Commission to take appropriate action."*. On that basis, because there was an agreement to develop the core HEN related to Galileo GNSS interoperability, but also a consensus that the requested schedule could not be met, and a clear lack of support to develop some of the other (unrelated) HENs requested under this Standardisation Request, the TC in charge (MSG) actually recommended a "Yes, but…" response to the ETSI Board. Considering that the response to be provided did not allow such remarks, this decision was converted at Board level into a rejection of the Standardisation Request:

- Although there is a consultation process between the ESOs and the Commission to finalize Standardization Requests, ESOs have only limited impact on the preparation of Delegated Acts, and their inputs on DAs can be completely disregarded by the Commission.

- In principle, a Delegated Act cannot introduce new terms that did not exist in the original legislation, nor redefine existing terms. Given that Article 3(3) of the RED dates back from the R&TTE directive of the late 1990s, the term "network" in the existing Directive cannot be reasonably understood by the average reader as the "Internet" without additional information. This is because the networking technologies have been developed and adopted to an astounding degree since the R&TTE was written. Therefore, the redefinition of "network" in the RED 3(3) d/e/f DA to include the Internet seems to contradict the established principle above.

- The Delegated Act decides on the legal framework that will serve as context to the Standardisation Request, e.g. NLF (DG GROW), CSA (DG CNCT), etc. Depending which part of the Commission initiates an action for a given purpose, different legal frameworks are likely to be proposed, some of which may be more appropriate to achieve a given purpose than others. For example:

    - Considering the wide objective of the Commission to increase the cybersecurity of ICT products, the decision to act under the NLF through activation of Articles 3(3) of the RED will require further actions to address all the ICT devices that do not qualify as "Radio Equipment". This is likely to create perpetual fragmentation between the radio and non-radio products in ICT, which introduces undue overhead in widely circulated products (e.g. laptops, desktops with vs. without embedded short range radio chipsets, etc).

- It is worth noting that the NLF suffers from inherent limitations when it comes to addressing ICT security, which, being largely impacted by third-party actions, is a moving target that cannot be measured absolutely, but only estimated by humans by means of Risk assessment, which itself requires knowledge of the use case and operating conditions, which are often unknown by manufacturers at time of placing their devices on the market. This also means that in the context of ICT security, there is no physical phenomenon to use as a reference for stable norms, in contrast to what existing harmonised standards for the RED largely rely upon.

- Furthermore, use of a market placement legislation assuming legal certainty to address ICT security directly contradicts the fundamental principles laid down by DG CNCT in the CSA for addressing ICT security (specifically, "consider the whole product lifecycle" and "use risk-based assessment").

- Generally, the Commission already prepares a well advanced draft before consulting the ESOs on a Standardization Request. Several points deserve immediate attention when reviewing such drafts:

  - It has been typically the case that the Commission issues a single SR per policy area, which results in requesting multiple HENs - often not technically connected - into a single SR. But since the ESOs can only accept or reject an SR in full, with no possibility to comment (even on the timeline), this means that disagreement to produce just one of the standards requested requires a full rejection from the ESO. Such an outcome for an SR is easily misinterpreted by the Commission as a disagreement to contribute to the overall intended goal under the policy area in question.

  - Finally, "the devil lies in the details": Careful wordsmithing is always necessary to ensure that meanings can be interpreted unambiguously, and contribute to the overall goal rather than introducing further confusion. This phase generally takes the most time, as all revisions of the text need to be checked carefully.

5.11.1 Recommendations

The following recommendations are made to resolve many of these issues:

- Many ambiguities could be avoided if the Commission would agree, as a Best Practice principle, to atomize its SR to the extent possible, i.e. one SR per HEN, or at least if the Standardisation Request could set specific timeline for each HEN it covers while the ESOs would be allowed to individually Accept or Reject the development of each HEN under such a combined SR.

- The Standardisation Request should define the scope affected and the overall goal to achieve, i.e. the "WHAT", without entering into technical details on "HOW" this goal has to be achieved. Frequently, the Commission has a tendency to enter far into ESO's territory when drafting its SRs (e.g. converting high level objectives into detailed technical requirements).

- Change process to allow partial acceptance of SRs and/or dialogue or ensure that SRs are split into appropriate and specific individual requests (with separate requests for separate deliverables whenever possible), with realistic timescales.

- EC comments should be submitted at a stage where they could be debated and acted upon in the normal process of standards production. This means as early in the process as possible and whilst this may place a burden upon the RED desk and others, submission of comments during the ENAP process should be seen as the appropriate place, thus making the act of citation a more straight forward step that does not get bogged down in revision of the standard when the work item is closed and the standard published. Furthermore submission of EC comments here also means that the EC comments along with everyone else's are subject to full public scrutiny as part of the established process for standards.

- The EC's right to fail/restrict citations comes at the end of the process - no time to remedy -- Update ENAP process, therefore, the ENAP process could be revised in such a way (see figure 1) that:

  1) An additional NSO/NSB assessment (in parallel to first HASTAC assessment) could be established to increase the NSO/NSB involvement during the EN preparation and not only NSO/NSB commenting possibility during the ENAP official public enquiry step (including vote). During the official public enquiry technical changes are limited and such involvement could reduce the probability to undergo additional public enquiries.

2) Another improvement could be that the second HASTAC assessment should take place during the public enquiry. With this parallel activity ETSI would receive for the resolution (after the public enquiry) the comments from both sides (HASTAC and NSO/NSB). This would reduce the possibility of negative comments after the resolution meeting (3rd HASTAC assessment). That this change would be successful it is be recommended that for the resolution meeting the HASTAC and NSO/NSB representative (if they provide comments) are present.

3) And final at the final stage (ETSI publication) the EC assessment should be prepared before ETSI publishes the "final" EN. This "freezing" of the EN could provide ETSI the opportunity to consider editorial changes (requested by EC) to improve clarification in the EN. This step might avoid a restart of the entire process, caused only by small editorials are changes for clarification. But this change would not avoid the necessity of a re-start if the EC has "technical/legal" concerns. But participation of the HASTAC and NSO/NSB would reduce the probability of such a situation occurring.

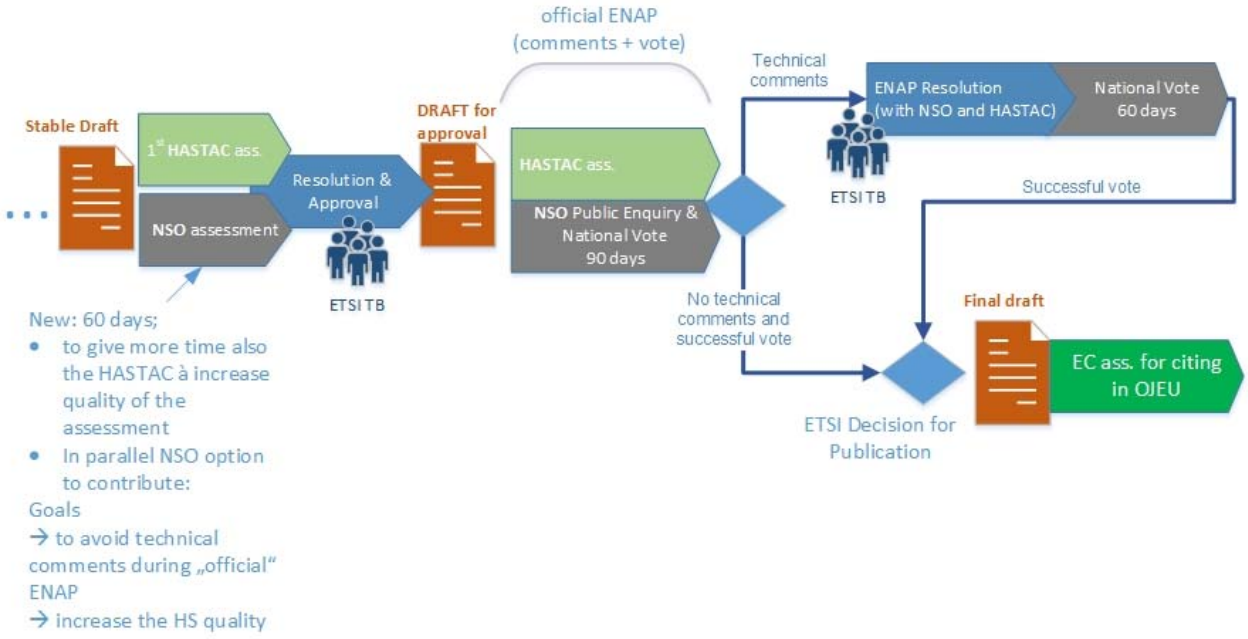

Figure 1

5.12 Relationship with National Standardization Organizations/Bodies (NSOs/NSBs)

5.12.0 Discussion

The Standardisation Strategy makes clear the EC's desire to ensure that NSOs/NSBs play a major role in the response of ESOs to SRs. As a minimum, NSOs/NSBs will be responsible for rubber stamping ESOs' response to SRs and the final deliverable. Several members commented, however, that NSOs/NSBs do not, typically, currently engage with these processes, which is left to industry participants. And, in fact, the majority of ETSI's work is driven by industrial representatives supported by representatives from national regulators. The nature of and timescales impact of this new decision-making process, therefore, is unclear.

Different funding participation models means that many NSOs/NSBs are incentivised to manage CEN/CENELEC standards, where revenue is available in the resale of these standards. No such equivalent revenue streams are available from ETSI standards. As a consequences some NSOs/NSBs are active where others are not. For example, the UK and Ireland (an EU member), at the moment, there is no sharing of comments on drafts. Their engagement here is important, but can only be achieved by them being funded to be members of and active in ETSI.

It is interesting to note, that ETSI works directly with members, which the EC recently highlighted as having undesirable connections of overseas organizations, but whose members are typically also members of national bodies and therefore, whilst the national body makes the final vote for acceptance or rejection of a standard, or can input at the draft stage, those taking part are, in the majority of cases, a common group.

5.12.1 Recommendations

The following recommendations are made to resolve many of these issues:

- The EC should clarify the process that it sees for enabling the 41 NSOs/NSBs of Europe to make decisions on responses to SRs and publication of the resulting standards.
- ETSI should work with the NSOs/NSBs to educate them as to their roles and responsibilities to ensure timely production of harmonised standards.
- National Governments should be encouraged to fund their NSOs/NSBs' access to ETSI in order to allow them to better engage with the standardisation process.

6 Conclusions

After consideration by the EC, EESC and ETSI a group should be set up between the three organizations to consider these issues and recommendations as a matter of urgency.

Once the issues have been resolved, Master Documentation setting out the requirements for harmonised standards should be agreed.

Annex A:
Detailed goals from EU Strategy on Standardisation: Setting global standards in support of a resilient, green and digital EU single market

Leveraging the European standardisation system - to deliver on the twin green and digital transition and support the resilience of the single market:

- Work with the ESOs, stakeholders and other partners to immediately address the identified standardisation urgencies, as regards COVID-19 vaccine and medicine production, critical raw materials recycling, the clean hydrogen value chain, low-carbon cement, chips certification and data standards.
- Set up a High-Level Forum to assist the Commission in anticipating upcoming standardisation priorities and engage with the European Parliament and Council to ensure political concertation on these priorities.
- Reflect the standardisation priorities in the Annual Union Work Programme on Standardisation from 2022 onwards.
- Review existing standards to identify needs for revisions or development of new standards to meet the objectives of the European Green Deal and Europe's Digital Decade and support the resilience of the EU single market.
- Set up an EU excellence hub on standards to bring together the standardisation expertise, and nominate a Chief Standardisation Officer, who will steer this network and ensure Commission oversight on the alignment of standardisation activities with EU policy objectives and strategic interests.
- Work with the ESOs on concrete solutions and targets to accelerate the development and adoption of standards, implementing concrete solutions to achieve higher consistency of standards offered for publication by reference in the Official Journal of the European Union.

Upholding the integrity, inclusiveness and accessibility of the European standardisation system - putting good governance principles in place:

- Presents a legislative proposal amending Regulation (EU) No 1025/2012, in which it proposes basic criteria when handling European standardisation requests under Article 10 of Regulation (EU) No 1025/2012 [i.37].
- Calls on the European standardisation organizations to make proposals by the end of 2022 to modernize their governance to fully represent the public interest and interests of SMEs, civil society and users and to facilitate access to standards.
- Will launch the evaluation of Regulation (EU) 1025/2012 [i.37] to assess whether it is still fit for purpose.
- Will launch a peer review process amongst Member States and national standardisation bodies by the end of 2022 to achieve better inclusiveness, including of civil society and users, and SME-friendly conditions for standardisation.
- Will develop a horizontal approach to the development of technical or common specifications through implementing acts under sectoral legislation.

Global standards-setting: supporting the EU's leading position as a forerunner in key technologies and promoting EU core values:

- Set up a mechanism with EU Member States and national standardisation bodies to monitor, share information, coordinate and strengthen the European approach to international standardisation (ISO, IEC, ITU and other relevant international fora), supported by the EU Excellence Hub on Standards.
- Foster the development and deployment of international standards for a free, open, accessible and secure global internet and establish an EU internet standards monitoring website.

- Monitor the effective implementation of existing commitments on standardisation in EU trade agreements and use such trade agreements, as well as regulatory dialogues and digital partnerships, to cooperate on standardisation with like-minded partners in strategic areas and coordinate positions in international standardisation bodies.

- Promote international cooperation on standardisation and EU standards with the Neighbourhood, Development and International Cooperation Instrument - Global Europe (NDICI-GE) and Horizon Europe, also with a view to support stakeholder participation in international standardisation (SMEs, civil society, academics).

- Fund standardisation projects in selected African countries as part of its development cooperation policy and the Global Gateway. The EU will promote key European standards in partner countries with accession perspectives/closer integration with the EU's internal market, starting in the EU's Neighbourhoods.

Cutting-edge innovation that fosters timely standards:

- Launch the 'Standardisation Booster' to support researchers under Horizon 2020 and Horizon Europe to test the relevance of their results for standardisation.

- Develop a Code of Practice for researchers on standardisation to strengthen the link between standardisation and research/innovation through the European Research Area (ERA), by mid-2022.

Ensuring future standardisation expertise - the need for education and skills:

- Organize Standardisation University Days to promote standardisation awareness among academics and students.

- Deploy initiatives for young researchers and networks from Horizon Europe and the Euratom Research and Training programme, including the COST Association, for the valorisation of research and innovation through standardisation and pre-normative research.

- Use the Commission's EU Academy platform for the dissemination of standardisation e-learning training material; promote the development and dissemination of standardisation academic teaching modules within the High-Level Forum to attract and train young professional in standardisation and promote re-skilling opportunities.

The way ahead - future of the European standardisation system:

- Publish along with the Annual Union Work Programme and the ICT Standardisation Rolling Plan on European standardisation an annual dashboard on the planned, current and completed standardisation activities for more transparency in the European standardisation system.

Annex B:
Procedures establishing secondary legislation

B.1 Procedure for delegated acts

The Treaty on the Functioning of the European Union stipulates in its Article 290 [i.31]:

1) *"A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act.*

   The objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts. The essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power.

2) *Legislative acts shall explicitly lay down the conditions to which the delegation is subject; these conditions may be as follows:*

   a) *the European Parliament or the Council may decide to revoke the delegation;*

   b) *he delegated act may enter into force only if no objection has been expressed by the European Parliament or the Council within a period set by the legislative act.*

   For the purposes of a) and b), the European Parliament shall act by a majority of its component members, and the Council by a qualified majority.

3) *The adjective "delegated" shall be inserted in the title of delegated acts."*

The procedure for delegated acts is one of the procedures used to establish secondary legislation. The European Commission may be granted the mandate to establish delegated acts, but only if primary legislation allows for it and only within the boundaries set by the primary legislation.

Delegated acts are generally used to establish measures of a technical nature. Specialist knowledge is usually required to draw up such measures. Despite the fact delegated acts focus on technical measures, such measures may have significant impact in the member states. As such, the seemingly politically less important delegated acts can still attract political attention. When secondary legislation is limited to establishing uniform European measures for implementing primary legislation, implementing acts are used instead.

In short the procedure proceeds as follows: basic legislation stipulates on which part of the legislation the European Commission has to establish further measures. The Commission, in co-operation with the member states, drafts the delegated acts. The Council of Ministers and the European Parliament can tacitly or explicitly approve the delegated act, or reject it. The full procedure is set out below.

B.2 Procedure for delegated acts in detail

The procedure for adopting delegated acts [i.32] are described below.

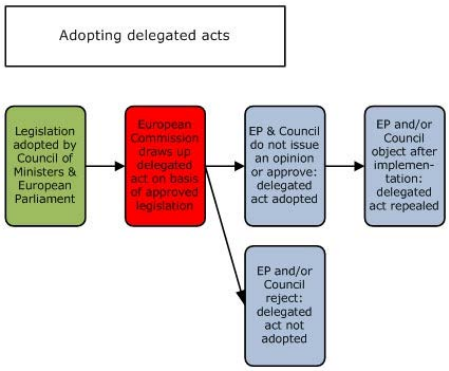

Figure B.1: The procedure of adopting delegated acts

Step 1: establish framework

Primary legislation establishes the framework and the boundaries in which the European Commission can draft further measures. The role of the Council of Ministers and the European Parliament is also established.

In some cases the mandate of the Commission is limited in time by a so-called sunset clause. When the mandate expires it can be extended, become subject to review or be terminated.

Step 2: establishing delegated acts

The Commission drafts a proposal for a delegated act. This process involves consultations of experts from the member states. Such expert committees - known as comitology - are made of member state appointed experts, almost always civil servants. In (rare) cases when the Commission does not require additional expertise no consultations are held.

After the Commission has issued a proposal for a delegated act there are three possible outcomes:

1) Council and EP do not issue an opinion; the delegated act will come into effect.

2) Council and EP raise no objections; the delegated act will come into effect.

3) Either Council or EP or both object to the proposed delegated act; the delegated act is rejected.

Both Council and EP are required to provide a motivation when objecting.

Both Council and EP have two months to conclude their evaluation of a proposed delegated act.

On voting procedures

The Council of Ministers decides by qualified majority vote. The European Parliament decides by the majority of its members.

In cases where the European Parliament is not co-legislator when establishing the primary legislation the EP generally does have a say in the procedure for delegated acts.

B.3 Application of delegated acts

The Commission may only issue delegated acts when the following conditions are met:

- the primary legislation has to be legally binding;
- the primary legislation provides the Commission with a clear mandate to issue delegated acts. The mandate includes the purpose, extent and goal as well as the duration of the delegation;
- delegated acts only amend or add to non-essential elements of the primary legislation;
- delegated acts are generally binding by definition; they cannot apply to individual or specific groups of legal entities.

As long as the following conditions are met any piece of primary legislation can include a mandate for delegated acts.

B.4 Legal framework

Delegated acts are based on the Treaty on the functioning of the European Union:

- delegated acts: part six TFEU title I chapter 2 section 1 Article 290 [i.35];
- working arrangements between Council, EP and Commission on delegated acts (Regulation 2011/182 [i.36]).

B.5 Adoption of delegated acts

The Commission adopts them on the basis of a delegation granted in the text of an EU law, in this case a legislative act.

The Commission's power to adopt delegated acts is subject to strict limits:

- the delegated act cannot change the essential elements of the law;
- the legislative act can define the objectives, content, scope and duration of the delegation of power;
- Parliament and Council may revoke the delegation or express objections to the delegated act.

The Commission prepares and adopts delegated acts after consulting expert groups, composed of representatives from each EU country, which meet on a regular or occasional basis.

As part of the Commission's better regulation agenda, citizens and other stakeholders can provide feedback on the draft text of a delegated act during a four-week period. There are some exceptions, for example, in case of emergency or when citizens and stakeholders have already contributed. More details in the better regulation toolbox.

Once the Commission has adopted the act, Parliament and Council generally have two months to formulate any objections. If they do not, the delegated act enters into force.

Adopted acts contain an 'explanatory memorandum' summarizing the feedback received and how it was used.

History

Document history		
V1.1.1	November 2022	Publication