

High-Level Forum on European Standardisation

“Alignment between European and International standards”

Final report elaborated by workstream 4

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1 Introduction

For more than 30 years, the EU has been a front-runner in standards-setting, also at the international level, underpinning its technological leadership. This leadership has limited the need to issue regional European deviations of international standards and therefore allowed an overall alignment between European and international standards - supporting EU companies' global competitiveness. The Vienna and Frankfurt agreements have contributed to strengthening the relationship between international and European standardisation stipulating that international standardisation takes precedence over national and regional standardisation. However, the digital revolutions (i.e., semi-conductor / personal computer, world wide web, mobile communication, artificial intelligence), the rising ambitions and commercial success of companies from developing countries, and the changing geopolitical landscape has led many standardisation experts from other countries to join international committees, with strategic competitors actively trying to influence international standardisation activities. In some cases, this may lead to a divergence in the suitability of the standardisation deliverables for the EU market.

The purpose of this Workstream (WS) has been to reflect on the existing relation between European and international standards, taking as an example the Machinery sector¹ and to identify recommendations to respond to challenges and seize opportunities. The planned activities included obtaining concrete data to have a solid base of “facts and figures” from which to start the workstream’s discussions and to explore how European actors can better influence the international standardisation work.

2 Findings

From the start of the activities, the coordinator of the WS, Orgalim, has been in dialogue with CEN and CENELEC, ETSI, the Commission and experts on machinery standardisation from the Orgalim membership to identify and evaluate available data on alignment. These findings have been discussed at a workshop with the members of the WS and external experts on 11 October 2023. The conclusions of that workshop, as highlighted in the workshop’s final report (see Annex III), identified:

- 1) The need for a common language to describe the different types of alignment and divergencies between international standards, European standards, and harmonised European standards cited in the Official Journal of the EU. On this, the WS has developed a proposal for terminology relating to how standards can deviate from an international standard towards adoption in Europe and then citation in the OJEU; and on standards that have non-equivalence internationally and in Europe respectively.
- 2) The difficulty of getting conclusive data for the different definitions identified in point 1 (more on this in the annex)

Following the workshop, the workstream has agreed on a proposal for a terminology to describe different types of alignment and divergence (Annex I). Furthermore, the workstream has described the challenges related to reporting data on divergence and provided recommendations as to how data can be collected and reported moving forward so that others can develop a framework to collect and

¹ Initially, the workstream planned to also consider the example of AI standardisation activities but as the work evolved and to avoid duplication, the group decided to share with WS 12 on AI standardisation what had been concluded so far and to focus on the Machinery case study only.

report data on alignment and divergence in the future (Annex II). The recommendations stemming from Annex I and II are included in this report.

Despite the impossibility to outline conclusive data on the state of play of alignment between European and international standards, the workstream decided to discuss and identify challenges and opportunities of the citation of internationally developed standards and of the development of homegrown harmonised standards respectively.

Opportunities and challenges of internationally developed and homegrown standards in support of EU legislation

Harmonised standards are developed based on a Standardisation Request (SReq) by the European Commission. The SReq is drafted by the Commission and consultations and discussions on it are held in parallel with the ESOs, the Annex III organisations, any other relevant stakeholders and Member States' sectoral experts. Once the SReq is adopted and accepted by the ESOs, it is sent to the relevant ESO technical committees (TC's) already working on market driven standards in the area to develop the requested deliverables. Sometimes a new TC and/or working group under an existing TC is established to do the work.

When it comes to harmonised European standards (hENs) as developed by CEN/CENELEC, they can be aligned with international standards through two different processes as illustrated below. Regardless of the process, once the standards requested by the Commission have been developed, they must be evaluated to ensure that they are suitable to respond to the requirements of the legislation and can therefore be cited in the OJEU, thus providing presumption of conformity.

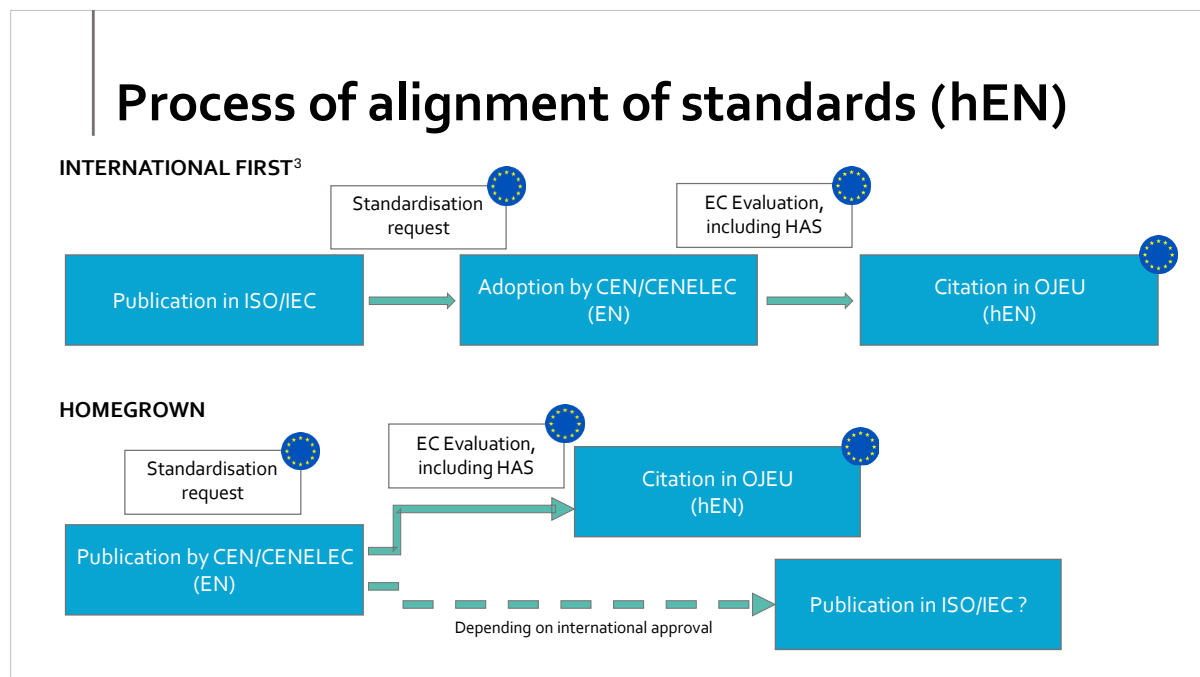
When standards are developed at international level by ISO and IEC they can be adopted in Europe (EN) by CEN and CENELEC through the Vienna and Frankfurt agreements² with or without amendments (common modifications)³. These standards can then be cited in the OJEU also with or without amendments. When standards are developed at international level through a consensus process, the secretariat of the TC can be headed by a European or a third country's national standardisation body.

When the homegrown approach is applied, the standard is developed by CEN and CENELEC. There may or may not be an international standard covering similar requirements. In the case there are relevant international standards, they can be used as the basis or portions of the European standard.

² The Vienna and Frankfurt Agreements parallel development and approval exists for projects which have global relevance. The draft standard is prepared in one TC (either ISO/IEC or CEN/CENELEC, depending who leads on the development), and expert participation from the other committee. The standard is balloted in two committees both at international and European level in parallel for approval as an international standard and EN standard. Within the Frankfurt agreement, CENELEC can first offer projects to IEC for development, and then adopt the resulting international standard as an EN standard.

³ Despite the international main text, Europe still has the option of adapting the standard for our market. The procedure can be outlined with an example of IEC and CENELEC. Standards developed at IEC, are reviewed at CENELEC in the mirror committee and assessed by HAS consultants. Comments from HAS are automatically forwarded to IEC. If the IEC TC does not implement the HAS comments due to their unsuitability for other IEC TC members, Common Modifications must be applied to adopt the standard in Europe. If IEC accepts comments, the IEC standard is "further developed" so that it can be listed as hEN. This includes formal additions such as Annex ZZ and Annex ZA and/or technical amendments (Common Modifications).

In the case in which there are no international standards available, the homegrown standard if globally relevant may be adopted internationally at a later stage.



Harmonised European standards (hENs) developed by ETSI follow a different process regarding the international uptake. There is no internationally recognised SDO equivalent to ISO/IEC from which ETSI could adopt standards or that could recognise ETSI standards internationally. Hence, there is no equivalent to the Vienna or Frankfurt agreement. All hENs developed in ETSI TCs are for the ICT sector.

Whilst being developed in Europe, many ETSI standards (harmonised or not) are used internationally. This is due to ETSI’s membership programme, which allows for direct participation of public and private, European and international entities. Being developed by an open, international community, many ETSI standards are international by nature. Furthermore, ETSI and other regional SDO have created the 3rd Generation Partnership Project (3GPP) that develops specifications for cellular systems. 3GPP specifications are regionally transposed by the participating SDOs and are globally recommended by the ITU.

As a consequence of ETSI’s set-up and ways of working, there cannot be any cases of misalignment or divergence as listed in Annex I.

By written consultation, followed by a discussion in an online meeting, the workstream identified advantages and disadvantages of the two approaches.

The below list of challenges and opportunities was identified with the support of all stakeholders in the workstream. An attempt has been made to quantify the relative importance of the arguments in order to provide a more detailed picture.

Opportunities and challenges of internationally developed standards becoming harmonised European standards:

Opportunities/Added value	Importance (low, medium, high)
Greater likelihood the same standard can be applied globally, resulting in economies of scale through global product development and global sales, lower cost of compliance and benefits for society at large (global relevance)	High
Greater knowledge base to develop better state-of-the art solutions with international foresight (quality of experts)	High
Greater incentive for European companies and their experts – which are the main financiers of standards - to participate in international fora that develop an international – rather than regional – standard.	High
Focus on topics important for Europe, possibility to influence globally	High
European standards based on international standards avoid trade barriers as required by the WTO	High
More expert capacity available to do the work (quantity of experts)	Medium
Better link to other related topics	Medium
Avoiding duplication of efforts, resources, or overlaps, and more efficient use of time resources of EU experts	Medium
Contributions put forward by EU stakeholders that are compelling from a technical and principles perspective and promote interoperability, are likely be adopted in the resulting international standard while meeting EU market needs. European standards based on international standards expand the influence of European public policies: with the involvement of Europeans at the international level, European public policies spread internationally.	Medium

Challenges/Risks	Importance (low, medium, high)
Experts developing standards are focused on developing state-of-the-art solutions to the legal requirements of the legislation. Experts consider fulfilling other requirements, for instance the request of separating requirements linked to essential requirements from requirements that are not linked to EU legislation; dated normative references; and other specific requirements of the Standardisation request not related to the legislative requirements, as constraining. That is because it may require amendments to the international standards that do not improve the quality of the technical solutions or distract focus from developing the best possible solutions. The adaptation can be done either at the international level or in a separate European TC.	High
Different setup for inclusiveness in standardisation between European and international SDOs might lead to less reflection of the European values and European market relevance	High
Missing effective funding schemes that support international standards development activities.	High

More expensive and potentially more time consuming to participate (longer travel arrangements), particularly for convenors and editors as their presence is required in person. Although most working groups do allow dial-in / virtual participation, physical presence still ensures better interaction.	High
Limited financial resources of NSBs/NCs for international activities limit the opportunity of Europe to influence strategic standardisation topics.	High
Facing competition from other countries who subsidise their experts' involvement.	Medium
More competition from non-European experts on the content of the standard. How much challenge depends on the number of European experts involved and their commitment to collaborate	Medium
Less influence on processes (if the international TC does not have a European secretariat)	Medium

Opportunities and challenges of homegrown standards in support of EU legislation

Opportunities/Added value	Importance (low, medium, high)
Only/greater European influence on the content of the standard.	High
Greater focus to addressing EU policy concerns or requirements	High
Established system of monetary support and access facilitation to societal stakeholders (greater participation and inclusiveness) which may impact the state-of-the-art and market relevance in a positive way.	High
Standard may be used or taken up internationally afterwards, EU as a standard-setter (remembering an EN is implemented as a national standard in 34 countries – the “Brussels Effect”)	Medium
Simplified planning of standardisation activities (related to legislation standardisation requests).	Medium

Challenges/Risks	Importance (low, medium, high)
Experts developing standards are focussed on developing state-of-the-art solutions to the legal requirements of the legislation. Experts consider fulfilling other requirements, for instance the request of separating requirements linked to essential requirements from requirements that are not linked to EU legislation; dated normative references; and other specific requirements of the Standardisation request not related to the legislative requirements, as constraining. That is because it may require experts to focus on aspects that do not improve the quality of the technical solutions or distract focus from developing the best possible solutions.	High
May not be taken up internationally resulting in greater compliance product development and implementation costs due to need to apply different standards in Europe compared to internationally/other regions.	High

Loss of competitiveness for the individual company on non-EU markets.	
In niche sectors, smaller pool of technical experts to carry out the work and to come up with technical solutions that are more and more complex, which can result in longer time needed for development and the standard not reflecting innovations that may have taken place outside of the EU.	High
Potential interoperability issues between international market and EU market.	Medium
Not suitable for topics where other nations are the leaders and their technological developments are fast and advanced in comparison to our level of knowledge (that would consequently slow down our internal market)	Medium
Missing effective funding schemes – in particular for non-commercial organisations, including public administrations – that support European standards development activities.	<i>No preference expressed</i>

3 Recommendations

On data collection

As a first step, we recommend that the proposed terminology presented in Annex I to this report is adopted as the standard and shared terminology when referring to the alignment, or not, of European and international standards. This is a prerequisite to the development of a coordinated framework for data collection as called for below.

As explained in more detail in Annex II, the workstream is not in a position to report any conclusive data on the alignment between international, European adopted and harmonised standards under the Machinery Directive. Instead, we have focused on describing the challenges encountered in our attempt to find the data and providing recommendations for how such data could be generated and reported in the future.

- 1) In order to be able to measure the degree of divergence between international and European standards, there is a need **to develop a systematic data collection that allows for the monitoring of the time past between international publication, date of adoption in Europe (EN) and citation in OJEU (hEN)**. Raw data exists, but the three elements mentioned above are not systematically collected today.
- 2) To increase transparency, **the data provided by the Commission at the Committee on Standards (CoS) meetings and to the CEN-CENELEC Technical Boards on the harmonisation process should be made publicly available to all stakeholders to review**. Currently this information is only available to Member States and Annex III organisations. They could be made available as part of a scoreboard, similar to others already in use (e.g. Single Market and Competitiveness Scoreboard; European Innovation Scoreboard, etc.). Need for granularity in data reporting should be evaluated in an open process involving all relevant stakeholders.
- 3) In addition to agreeing on the three data points to be collected (recommendation 1), **there should be agreement on the methodology for the data reporting**. The use of consistent and

relevant data would be an excellent tool for the Commission and relevant stakeholders to identify priorities at international level.

- 4) To be able to track if amendments of international standards constitute divergence with an impact on the design of the products it covers, i.e. result in a partial decoupling, **we recommend CEN and CENELEC to consider identifying partial decoupling and reporting on the basis of the TCs experts' judgement. At the same time, it should be considered to monitor if newer versions of international standards not yet adopted in Europe constitutes a partial decoupling.** This would increase the knowledge on how and to what extent international standards are amended to become harmonised European standards and help tracking the time needed for the harmonisation of newer generations/versions of an international standard in Europe.

Such a reporting should be included in the scoreboard mentioned in Recommendation 2.

In order to enact these recommendations, **we propose the establishment of a research project to develop a framework for collection and reporting of data in line with the recommendations provided in this report. It should be publicly funded and allow for the engagement of all stakeholders in an inclusive and transparent development process.**

Constant dialogue between the European Commission and CEN, CENELEC and ETSI is needed to ensure that data is consistent.

The ultimate goal would be to have a framework for collection and reporting of data that the data holders and stakeholders understand and interpret in the same way. The data should be reported on a regular basis like the EU scoreboards on other instruments. It should allow for the evaluation of the importance of the individual standards in the market.

On internationally developed and homegrown standards in support of EU legislation

- 5) To recommend to **CEN and CENELEC** to initiate the creation of national **databases of experts** at the NSBs/NC level and use them as the basis for monitoring of the expertise level in European standardisation (the ability to cover relevant standardisation topics, availability of experts, their knowledge, expertise, etc.). Actual information on available experts' resources would allow for better planning of standardisation work, identifying missing capacities and knowledge.
- 6) To improve the link between the legislation and the standards that are to support the EU legislation (hEN), **adjustment of the HAS process could be considered in order to achieve better alignment** already during the standards development process. Thus, deviation from the intended objectives of the legislation and time losses would be avoided.
- 7) The **ESOs should consider developing and implementing internal capacity to support TCs in their work on harmonised standards** with legal expertise and to systematically run quality checks, ensuring compliance with legal requirements.
- 8) To ensure a proportionate system for the request, development and citation of harmonised European standards, **striking a balance between legalistic procedures and efficiency in view**

of ensuring the safety of the products as required by the relevant legislation, while at the same time ensuring the sustainability of the system, keeping it possible to use international standards as the basis for hENs, when this makes sense.

- 9) A thorough **assessment of the current levels of alignment**, the benefits connected to it and the risks associated with decoupling is important to make informed decisions in this sense.

4 Annex I: Proposal for a terminology related to the decoupling and misalignment of European standards and international standards

This paper aims to develop a proposal for common understanding of the terminology linked to the decoupling and misalignment of European standards and international standards. This issue was identified as a challenge during the works of Workstream 4 of the High-Level Forum when participants found that it was hard to clearly identify what the words decoupling and misalignment really mean. In particular, the members of the workstream realised that there are different reasons and ways in which international and European standards diverge and that the use of the word “misalignment” should be avoided because it carries an implicit negative connotation and an expectation that every standard should always be aligned at international level. Instead, it should be replaced by the term “non-equivalence”.

The paper focuses specifically and only on the relationship between international and European standards that are harmonised and cited in the OJEU, although it is possible to also have harmonised standards that are not cited. However, it is important to notice that the vast majority of standards created at international or European level are not part of the hEN framework. These standards remain extremely important for the industry as part of their strategy to deploy their innovation world-wide and constitute up to 94% of all standards.

The benefits of having alignment between International and European standards are several. Standards ensure compatibility which allows companies and consumers to have access to interchangeable products. This element is key in global supply chains where suppliers can contribute to a production line by conforming to a standard and focusing on developing their own specific component, thus increasing product specialisation. Standards also provide fertile ground for innovation. International standards also guarantee easier access to markets and lower administrative burdens and costs for companies. When a product needs to comply with different standards in different regions, it poses a number of challenges from a design perspective and from a conformity assessment perspective. Depending on the level of divergence the product design may need to be changed, possibly requiring different production lines. At the same time, manufacturers may be forced to do multiple testing and keep multiple levels of documentation for the same product. This can result in higher production costs, longer time to market and competitiveness loss.

At the same time, when it comes to harmonised European standards and considering that they grant presumption of conformity with EU law, close alignment between European and international standards may pose risks. In these cases, alignment may not be possible and “healthy” non-equivalence may be needed in light of European values and/or specificities of the European market, including legal requirements for products.

Relationships between European and International standards

This paper is going to describe the different existing relationship between European and International standards. For each relationship type, it provides a description of the reasons, challenges and opportunities related to the decoupling and non-equivalence of European and international standards. Based on those, we provide suggestions for definitions of full, temporal and partial decoupling, respectively.

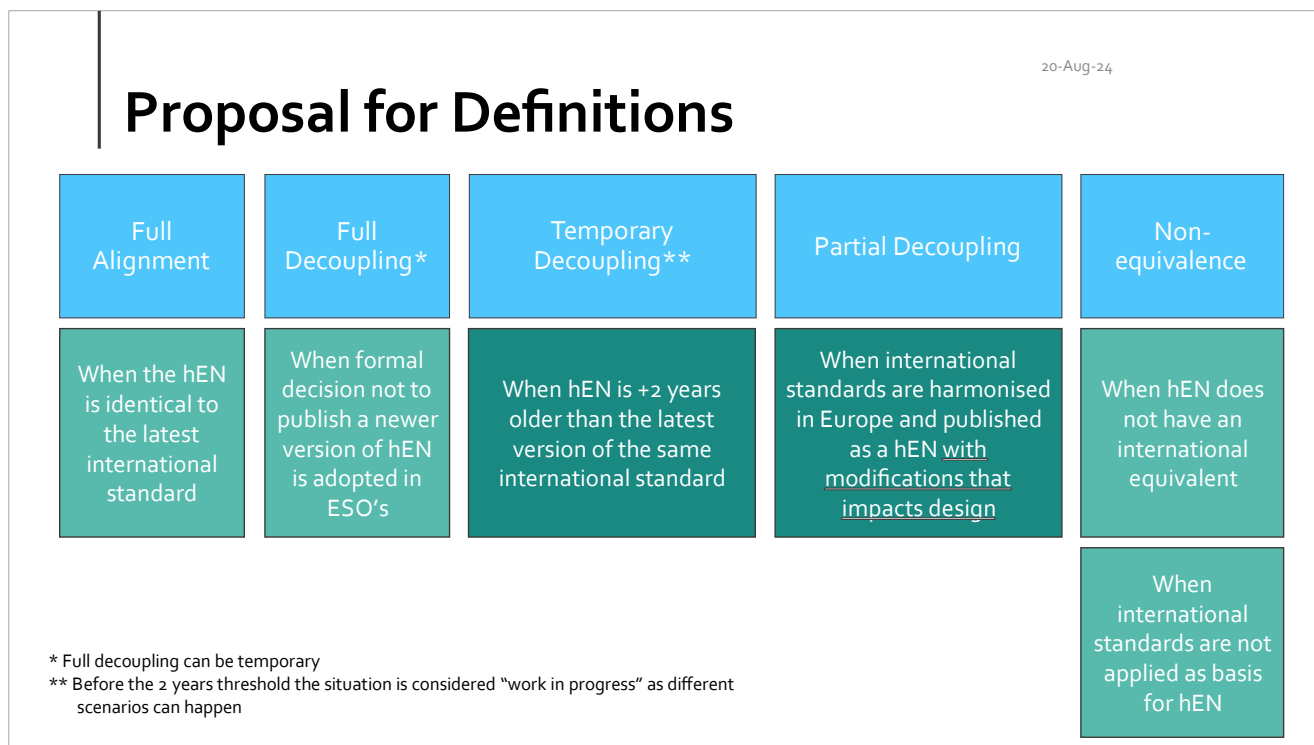


Figure 1 Visual overview of the definitions identified by the HLF-WS4 to describe the different types of relationship between international and European standards

The first relationship can be defined as “**full alignment**”, and it looks like this:

$$\text{ISO/IEC} = \text{EN ISO/IEC} = \text{hEN ISO/IEC}$$

Where ISO/IEC is used as an abbreviation for a standard developed internationally under the Vienna or Frankfurt agreement.

EN ISO/IEC is used as an abbreviation for a standard developed at international level which has been adopted in Europe by CEN/CENELEC. It may or may not have been requested by the European Commission.

hEN ISO/IEC is used as an abbreviation for a standard developed at international level, adopted in Europe as a harmonized European standard and cited in the OJEU granting presumption of conformity with EU law.

Delays in the transposition of international standards to the European system

The adoption of standards from ISO/IEC to CEN/CENELEC normally happens automatically within a short time frame 1-2 months if the standards comply with the European TC's requirements for adoption and/or the EC requirement for harmonisation, but will be delayed if they do not.

The delay can be caused by the following reasons:

1. The international TC responsible for the development decides not to take into account European legal requirements, when the standard under development has the potential to become a hEN, hindering the potential for it to underpin EU legislation.
2. CEN/CENELEC does not have a TC responsible and/or doesn't have the needed resources and/or decides not to appoint a responsible TC and therefore the transposition requires common modifications to make the adjustments needed for the standard to become a European standard, EN or hEN.
3. The standard has been adjusted but has not been able to receive a positive assessment by the HAS consultant and/or the relevant Commission desk officer and therefore needs to be further reviewed. Challenges in getting a positive assessment are:
 - a. Too cumbersome requirements
 - b. Lack of clarity of requirements

Importantly, the delay can occur before the standard is adopted as an EN ISO/IEC or before the standard is adopted as a hEN ISO/IEC regardless of the reason for the delay. As a consequence of the above, decoupling of European and international standards will occur.

The above challenges may also be a reason for deciding not to use international standards as the basis for harmonised European standards (“non-equivalence”).

Full, temporary, and partial decoupling

The wording **full decoupling** should only be used when the ESOs TC has requested not to have a newer version of the standard published in OJEU on a permanent basis and such request has been adopted at the level of the Technical Board (or similar depending on the organization responsible for the development). Such a request can be made for both homegrown standards and standards developed internationally. Both would result in a divergence.

Due to internal processes a certain amount of time is always needed to transpose ISO/IEC standards and their updated versions into ENs and then into hEN.

Thus, an appropriate amount of time should be allowed to pass before one can talk about temporary decoupling. Two years has been suggested as a reasonable amount of time.

During this time the TC would develop the needed modifications, Annex ZZ and other legal requirements, approval for publication and actual publication.

We suggest using the term **temporary decoupling** when more than 2 years have passed from the international publication and the standard is still not cited in the OJEU, regardless of the reason for the lack of citation (rejection or not by the Commission).

Temporary decoupling implies that later versions of the same standard are available internationally compared to the version cited in the OJEU. Depending on the degree of delay it may also imply that a newer generation of the standard is available internationally than at European level. New generations of standards imply an update in the state of the art, often constituting a major change in content and/or structure of the standard. It should be noted that newer versions of standards are not automatically cited as hENs and have to go through the same assessment as the previous version.

When international standards are adopted in Europe and eventually published as hEN they may be accompanied by a European amendment or common modifications and shall be accompanied by Annex ZZ(s). The common modifications can be minor, or they can have an impact on the design of the products covered by the standards. We suggest that, when the modification has an impact on the design of the products, the standard in question is considered as **partially decoupled**.

Therefore, standards can be decoupled in three ways:

- 1) **Fully decoupled** when an earlier version of the standard has been published in the OJEU, but the TC decides not to have a newer version published, requests the deletion to the BT for approval, and the decision is adopted. This decision may be temporary and reversed for a newer version of the standard.
- 2) **Temporary decoupled** when delays beyond 2 years take place between the international publication and the citation in the OJEU.
- 3) **Partially decoupled** when the European amendments or common modifications have an impact on the design of the product the standard covers as compared to its international version.

The above definitions allow for a situation where standards are neither fully decoupled nor temporary decoupled (see case of temporary decoupled standards), in a grey zone which could have multiple reasons and that we could consider as “work in progress”. Furthermore, a standard can be partially and temporary decoupled at the same time.

Non-equivalence

Homegrown standards that are cited in the OJEU are not necessarily adopted internationally. However, sometimes these standards are used by companies internationally with reference to their hEN status (that is granting presumption of conformity with EU law). This scenario can be summarized as:

hEN ≠ ISO/IEC

Such hENs might have an international counterpart which is completely different from the hEN. However, when a hEN doesn't have an international counterpart (yet?), it can represent an opportunity for the European standardisation community to become the standard setter.

Another type of non-equivalence occurs when an international standard already exists and is considered not adequate as starting ground for a hEN on the basis of the Standardisation Request (SReq) issued by the Commission.

ISO/IEC ≠ hEN

This could be the case if an existing international standard does not meet the legal requirements in the legislation as expressed in the SReq or if the TCs in the ESOs evaluate that the (positive) outcome of the HAS assessment is too uncertain. This scenario could result in the development of a new European harmonised standard, which while in line with EU legislation, would force companies trading internationally to apply different standards to their products depending on whether they are sold in Europe or elsewhere. That is also the case if other Regions decide not to align with the international standards.

5 Annex II: Outcome of the data collection on standards under the Machinery Directive

In order to achieve the objectives of workstream 4 (WS4), participants agreed that it was important to collect data in order to establish the degree of deviation between international and European standards adopted by CEN and CENELEC (EN), and ETSI and harmonised European standards. One needs to know the magnitude of a phenomenon to discuss its relevance and evaluate if proposals for improvement are needed. However, to keep the task manageable, it was agreed to only look at a specific standardisation sector: Machinery standardisation, for standard categories relevant for B2B applications. The intention was to look at an area in which European players can boast an historical technological leadership.

Between July and September 2023, the WS4 has been in dialogue with CEN and CENELEC, ETSI, the Commission and experts on machinery standardisation from the Orgalim membership to identify and assess the relevant data. These initial findings have been discussed at a workshop on 11 October 2023. The conclusions of the workshop are available in Annex III.

From the discussions that took place during the workshop, the following conclusions were drawn:

- A common terminology is needed to avoid ambiguities and define the type of data that is needed.
WS4 has developed a proposal for terminology relating to how standards can deviate moving from an international standard towards adoption in Europe and later harmonisation, and standards that have non- equivalence internationally and in Europe respectively. This paper is available as Annex I
- The data collected until then was not enough to determine the degree of decoupling/misalignment and to what extent it constitutes a problem.
Therefore, WS4 attempted to find additional data.

While the need to collect data in a coherent way is relevant for the three ESOs, it is important to highlight that the research carried out in this workstream focused solely on CEN and CENELEC data and processes. ETSI’s standards do not require alignment with international standards as they are international by nature.

Findings from our research:

Deviations between international standards, international standards adopted in Europe and harmonised European standards cited under the Machinery Directive

To our knowledge, neither the ESO’s nor the EC track information on when a standard that is adopted in Europe (EN) and cited (hEN) is first published internationally. Without a collection of this information (which is publicly available) it is not possible to fully identify delays across the whole harmonisation process. Delays in the harmonisation process will impact not only which standards are available internationally, as ENs and as hENs, but also what version or generation of the standard is available at the different stages of the harmonisation process.

As coordinator of WS4 and main lead on the data collection, Orgalim has collected raw data from two technical committees (CLC/TC 116 and CLC/TC 44X) of relevance to the Machinery Directive. The case study showed major time differences in the harmonisation process – from less than a year to more than 10 years. However, a verification procedure also identified inconsistencies in our data collection, which call for further verification and understanding of the different data sources available.

Recommendation 1

In order to be able to measure the degree of divergence between international and European standards, there is a need **to develop a systematic data collection that allows for the monitoring of the time past between international publication, date of adoption in Europe (EN) and citation in the OJEU (hEN)**. Raw data exists, but the three elements mentioned above are not systematically collected today.

Relevant variables that may impact the interpretation of the results (i.e. reasons for delay) should be captured, for instance whether the secretariat of the international TC developing the standard is European or not, what is the composition of the international TC (how many EU members as compared to other countries) and to what extent a mirror European TC exists. It is also important to monitor the time needed for the European adoption by CEN and CENELEC once the standards have been adopted at the international level, as well as the estimated time before the Date of Withdrawal (DOW) included in the European adoptions, which might also impact the timing of the technical uptake of the international standard by European companies.

European standards (ENs) and harmonised European standards (hENs) that have no equivalence internationally may be taken up internationally after adoption. The data collection framework should also track percentages and delays in international adoption of European standards and non-adoption.

Delays between European adoption (EN) and citation in the OJEU (hEN)

In the past two years, ESOs and Commission carried out intensive work to align statistic tools and document the time spent at each step of the harmonisation process in Europe, including time spent for HAS assessment, time gap between final vote in CEN and CENELEC and publication in the OJEU, etc. Those numbers are not publicly available, but they are regularly shared at CoS meetings and meetings with CEN and CENELEC partners.

Monitoring delays in this area is important because the longer the harmonisation process takes the greater the potential of divergence with the newer versions of the standards adopted by international organisations which continue their work to develop state-of-the art solutions by updating the international versions of the standards.

Since we do not have collected data on the dates of international adoption of the hEN's under the Machinery Directive, we cannot conclude how many standards are temporarily decoupled (+2 years from international adoption, according to the definitions provided in Annex I).

The ESO's and the Commission are documenting the reasons for rejection of (draft) standards by HAS consultants. This data can explain the challenges related to harmonisation and be used to identify solutions for improvements. ESOs also track other reasons for delay and this data is available and

usually presented at Technical Board meetings of the ESOs. A checklist has been developed jointly by the Commission and ESOs, which makes it easier to identify reasons and hopefully avoid delays.

CEN and CENELEC keep track of decisions by the Technical Board (BT) to decouple standards that have been meant to become harmonised standards. The data includes information on whether this is considered a permanent decision, or a temporary measure. They may decide to decouple temporarily if the TC has an intention to harmonise a later version of the same standard. However, as CEN and CENELEC record data according to work item and not by standard, the relevant data is not easily identifiable.

Recommendation 2

To increase transparency, the data provided by the Commission at the Committee on Standards (CoS) meetings and to the CEN-CENELEC Technical Boards on the harmonisation process should be made publicly available to all stakeholders to review. Currently this information is only available to Member States and Annex III organisations.

They could be made available as part of a scoreboard, similar to others already in use (e.g. Single Market and Competitiveness Scoreboard; European Innovation Scoreboard, etc.). Need for granularity in data reporting should be evaluated in an open process involving all relevant stakeholders.

Source of standards under the Machinery Directive (homegrown vs. international), type of standards and trends

The European Commission and CEN and CENELEC both report data on the origin of the hENs. But the numbers seem to vary due to different ways of reporting. As showed in Table 1 below, to the best of our understanding, the data is not fully aligned.

One explanation is that CEN and CENELEC count work items (standards, amendments and corrigenda) and amendments and corrigenda always are considered European even though they are made to an international standard. Furthermore, it appears that standards that are requested by CEN and CENELEC to ISO or IEC (not developed in parallel process) are considered homegrown.

Thus, the CEN and CENELEC data suggest a higher percentage of homegrown standards. We do not know whether there are other differences in reporting, for instance inclusion of withdrawn standards or more versions of the same standard. However, we know withdrawal of standards is conducted in different ways by the Commission, and CEN and CENELEC and ETSI, respectively. For the Commission, a withdrawal is when the reference of a harmonised standard is removed from the OJEU, while for the ESOs by withdrawal it is meant when a harmonised standard is replaced by a new version (independently from citation in the OJEU). Despite the discrepancies, it appears both the Commission and the CEN and CENELEC data align on the fact that most harmonised standards under the MD is homegrown.

Table 1: Source of harmonised standards under the Machinery Directive (in percentage of units: standards or work items) – not taking into consideration other possible differences in the datasets

Source	International	European
EC based on 06102023 (OJEU) Number of standards	36	64
CEN and CENELEC on 0825/2023 (Based on CEN and CENELEC data) Number of work items	30	70

The data show⁴ that a higher percentage of standards under CENELEC technical committees are developed internationally than under CEN’s. Therefore, it would be relevant to look at differences between the two organisations, also because they work under different systems and governance structures which may impact the reasons for deviations and delays. In addition, from an industry point of view, it would be important to get data in relation to the different type of standards as their importance varies. For example, under the Machinery Directive standards are divided into three categories: A standards, which are broad horizontal standards, B standards that are linked to specific health and safety requirements in the directive, and C standards that apply to specific types of machinery and refer to the A and B standards. A and B standards are far more important than the C standards for the industry because they have more impact than the C standards on the market. They need to be applied across the board whereas the C standards are only relevant for smaller parts of the market, for instance garden machinery vs all machinery products. To better understand the relationship between European and international standards, we should be able to list where A, B and C standards are developed (see table 2).

Table 2: example of data on A, B and C standards needed.

ISO	CEN	IEC	CENELEC	All MD hEN
A standards	A standards	A standards	A standards	A standards
B Standards	B Standards	B Standards	B Standards	B Standards
C Standards	C Standards	C Standards	C Standards	C Standards
Total ISO	Total CEN	Total IEC	Total CENELEC	Total

A preliminary and non-exhaustive analysis of data conducted by an expert in machinery standardisation based on publicly available European Commission data shows that 90% of hENs under CENELEC/IEC is developed internationally whereas the number for CEN/ISO is 30%. However, when looking at only A and B standards, it appears that 100% under CENELEC/IEC and almost 60% under CEN/ISO is generated at international level. Furthermore, the data suggests that in recent years an increasing number of C-standards have international origin. This result is not aligned with the broader picture (see Table 1) and shows that further granularity in the data collection could help understanding the situation better. A better understanding, in turn, could help the European Commission to identify priority activities at international level and therefore channel resources more effectively.

⁴ CEN-CENELEC, Global Outreach Report, January 2023

The new framework for data collection should prevent confusion in interpreting the data. A consensus is needed as to what specific data elements and parameters need to be reported for the three standardisation phases (international, adopted by national standards organisations in Europe (EN) and cited in the OJEU (hEN)), and how to interpret them. The different approaches applied today i.e. work items (including amendment and corrigendum), standards (including/not including withdrawn standards or more versions of the same standard), origin of a standard or who initiated a work item related to a standard, create confusion and make it impossible to provide a full picture of the state-of-play.

When evaluating the data, it may also be relevant to consider when the standards were developed. Standards under the Machinery Directive have been developed over more than 40 years. The standardisation landscape has changed considerably in that amount of time, both in Europe and internationally.

Recommendation 3

Based on the case study above, we recommend that in addition to agreeing on the three data points to be collected (recommendation 1), **there should be agreement on the methodology for the data reporting. The use of consistent and relevant data would be an excellent tool for the Commission and relevant stakeholders to identify priorities at international level.**

Data on partial decoupling

According to the developed terminology (please refer to Annex I for further information on these definitions) partial decoupling happens when a European amendment to an international standard has an impact on the design of a product. It may also be the consequence of different generations of standards being available internationally and at European level respectively. Currently, data on partial decoupling does not exist and requires expert knowledge to detect. It may be possible to establish retrospectively by involvement of the TC's that developed the standards, but the benefits of this time-consuming activity would probably be too limited to justify the effort. The data could, however, be recorded moving ahead, if the TCs responsible for the adoption and harmonisation process of standards originated at international level are required to do so.

Recommendation 4

To be able to track if amendments of international standards constitute divergence with an impact on the design of the products it covers, i.e. result in a partial decoupling, **we recommend CEN and CENELEC to consider identifying partial decoupling and reporting on the basis of the TCs experts' judgement. At the same time, it should be considered to monitor if newer versions of international standards not yet adopted in Europe constitutes a partial decoupling.**

This would increase the knowledge on how and to what extent international standards are amended to become harmonised European standards and help tracking the time needed for the harmonisation of newer generations/versions of an international standard in Europe.

Such a reporting should be included in the scoreboard mentioned in Recommendation 2.

In conclusion

Despite extensive effort, the workstream is not in a position to report any conclusive data on the alignment between international, European adopted and harmonised standards under the Machinery Directive.

Instead, we have focused on describing the challenges encountered in our attempt to find the data and providing recommendations for how such data could be generated and reported in the future, not only for standards under the Machinery Directive, but across sectors. This work also contributes to illustrate the complexity of the topic and the need for clear terminology all parties involved can agree on.

The workstream believes that the ESS would benefit from better aligned and more detailed datasets which could identify trends in the relationship between European and international standards and help prioritising areas or topics where EU resources are needed.

Therefore, we propose the establishment of a research project to develop a framework for collection and reporting of data in line with the recommendations provided in this report. It should be publicly funded and allow for the engagement of all stakeholders in an inclusive and transparent development process.

Constant dialogue between the European Commission and CEN, CENELEC and ETSI is needed to ensure that data is consistent.

The ultimate goal would be to have a framework for collection and reporting of data that the data holders and stakeholders understand and interpret in the same way. The data should be reported on a regular basis like the EU scoreboards on other instruments. It should allow for the evaluation of the importance of the individual standards in the market.

Based on what our exercise highlighted, the workstream advises against collecting data retrospectively on the standards used in support of the Machinery Directive.

Based on individual cases we have seen from other sectors and the great divergence in the data even under the Machinery Directive, we expect that future datasets built following our recommendations will provide very different results and trends, depending on the legislation. This should be taken into account when developing the scoreboard.

6 Annex III: Conclusions of the WS4 workshop of 11 October 2023

Objectives of HLF Work Stream 4

Work Stream 4 of the High-Level Forum (HLF) – led by Orgalim and comprising a group of interested HLF members across the whole stakeholder spectrum – explores the "international first" principle, examining its impact on open strategic autonomy and technological sovereignty, and considers solutions to ensure that international standards align with the EU Single Market's unique requirements, especially in new technology areas where EU values are at stake.

Report of the in-person workshop

The in-person workshop took place on 11 October 2023 and saw the participation of 27 experts from the European Commission, national authorities, the three ESOs, industry, civil society and academia. The objective of the meeting was to analyse and discuss in more depth the processes around alignment between European and international standards, looking in particular at two aspects: the issue of decoupling of harmonised European standards (hENS) from international standards, taking the example of machinery standardisation, and the increased focus on EU values when it comes to the development of standards for new technologies, taking the example of AI standardisation. The full agenda of the meeting is available as an annex to this report, however for the sake of better representing the discussions, the report will not follow the structure of the agenda and simply provides an overview of the two topics considered.

Decoupling of harmonised European standards (hENS) from international standards

At the beginning of the meeting, it was stated that in order to be able to talk about *decoupling*, it was important to clarify what is considered decoupling. A draft proposal for definitions was therefore showed to participants who had the opportunity to discuss it during the breakout sessions.

Possible Definitions

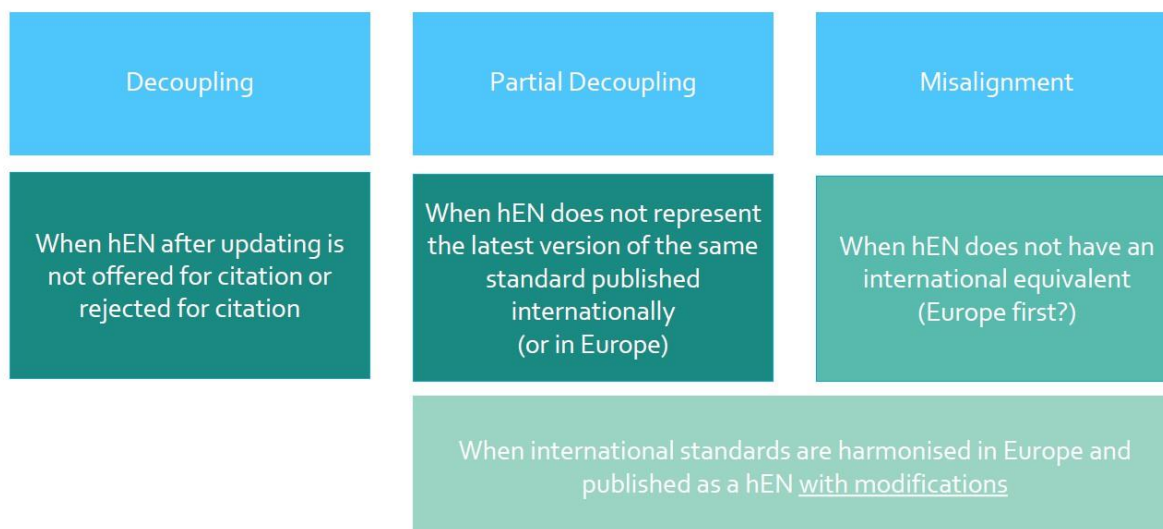


Figure 2 - Draft proposal of definitions of the terms "decoupling", "partial decoupling" and "misalignment". These definitions have changed in the final version which is included in Annex I

The proposed definitions were developed by Orgalim in the process of collecting data to quantify the degree of misalignment between European and international standards, where data illustrated different kinds of deviations between European and international standards. The draft definitions looked at the situation from the manufacturers' perspective, particularly when they trade products internationally and look at the availability of standards and the number of standards that they need to comply with. The definitions do not consider standards developed in consortia or other regional standardisation systems, as they are not a viable source for harmonised standards published in OJEU.

These definitions have been proposed as a starting point for the workshop discussion.

During the plenary session, participants heard the presentations from CEN and CENELEC on the functioning of the Frankfurt (IEC/CENELEC) and Vienna (ISO/CEN) Agreements. The presentations highlighted differences in how alignment is done through the two agreements, with the Frankfurt agreement allowing for CENELEC to automatically start parallel work as soon as there is a new item initiated at IEC level. In the case of the Vienna agreement, on the other hand, there exist different layers of cooperation between ISO and CEN. The full presentations, including on the data collected, are available in the master deck uploaded in the Wiki.

Furthermore, CEN-CENELEC and Orgalim presented the data collected until then, showing the situation of standards in the machinery sector and pointing at specific cases in other sectors which outlined challenges that might exist also in the machinery sector, but further data would be needed to ascertain that. Participants agreed that the data presented during the workshop can provide for hypothesis to be tested and that, once the group agrees to the definitions, it will be easier to search for more data.

Summary of discussion in the breakout sessions (groups 1 and 2)

There seems to be agreement that the words *decoupling* and *misalignment* cover different types of deviations between international and European standards and that a common understanding of what is what is needed.

One group suggested major changes in the proposed definitions, with partial decoupling becoming misalignment and misalignment being referred to as “international first” for strategic reasons. The other group agreed on the overall definitions with minor modifications. However, after the presentation of each group’s conclusions and a brief exchange of views, it seemed that both groups could agree to the proposed definitions, although with some changes. In the below summary, the definitions above are used as a reference.

As a starting point, it should be clarified that both *decoupling* and *misalignment* are linked to the additional constraints and delays generated by the European process to turn ENs into hENs (Standardisation request, assessment by a HAS consultant, citation). The European process may be considered too slow compared to market needs or present too many obstacles before reaching the OJEU citation. Moreover, consensus needs time and often European experts feel that they do not have the necessary time to adapt the international standards to the European requirements.

Decoupling

- It should be clarified that by the term decoupling it is intended that an international standard, as published internationally and transposed into an EN, does not provide presumption of conformity in support to European legislation anymore.
- When talking about decoupling it is necessary to distinguish the case in which the standard is rejected by the HAS consultant or by the European commission (after a negative assessment), from the case in which the standard is not offered to the Commission for citation by the relevant Technical Committee (TC) of CEN CENELEC or ETSI.
- Reasons mentioned for the TC to decide not to seek publication include fear of rejection by the Commission and need to have faster access to the standard even though it complied with new European requirements. It was mentioned that, in the case in which a new version of the standard is needed quickly, the process required for citing in the OJEU (assessment by a HAS consultant, citation) may be considered too long compared to market needs or present too many obstacles before reaching the OJEU citation.
- Decoupling requires the relevant TC to get approval from the Technical Board (BT) to do so. When such a decision is made by the BT, the decoupling should be considered permanent or at least not of temporal nature anymore.
- It was agreed that only standards which were “coupled” before (i.e published in the OJEU in a previous version - with or without modifications), can “decouple”.

Partial decoupling

- There is agreement that partial decoupling can be of temporal nature while waiting for the international standard to be published as an EN.
- Given that time is needed to transpose the international standard into a European standard, it was suggested that a certain amount of time between the publication as international

standard and the publication as an EN should be allowed before considering that there has been partial decoupling.

- Two years was suggested as realistic framework to ensure a newer generation of an international standard to be published in the OJEU before talking about partial decoupling.
- Partial decoupling can also happen when modifications from the international standard are needed for it to be published in the OJEU. The modifications can be purely administrative or provide for different technical requirements. In the latter case, the decoupling relates to the content.
- Partial decoupling can have both a temporal and a content-related component.

Misalignment

- Misalignment can happen when a hEN has no equivalent at the international level (technical misalignment). All “homegrown” European standards correspond to “misalignment” because there is a priori no equivalent at the international level.
- Misalignment can represent an opportunity, as it offers the possibility to promote a European standard at international level, or it can be a source of constraint because the standard may contain restrictive provisions not needed for global market access.
- Misalignment is more prominent in those sectors in which regulations are different from country to country around the world (e.g. on machinery). This is often the case when there are different approaches to safety, and it explains why there are few international standards related to machine safety.
- Misalignment between standards in Europe and internationally does not require that a previous version of the standard had been published before.
- When there is misalignment, there is a hEN that grants presumption of conformity in Europe, but there is no equivalent in the ISO/IEC/ITU. Therefore, a European company that trades their products internationally will experience misalignment as they will need to design their products in a way that is in line with both the hEN, for the EU market, and the other international standard for the international market.

Challenges/consequences with decoupling and misalignment

- Uncertainty of manufacturers and challenges related to conformity assessment.
- Notified bodies and market surveillance authorities may also be uncertain which standards to apply; whether they should use the latest version of the standard available at international level but not cited in the OJEU, or the older version cited as a hEN. This consequently brings legal uncertainty for companies.
- When there is a delay/gap between the development of an international standard and its transposition into a hEN, there may be a competitive disadvantage for European companies as companies in other countries may already develop products based on newer standards and place them in their domestic markets, thus gaining experience. This would not be the case for European companies, thus risking lagging behind.
- Sometimes the delay in the transposition of international standards into hENs cited in the OJEU also result in a situation where the published standard does not represent state-of-the-art. If the standard cited has been subject to a revision at international level, presumably better adapted to the market, manufacturers face a situation in which the old standard

continues to grant presumption of conformity, while the new international version better corresponds to market needs.

- The added value of citing a standard in the OJEU lies in the presumption of conformity that it grants in relation to the essential health and safety requirements established in the legislation. Nevertheless, standards not cited in the OJEU (85% of CEN and CENELEC standards) are even more important for the industry and exporting these standards internationally should also be a priority for the EU strategy.
- Lack of inclusiveness in the development of international standards is a challenge which is brought into the European system as well, in light of the international first principles.
- For environmental organisations in Europe, it is more important that the standard reflects high environmental ambitions and democratic values rather than alignment with international standards.
- The participation of societal stakeholders (consumers, environmental protection associations), to normative work, which is essential for the quality of the standard, is easier at European level (homegrown standards), where they are recognized. At the international level, they are still poorly accepted.
- Harmonized European standards transposed from international standards can be criticized for not having been developed taking into consideration inclusiveness principles.

Who benefits from alignment

Alignment between European and international standards is beneficial to industry, market surveillance authorities and ultimately the European economy.

Alignment is important to standardisation organisations as well, since they avoid duplication of work and can focus on faster development.

EU values and the development of standards for new technologies

During the plenary session, DG GROW presented the European Commission approach to international standardisation. It was explained that the EU takes an *ex-ante* approach to standardisation, while many other countries, including the US, take an *ex-post* approach, meaning that they design the law first and then they screen the standardisation landscape to identify the standards that are better suited to their needs. In the latter approach, standards used could be from ISO and IEC, but also from other standardisation organisations such as ASTM, 3GPP, etc. The EU approach has many advantages, but it also amounts to increased constraints for standard development and it is a political choice whether we should keep this approach or not.

DG GROW pointed to the fact that it is not clear to what extent international standards developed by ISO and IEC really provide access to global markets, given that regulators around the world may use different standards for their legislative requirements. It was also mentioned that discussions with international counterparts on standardisation continue on a regular basis and that getting other countries to commit to recognising ISO, IEC and ITU standards only is often highly debated.

For the European Commission, the first priority is to ensure that products in the Single Market are produced in a way that is right for European citizens and that respect EU values. As a second step, the focus is to try and ensure to the extent possible that there is coordination and alignment at international level. The case of AI standardisation provides a good example of how the Commission is

proceeding in new technology areas. Europe is the first region developing legislation to regulate AI and the Commission made a strong commitment to use standardisation for the technical implementation of the legislation. Through ISO/IEC JTC21, they are looking at existing standards within ISO and IEC with the aim of ensuring alignment as much as possible.

The HLF can play an important role in advising the Commission on areas in which international standardisation is really key. As an example, in the case of the Raw Materials Act, the members of the HLF voiced the importance of aligning to international standards and the Commission is following this recommendation.

DG GROW also provided an overview of the international standards cited in the OJEU. Currently, there are approximately 3650 standards cited in the OJEU in support of legislation. 656 come from ISO, 823 come from IEC and 600 have been developed by ETSI. The rest of the standards cited are homegrown, but there's no data available on the reasons why that's the case.

In the past year, the Commission and the ESOs have established a Task Force on Timely European standards for a Green and Digital, Single and Global Market, which addressed several issues in the Public-Private-Partnership (PPP). The solutions designed within the TF are now being rolled out. The main measures identified include: 1) faster development of clearer standardisation requests (sReq); 2) involvement of HAS consultant early in the process; 3) first legal quality checks carried out by CCMC; 4) fast-track process to speed up the citation.

Looking at international alignment, the Commission is trying to put in place similar processes with ISO and IEC for those items that are important for European legislation and has appointed considerable resources to participate in relevant ISO IEC committees, including from the Joint Research Centre (JRC). While this process is more difficult, there is now an understanding from the international standardisation organisations as well that cooperation on the development of standards is to the benefit of all parties involved, as international standards cited in the OJEU provide access to the biggest market in the world.

DG GROW concluded that, whenever possible, the Commission is fully committed to align European and international standardisation, but not to the expense of EU values and fundamental rights.

DG CNECT presented the work on AI standardisation and how the Commission is looking at alignment with international standardisation in this area. He explained that the Commission reached out to ESOs at a very early stage of the legislative process of the AI Act, in order to start working on the standards needed to support the legislation. Thank to this work, the Commission finalised the first AI sReq in May 2023. The objective is to have standards available for when the legislation will enter into application. Similarly to what stated by GROW and CNECT confirmed that the Commission is making efforts to ensure alignment with international standards, although they will not compromise on EU values and fundamental rights, which need to be safeguarded as a priority.

According to his experience, the work carried out at international level often covers the basis for most of the requirements in the AI Act, but in many cases adjustments are needed to align with the legislation.

Further information on the progress of AI standardisation activities is available in the master deck [uploaded in the Wiki](#).

Summary of discussion in the breakout sessions (groups 3 and 4)

Groups 3 and 4 took very different approaches to the discussion on EU values and international standardisation. The below summary is an attempt to merge the main highlights of both groups.

Alignment between AI standardisation at European and international level

- The alignment on AI standardisation is falling under the Vienna agreement (ISO/CEN) because the secretariat in charge of JTC21 belongs to CEN. Because of the more layered structure of the Vienna agreement as compared to the Frankfurt agreement, one group found that alignment in this case may be more difficult.

EU values in standards

- One group clarified that fundamental rights and EU values should not be treated as synonyms. Fundamental rights refer to the EU Charter of Fundamental Rights, whereas European values are described in Article 2 of the Treaty of the EU. Most countries globally agree with the fundamental rights, but it is through the balancing / prioritisation of the rights that values occur. Values hence differentiate and de-fine preferences between the rights.
 - Fundamental rights are typically not addressed by standards. Both groups agree that with new technologies, including AI, there is a challenge to recruit the right expertise (e.g. ethics and AI experts)
 - It was also clarified that the sReq doesn't require standardisation experts to define EU values or fundamental rights, but rather to apply those rights when developing the standards.
 - The AI-Act itself provides the guarantees that European values are included, whereas the standards allow the providers to conform with the requirements.
 - Standards should define methods for AI system providers or deployers to determine trade-offs between European values. These trade-offs may depend on the use cases and may be defined by legislation at the European, national, regional, or local level.
 - In order for the technical experts to be able to implement the fundamental rights in the technical specifications, political decisions on e.g., preferences / balance / trade-offs must be made clear. This can be done through literature studies that map the balancing of fundamental rights already present in other areas or discussions. If this is not possible, the standards can be made configurable so that it is the 'deployer' who decide on the application.
 - Differentiation must be made between political level (discussion among EU members on EU values) and technical level / implementation via standardisation (where experts from all over the world can be involved, also in ESO's)
-
- Differences between AI standardisation and other more traditional sectors
 - NFL compliance used to look at safety of products, now it also regulates services / software, the technology of which is rapidly evolving (moving target)
 - Traditional standardisation is usually vertical and specific per sector. New digital regulations are often horizontal and applying to a large number of products (CRA, AI, Data, RED)

Benefit of European approach to AI standardisation

- The fact that the EU is following the New Legislative Framework to develop technical solutions in line with the legislation shows commitment to the ESS and trust in the know-how of industry. The alternative, that is the use of common specifications, would be a suboptimal approach
- The fact that the EU is maintaining the “international first” approach to AI standardisation by looking at all existing standards and taking all that are compatible with the sReq, is also positive
- The EU focus on trustworthiness and values could become a quality feature for EU-developed standards. This could be an opportunity and result in a competitive edge for EU industry

Challenges of European approach to AI standardisation

- Speediness is an issue: on one hand, there is political pressure to implement legislation quickly; on the other there are only a few existing standards and SMEs and societal stakeholders are put under pressure, to the detriment of the principles of inclusiveness and openness
- Financing of participation of required experts, including ethical experts and societal stakeholders
- Lack of skills, especially of ethic experts

Recommendations

- Societal representation should be adequate when dealing with questions lined to fundamental rights and EU values, and, therefore, appropriately funded
- A differentiation should be made between B2B and B2C products and the needs of different users
- Lessons can be learnt from sectors in which the interconnection between AI and EU values has already been tackle (e.g. medical devices) and from past experiences where horizontal and sectorial standards were needed (e.g. cyber security).
- Common specifications should be avoided. They go against one of the principles of the NLF, which is about industry involvement and they do not ensure the market relevance of standards, which is essential for standards to be used by manufacturers
- In order to speed up the process of developing standards for the AI Act, a staggered approach should be considered. Notably, horizontal standards should be developed first, followed by vertical standards for the various product groups.
- To better align technical and political ambitions in international standardisation, European standardisation experts in ISO, IEC and ITU need to be aware, mindful and supportive of the EU goal of promoting EU values in standardisation (an example of an EU-funded project in this sense is Blockstand on international blockchain standardisation)
- In order for the technical experts to be able to implement the fundamental rights in the technical specifications, political decisions on e.g., preferences / balance / trade-offs must be made clear. This can be done through literature studies that map the balancing of fundamental rights already present in other areas or discussions. If this is not possible, the standards can be made configurable so that it is the ‘deployer’ who decide on the application.

Conclusion and next steps

As a conclusion of the workshop, it was agreed that supporters of workstream 4 will engage in further discussions to decide on the terminology to be applied. The definitions will also help defining what additional data should be collected. The decision on the data collection should take into account the following elements:

1. Availability of data and ease of collecting them.
During the workshop it became apparent that we do not have the necessary data to determine the degree of decoupling/misalignment and to what extent it constitutes a problem. It was also considered that, while this workstream focusses on machinery standards, it would be relevant to look also across different sectors as the outcomes may differ.
2. The current transition phase for machinery standards which are in the process of being updated on the basis of the new MR and the question of relevance of historical data.
3. How/whether the data can contribute to a successful update of published standards under the MR.

Next steps on the topic of EU values and the development of standards for new technologies were not agreed during the workshop. The members of the Work Stream will be asked to decide on the way forward on this part of the project at the next meeting.