

Webinar 13. oktober 2021

Harmoniserede standarder og ny tjekliste



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Praktik

- I løbet af webinarret kan I stille spørgsmål i chatten. Vi besvarer spørgsmål efter hvert emne.
- Til sidst i webinarret har vi afsat et kvarter til at samle op på yderligere spørgsmål eller kommentarer som I kan skrive i løbet af webinarret.
- Vi sender vores powerpoints ud til deltagerne efter webinarret
- Vi optager webinarret og vil evt. lægge det op på DS hjemmeside, sådan så I kan gense enkelte dele eller evt. anbefale det til andre eksperter i jeres udvalg.



Program

- Ny Metode – baggrunden for brug af standarder i forbindelse med europæisk lovgivning
- HAS-konsulenterne, hvordan og hvornår inddrages de?
- Den nye tjekliste og vejledningsmateriale
- Internationale aspekter – hvad er vigtigt?
- Offentliggørelse i EU's Lovtidende
- Spørgsmål og opsamling



Hvad er det særlige ved harmoniserede standarder?

– Og hvordan bruges de i forbindelse med europæisk lovgivning?

Standarder er frivillige indtil nogen sætter dem i kraft!

Standarder sættes i kraft på 3 måder

- Aftale mellem 2 parter
- Dansk Lovgivning, love, bekendtgørelser, regler
- EU-lovgivning, Direktiver, CE-mærkning



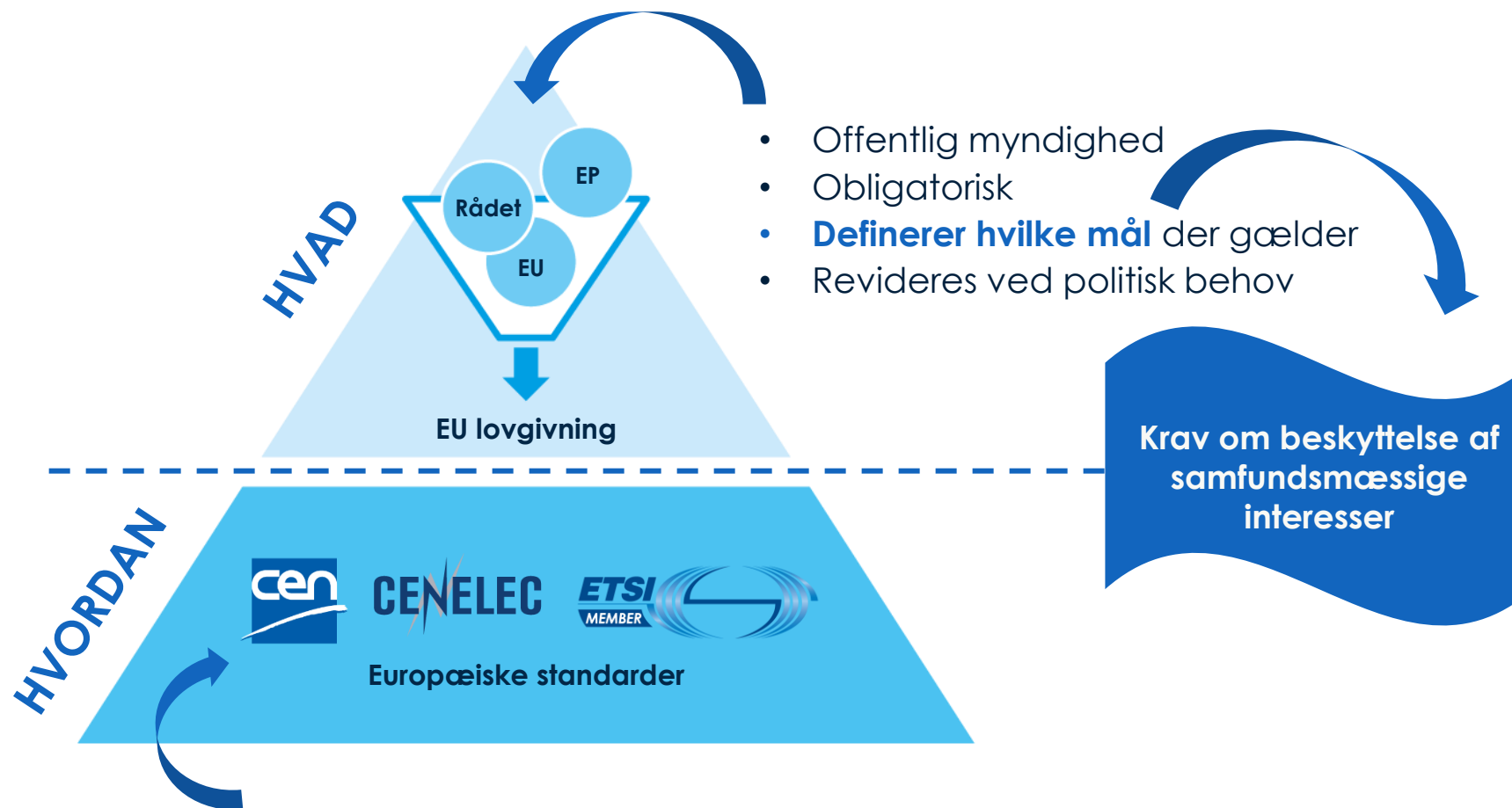
Andelen af CEN CENELEC-standarder som er harmoniserede

14 %

af CEN CENELECs standarder er
harmoniserede standarder

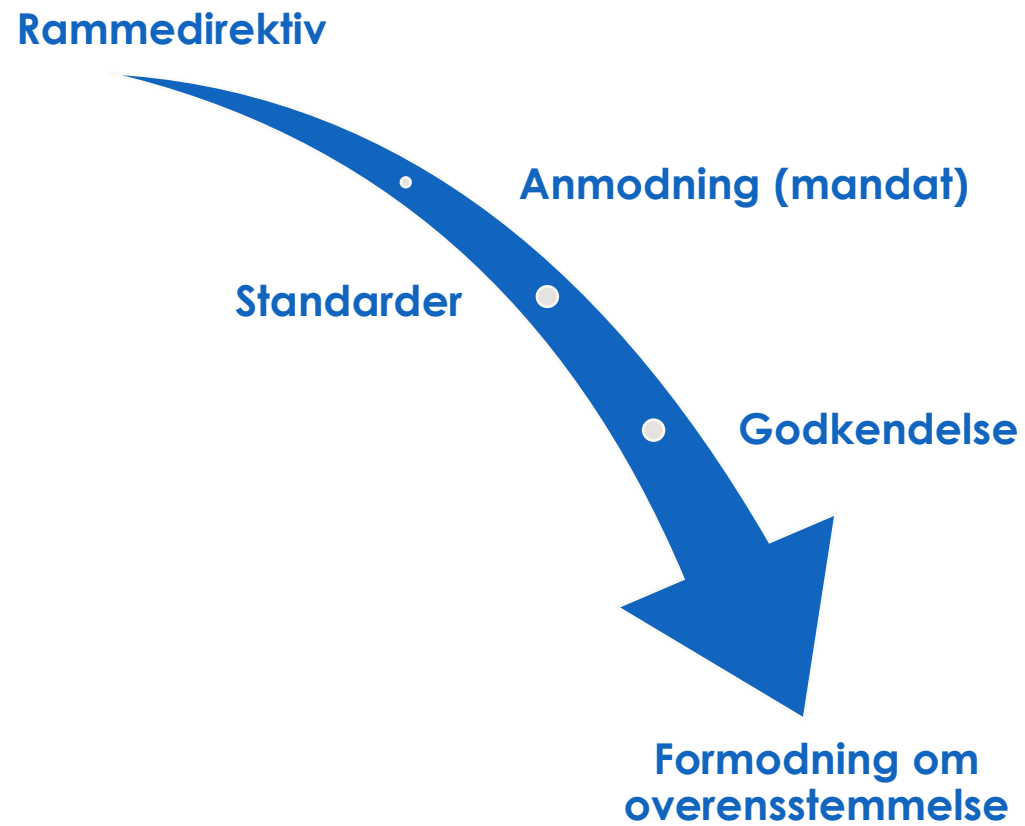


EU's harmoniserede lovgivning for produkter (Ny Metode)

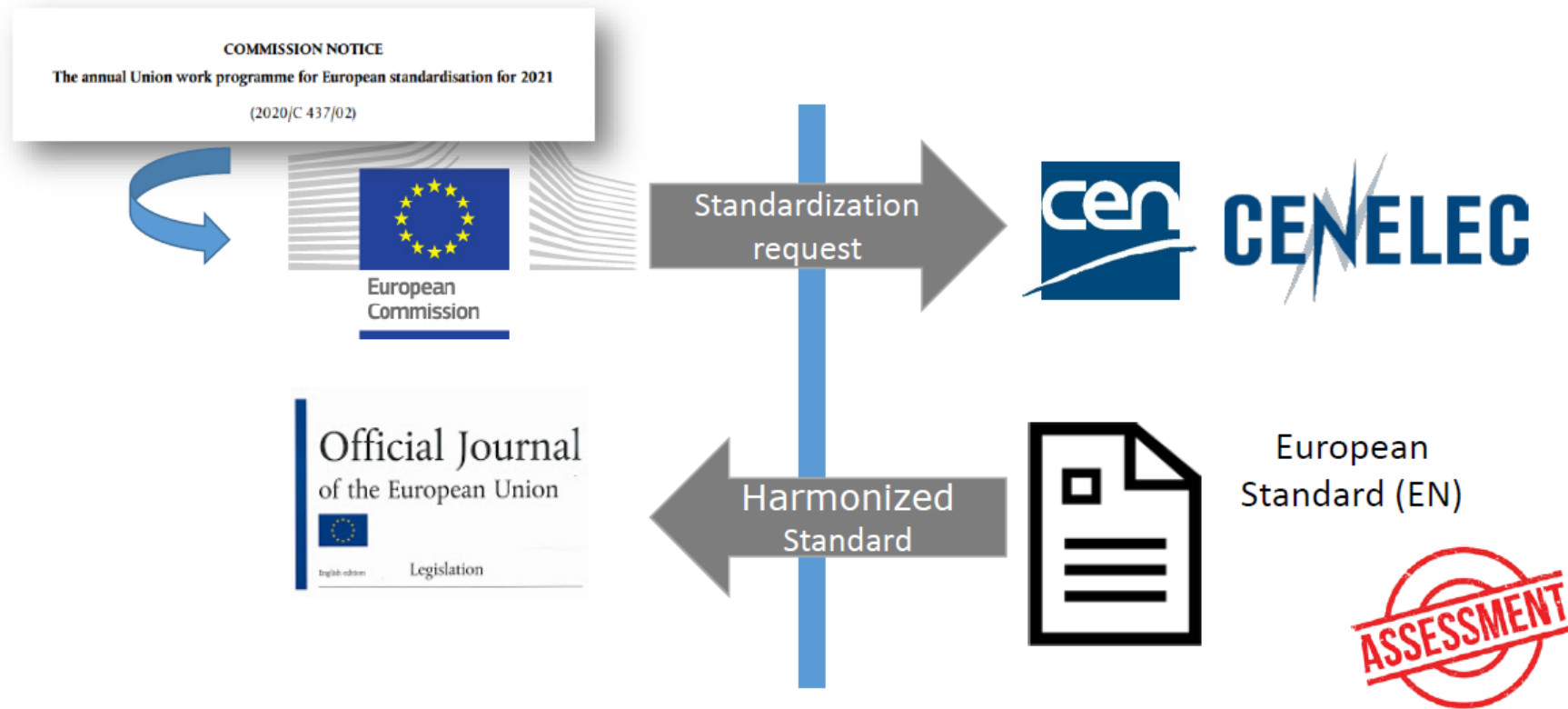


Ny Metode

– fra direktiv til produkt på markedet



Standardization Requests – Process



Standardization Request a **precondition** for citation of harmonized standards in OJEU

Harmoniserede standarder

Kendetegn

- Vurderes med henblik på overensstemmelse med EU lovgivningen
- Obligatorisk annex ZA/ZZ som redegør for overensstemmelse med lovgivning
- Først når en henvisning til standarden er offentliggjort i EU's lovtidende (OJEU) giver standarden formodning om overensstemmelse
- Anvendelsen af harmoniserede standarder er fortsat frivillig, man har også ret til at vise overensstemmelse med lovgivningen på andre måder

Drafting European standards for citation in the OJEU

This page provides guidance to Technical Bodies and Working Groups (WGs) on horizontal aspects to be considered when preparing harmonized European standards in support of EU harmonization legislation intended to be cited in the Official Journal of the European Union (OJEU). Information on the HAS process and how to interact with the HAS consultants can be found on the page [HAS assessment process](#).

Regulation (EU) No 1025/2012 on European standardization defines a harmonized standard as “a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation”.

1 PREPARATION OF NEW WORK ITEM

The starting point for the development of a harmonized European standard is the request for a standard in the scope of the relevant EU harmonization legislation which was accepted by the Technical Boards.

If it is covered, the development of harmonized European Standards.

3 HORIZONTAL TRAINING MATERIAL

This section lists available horizontal training material.

- › 2018-04-18: [The HAS consultant framework](#) (10-10 webinar)
- › 2018-06-06/13: [Dedicated HAS consultant framework webinars](#) (10-10 webinar)
- › 2018-07-12: [CEN-CENELEC Workshop – preparation of harmonized standards](#)
- › 2019-05-10: [Use and justification of normative references for harmonised standards](#) (10-10 Webinar)
- › 2019-11-08: [Risk assessment in standards tool for harmonisation](#) (10-10 Webinar)
- › 2020-12-10: [Annual training session dedicated to newly appointed CEN & CENELEC TB officers](#)
- › 2021-06-29: Webinar 'Harmonized European standards (hENs): Drafting standards compliant with EU legislation' (see [Part 1](#) and [Part 2](#) videos)

4 TEMPLATES

- › [Checklist - Generic](#)
- › [Annexes ZA](#)
- › [HAS Assessment report - Generic](#)
- › [HAS Assessment report - CPR](#)
- › [HAS Assessment report - Machinery](#)

5 SECTORAL GUIDANCE

[Forms & Templates](#)

[Related decisions](#)

[Reference document](#)

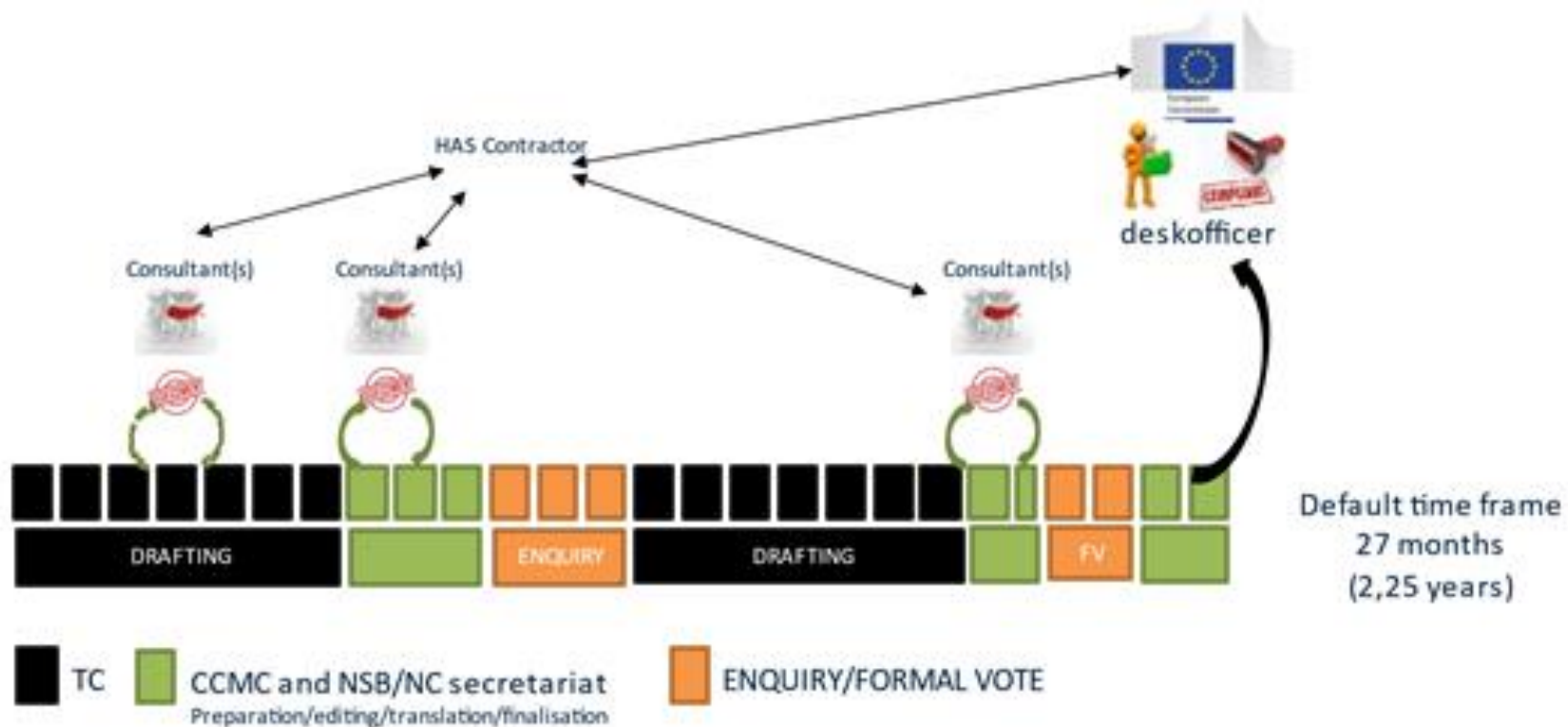
[Internal Regulations](#)

Samarbejdet med HAS-konsulenter

– Og hvordan bruges de i forbindelse med
europæisk lovgivning?

https://boss.cen.eu/developingdeliverables/pages/en/pages/has_assessment_process/

Udvikling af harmoniserede standarder





HAS-konsulentens funktion

- Vurdering af overensstemmelse mellem lovgivningens essentielle krav og standardens tekniske løsninger
- Kun for standarder med mandat (Standardisation request)!
- Vurderingen fungerer som rådgivning til EU-Kommissionen
- Den er ikke bindende for EU-Kommissionen

HAS-konsulentens opgaver

- Vurdering af standardiserings dokumentet baseret på
 - Lovgivning
 - Mandat
- Bidrage til at dokumentet kan blive "Compliant" gennem rådgivning
- Konsulenten må ikke skrive tekst til standarden

Assessment report

HAS-konsulentten skal udfylde vurderingsskemaet og vurderingen kan enten være:

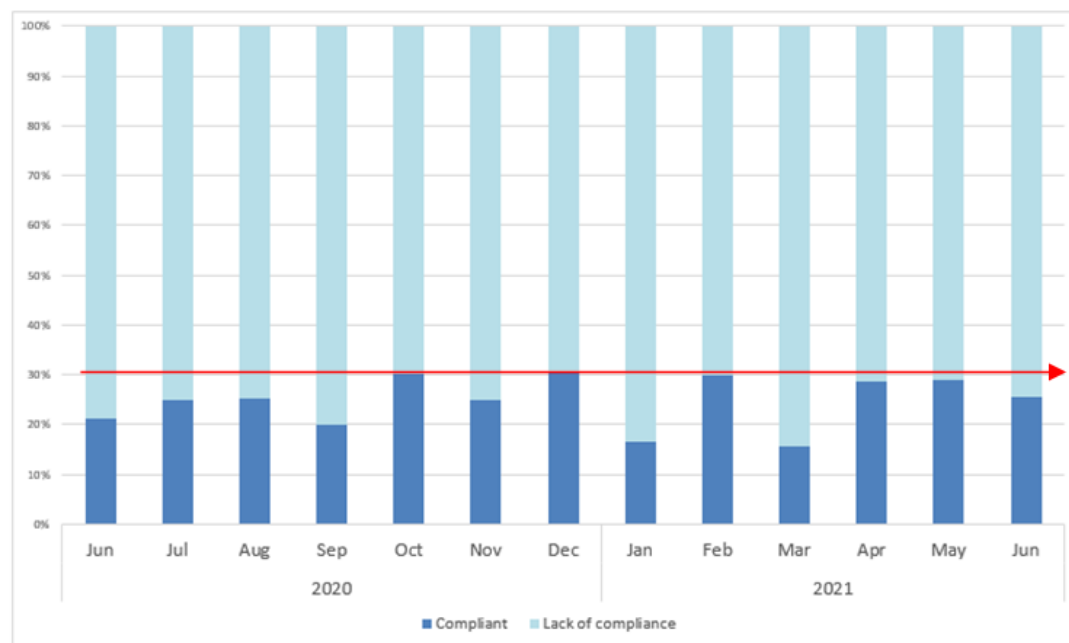
- Compliance 
- Lack of compliance 

*Det er vigtigt at eksperterne arbejder med de bemærkninger der kan stå i afsnittet:
Critical findings leading to a Lack of compliance'*

Assessment report under service contract SI2.770800 ¹	
Date of the report	XX/XX/20XX
Nature of the report	<input type="checkbox"/> Initial report <input type="checkbox"/> Reviewed report after the initial report was challenged by ESO
Internal reference	Indicate the reference of the work order from EY
Assessed document standard reference and full title including date or version of the document	
ESO work item reference	
Main objective and purpose of the assessed document, including its relation to other standards within the 'harmonised context' describe briefly to set the context under which the assessment was carried out	
Relevant normative references partly or fully verified and assessed give actual dated reference numbers of those standards checked or assessed as part of this assessment	
Nature of the assessed document	New project / Revision of Harmonised standard or a standard that was cited under GPSD / Revision of a standard that was not cited If the draft amends a standard that was cited or non-cited under the relevant Union legislation, please provide information on this, in particular when Lack of Compliance is based on this situation
ESO technical body	Reference of the Technical Body
ISO/IEC in lead	<input type="checkbox"/> No <input type="checkbox"/> Yes
Assessment phase	Phase at which the draft is assessed
Regulated aspects covered by this assessment report	(1) <input type="checkbox"/> All aspects (2) <input type="checkbox"/> All other aspects except (give those excluded) _____ (3) <input type="checkbox"/> Only (give the aspect(s) assessed) _____
Legislation supported indicate legal act reference(s), its short title (or acronym) and relevant articles and/or annexes supported	Indicate which is the legislation that is being assessed here (e.g. Directive/Regulation XXXX/XXXX, Short title, Article X/Annex X) If the aspects assessed have a link with another legislation (e.g. electrical safety for LVD and RED) indicate whether a coordination took place or not
Standardisation request(s) give reference number and relevant point of a request	Indicate the Standardisation Requests corresponding to the legislation above (i.e. the one that is being considered in this assessment.) [e.g. M/xxx, Annex I point 3 of Table 1]
Consultant(s) involved	Name of the consultant
Commission service(s) DG/Unit	DG GROW/Unit XX or DG SANTE/Unit YY

Udviklingen for harmoniserede standarder

Knap 30 % compliant de sidste 12 måneder



Graf: HAS-konsulent vurdering per måned

34 % compliant siden introduktionen af HAS-konsulenter

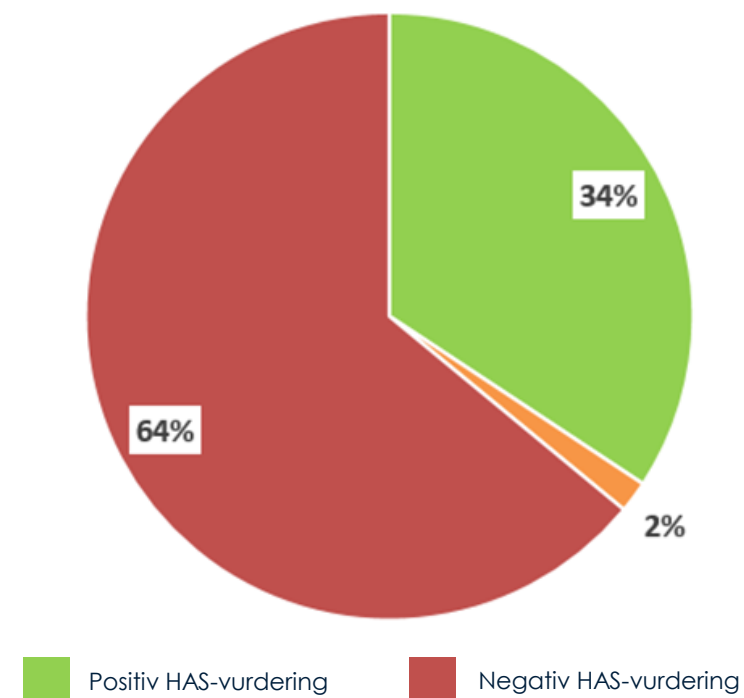


Diagram: Resultat af HAS- konsulent vurdering for CEN og CENELEC (01.04.2018 – 30.06.2021)

Den nye tjekliste

– Hvad er baggrunden for den og hvilke elementer indeholder den?

Tjeklisten

Tjeklisten er obligatorisk at medsende når en et udkast til standard sendes til CCMC til Høring eller Formel afstemning

<https://boss.cen.eu/developingdeliverables/pages/en/pages/enforojeu/>

Checklist – Items to be considered when drafting standards answering a Standardisation Request and to be offered for citation in the OJEU

This checklist was prepared following the format of Internal Regulations CEN/CENELEC Part 3 – Annex A “Checklist for writers and editors of document”. All CEN/CENELEC standards and deliverables shall follow the provisions of IR 3.

This checklist is applicable for all sectors, except construction.

This checklist shall be fulfilled before dispatch for:

1. the First Working Draft for optional assessment (if any),
2. the draft for Enquiry,
3. the final draft for Formal vote,
4. In case of lack of compliance assessment, a new optional assessment after Formal vote (PUB assessment).

The Technical Committee secretary in CEN and the Technical body secretary / Reporting Secretariat in CENELEC are responsible for ensuring that the checklist below is filled out and submitted to CCMC with the draft candidate harmonized standards and their supporting documents/justifications where relevant. In CEN, the [matrix of responsibilities](#) shall be followed (see decision BT C081/2018).

It is strongly recommended to use of the checklist for the drafting of harmonized standards in support of EU Legislation under VA and FA (with ISO or IEC lead).

	Check the following questions – if you answer yes to all the questions, the draft is probably ready for submission to CCMC (and HAS Consultant assessment).	Check
General	Is this draft standard listed in a Standardisation Request / covered by a Mandate? Is this reflected in Projex-online database? <i>NB: This information is normally already provided in the NWIP form.</i> <i>NB: If not, contact the TC secretariat. A possible way forward is to propose to the European Commission to add this work item in a (revised) Standardisation Request. This is not applicable if the standard is covered by an open Mandate (e.g. M/396 Machinery)</i>	<input type="checkbox"/> <input type="checkbox"/>

Tjeklistens elementer

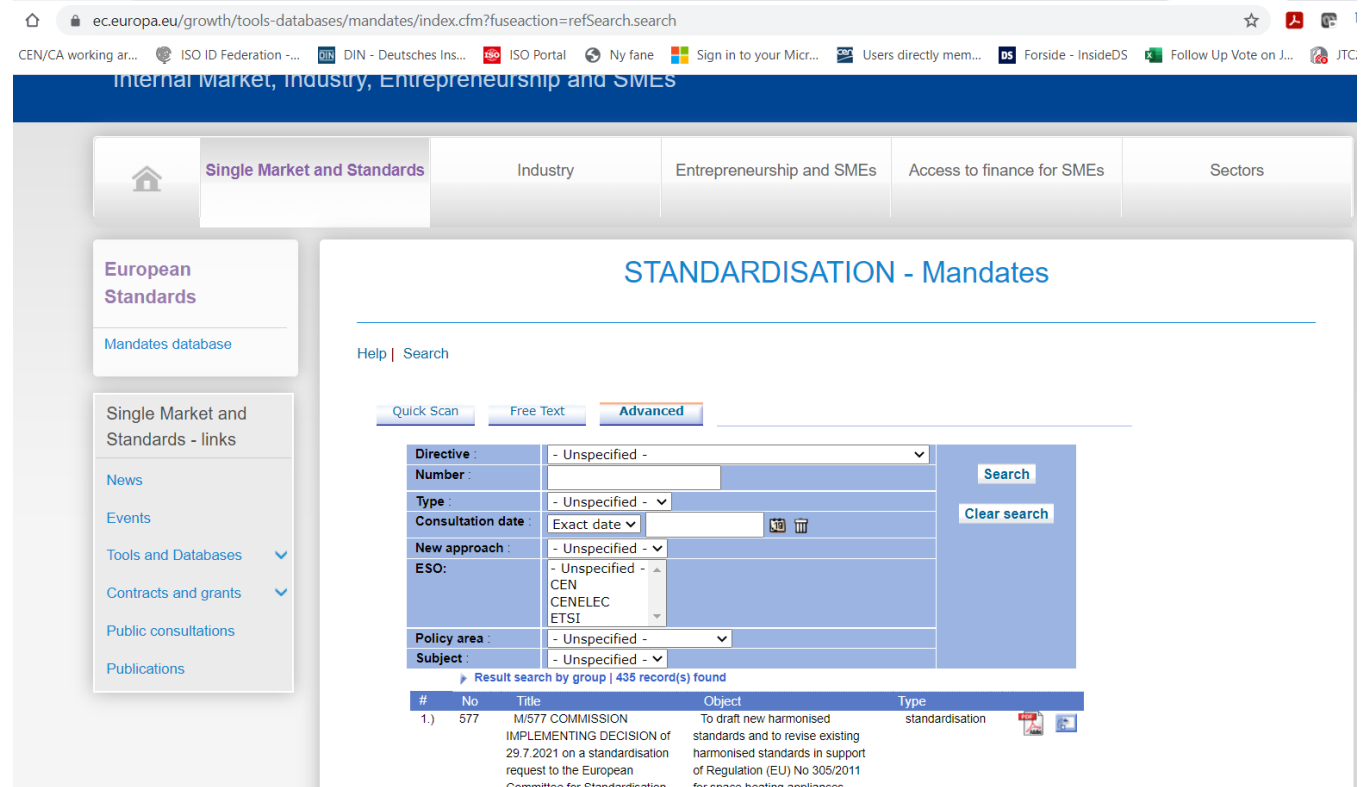
- General
- European foreword
- Scope
- Normative referencer
- EU Legal text in the standard
- Risk reduction
- Neutrality principle
- Annex Z (ZA in CEN, ZZ in CENELEC)

[CEN BOSS Drafting European standards for citation in the OJEU \(cen.eu\)](http://cen.eu)

[Cenelec BOSS Drafting EN IEC standards for citation in the OJEU \(cenelec.eu\)](http://cenelec.eu)

Falder standarden under et gældende mandat (Sreq)?

- Er det nødvendigt at få standarden
- Vurderet af HAS-konsulenten og offentliggjort i OJEU eller fungerer standarden fint som EN?



The screenshot shows the 'STANDARDISATION - Mandates' search results page on the European Commission's website. The search criteria are as follows:

- Directive: - Unspecified -
- Number: (empty)
- Type: - Unspecified -
- Consultation date: Exact date (empty)
- New approach: - Unspecified -
- ESO: CEN, CENELEC, ETSI
- Policy area: - Unspecified -
- Subject: - Unspecified -

The search results show 435 records found. The first result is:

#	No	Title	Object	Type
1.)	577	M/577 COMMISSION IMPLEMENTING DECISION of 29.7.2021 on a standardisation request to the European Committee for Standardisation	To draft new harmonised standards and to revise existing harmonised standards in support of Regulation (EU) No 305/2011 for space heating appliances	standardisation

Normative referencer

Normative referencer betyder at en standards tekst stiller krav om at hele eller dele af andre standarder "skal" anvendes.

Sådanne referencer skal fremgå af oversigten i standardens afsnit 2

- Daterede
- Aktive
- Offentliggjorte (ikke udkast)
- EN-, IEC-, ISO-standarder

Daterede

Specifik udgave af en standard

Hele eller dele af standarden

Angives med årstal

Udaterede

I udgangspunktet bør udaterede referencer undgås

Anvendes kun når der refereres til standarden i sin helhed og når alle fremtidige revisioner af standarden kan anvendes til formålet

Der angives en begrundelse

European foreword

Scope of hEN's

Europæisk forord:

Ved revision af eksisterende standarder skal de væsentlige ændringer beskrives ordentligt i forordet på den nye udgave. Dette er vigtig viden til læseren af standarden

Der skal være information om at standarden er lavet efter et "standardization request"

Anvendelsesområde:

Dette afsnit skal være kortfattet og præcist.

Der må ikke være krav, tilladelser og anbefalinger heri

European foreword

This document (EN 60204-1:2018) consists of the text of IEC 60204-1:2016, prepared by IEC/TC 44 "Safety of machinery - Electrotechnical aspects", together with the common modifications prepared by CLC/TC 44X "Safety of machinery: electrotechnical aspects".

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2019-03-14
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2021-09-14

This document supersedes EN 60204-1:2006.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Clauses, subclauses, notes, tables, figures and annexes which are additional to those in IEC 60204-1:2016 are prefixed "Z".

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directives, see informative Annexes ZZA and ZZB, which are integral

EU Legal text in the standard

Risk reduction

Neutrality principle

EU lovtæst i standarden

Hvor terminologi i standarden afviger fra terminologi EU lovtæsten skal dette anføres i forordet og annekst Z

Der må ikke være krav som er modstridende lovtæstene ligesom at lovtæst ikke må repeteres som normative krav i standarden

Risiko reduktion

Produktstandarder omhandlende sikkerhedsaspekter skal identificere alle relevante risici og reducere disse tilstrækkeligt.

(Se evt. Guide 32)

Neutralitetsprincip

Standarder må ikke indeholde afsnit der stiller krav om første, anden eller tredjeparts overensstemmelsesvurdering

Annex Z (ZA+ZZ)

Anneks ZA i CEN (ZA, ZB etc.)

Anneks ZZ i Cenelec (ZZA, ZZB etc.)

Den seneste (og rigtige) version af skabelon for anneks ZX skal bruges.

Skabelonerne findes på BOSS-siderne

De væsentlige krav skal være i venstre kolonne

Hævdes et væsentligt krav dækket i anneks ZX skal der være en tydelig anførsel af hvilke afsnit/undersnit i standarder

Annex ZZA (informative)

Relationship between this European Standard and the essential requirements of Directive 2006/42/EC [2006 OJ L 157] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/398 EN to provide one voluntary means of conforming to essential requirements of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) [2006 OJ L 157].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding requirements of that Directive, and associated EFTA regulations.

Table ZZA.1 – Correspondence between this European Standard and Annex 1 of Directive 2006/42/EC [2006 OJ L 157]

Essential Requirements of Directive 2006/42/EC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1.2.1	Clause 4, 5.4, 7.4, 7.5, 7.6, 7.8, 7.10, 8.4, Clause 9, 10.6, 10.9, 11.2.3	
1.2.2	4.4, Clause 10, Clause 11, 16.3	
1.2.3	7.3.1, 7.5, 9.2.3.2, 9.3.1	
1.2.4.1	9.2.2, 9.2.3.3	

Internationale aspekter

Vienna agreement – ISO/CEN

Frankfurt agreement – IEC/CLC

Day to day management

[Drafting European standards for citation in the OJEU \(cen.eu\)](#)

Non compliant HAS assessment:

Resolved editorial = Publiceres med det samme i ISO og i CEN efter en BT godkendelse

Cannot be resolved editorial = ISO kan publicere direkte og CEN det samme, men uden "ophæng" til harmonisering

Omskrivning af forslaget og ny parallel afstemning

De-kobling fra VA og ISO/CEN fortsætter efter egne regler med hver sin standard.

Result of the HAS assessment	ISO	CEN
Compliance	ISO and CEN publish under VA	
Partial or Lack of compliance → Need for a discussion between CCMC, ISO/CS, ISO & CEN committee leaderships including the project leader which leads to the following 4 options	<u>Option 1 – Publication of a harmonized deliverable</u> (only possible when HAS assessment is resolved through editorial changes)	
	ISO publishes under VA without waiting for CEN publication (with any relevant editorial modifications)	CEN publishes under VA (after approval by CEN/BT of any required changes to e.g. Annex Z)
	<u>Option 2 – Publication of a non-harmonized deliverable</u> (when modifications cannot be resolved through editorial changes)	
	ISO may publish under VA directly without waiting for CEN publication	CEN publishes under VA but deliverable is not harmonized (after approval by CEN/BT, i.e. Annex Z and links to legislation are removed)
	<u>Option 3 – 2nd parallel ballot</u>	
	2 nd FDIS vote (after ISO committee resolution)	2 nd Formal vote (after CEN committee and CEN/BT decisions)
	<u>Option 4* – Decoupling from VA</u> by ISO committee resolution or CEN committee decision. Each organization proceeds in accordance with its own rules.	

Day to day management

[Drafting EN IEC standards for citation in the OJEU \(cenelec.eu\)](https://www.cenelec.eu)

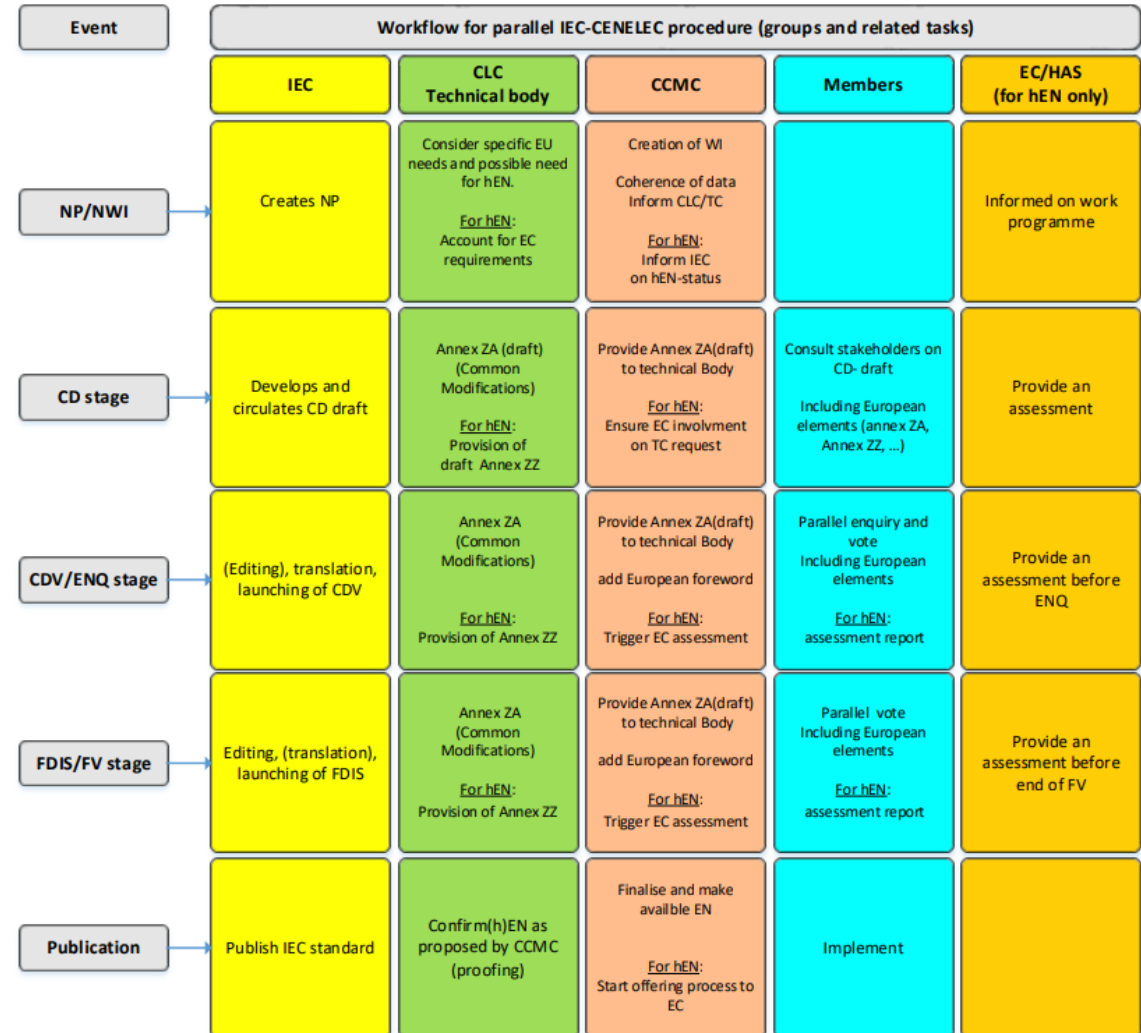
Fælles Europæiske ændringer og et rent Europæisk tillæg (EN IEC 6xxxx:yyyy/A1x:20XX):

Mulighed for ændringer til IEC'en for at lykkes med Harmonisering

Fælles Europæiske ændringer udarbejdes og udgives altid i et rent europæisk tillæg

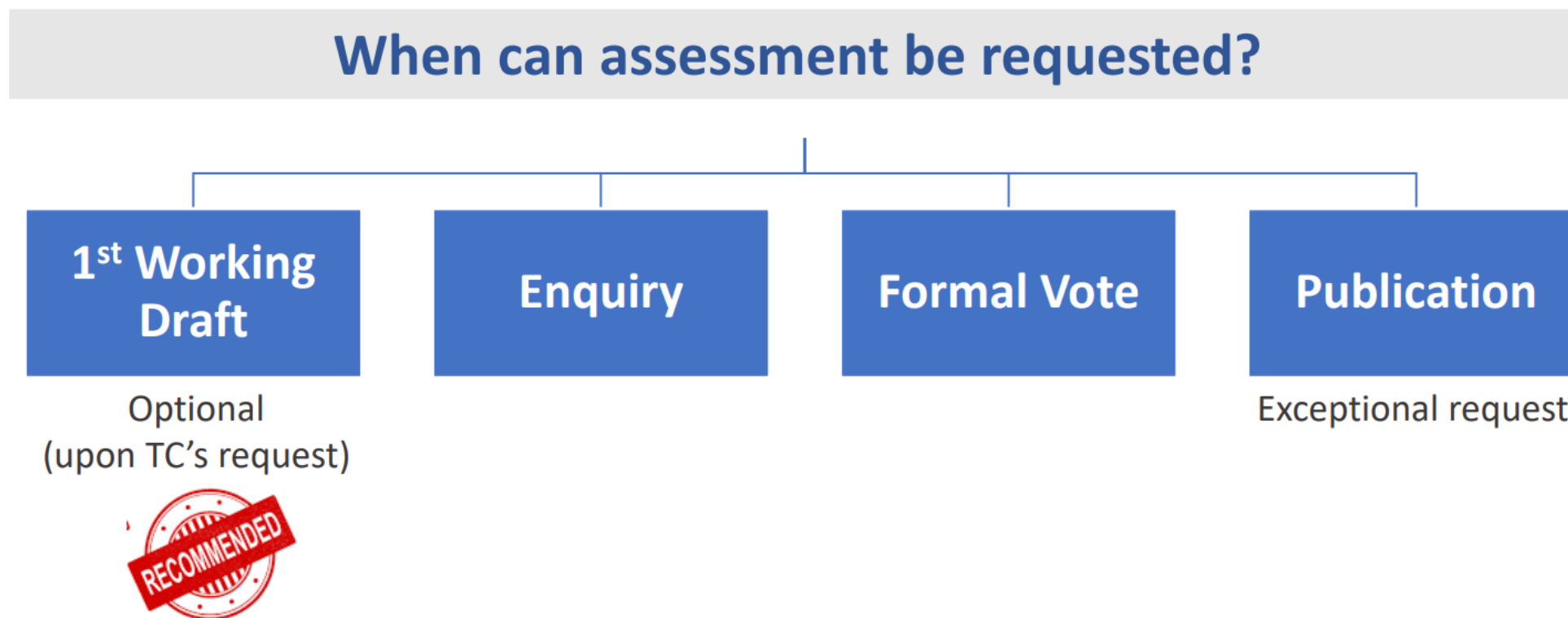
Hvis der ikke er tekniske ændringer Annex ZA og ZZ

Fælles ændringer bliver tilbudt til IEC efterudgivelse og kan medtages internationalt ved et kommende review



Succesfaktor #1 – Rettidig omhu

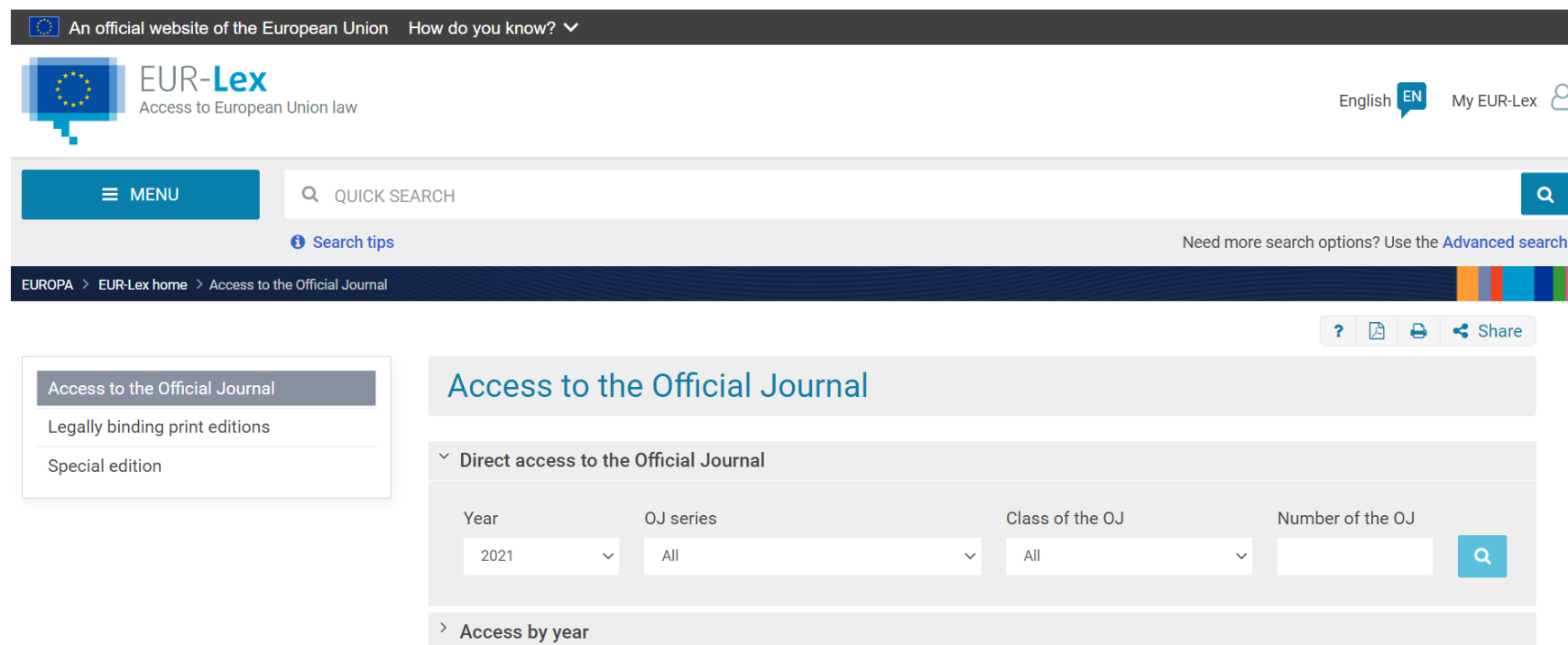
Intet tab bør ramme os, som kan undgås ved rettidig omhu, bør være et løsen, som går gennem hele organisationen. A.P. Møller




Offentliggørelse i EU tidende



Den Europæiske Unions Tidende



Den Europæiske Unions Tidende er et tidsskrift der udgives af Den Europæiske Union, som et dagblad på samtlige 23 officielle sprog, og som har til formål at sikre EU-retsakternes bindende virkning.




An official website of the European Union How do you know? ▾



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▾ Direct access to the Official Journal

Year	OJ series	Class of the OJ	Number of the OJ
2021 ▾	All ▾	All ▾	<input type="text"/>



> Access by year

L-series – Summary list

Since 1 December 2018 the references of harmonised standards are published in, and withdrawn from the Official Journal of the European Union by means of 'Commission implementing decisions'.

The summary list gives a consolidated overview of all publications in the Official Journal.



EUROPEAN COMMISSION
 Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
 Goods in the Single Market and Enforcement
Standardisation

Brussels, 3.3.2021

Summary of references of harmonised standards published in the Official Journal – Directive 2006/42/EC¹ of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC

The summary below consolidates the references of harmonised standards published by the Commission in the *Official Journal of the European Union (OJ)*. It reproduces information already published in the L or C series of the OJ as indicated in columns (2), (5) and/or (7). It contains all references which, when the summary was generated, still provided a presumption of conformity together with references already withdrawn from the OJ.

The Commission services provide this summary for information purposes only. Although they take every possible precaution to ensure that the summary is updated regularly and is correct, errors may occur and the summary may not be complete at a certain point in time. The summary does not as such generate legal effects.

This summary was generated on 3 March 2021.

Legislation reference (A)	ESO (B)	Reference number of the standard (C)	Title of the standard (D)	Type (E)	Date of start of presumption of conformity (1)	OJ reference for publication in OJ (2)	Restriction (3)	Date of start of presumption of conformity with restriction (4)	OJ reference for publication of a restriction in OJ (5)	Date of withdrawal from OJ (end of presumption of conformity) (6)	OJ reference for withdrawal from OJ (7)
2006/42/EC	CEN	EN ISO 12100:2010	Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)	A	08/04/2011	OJ C 110 - 08/04/2011	-		-		-

Citation with restrictions

Her er et eksempel hvor begrænsninger i standarder bruges som middel til at få den publiceret i EU tidende

Legislation reference (A)	ESO (B)	Reference number of the standard (C)	Title of the standard (D)	Date of start of presumption of conformity (1)	OJ reference for publication in OJ (2)	Restriction (3)	Date of start of presumption of conformity with restriction (4)	OJ reference for publication of a restriction in OJ (5)	Date of withdrawal from OJ (end of presumption of conformity) (6)	OJ reference for withdrawal from OJ (7)
2016/425	CEN	EN 342:2017	Protective clothing - Ensembles and garments for protection against cold	21/04/2018	OJ C 113 - 27/03/2018	-		-		-
2016/425	CEN	EN 343:2019	Protective clothing - Protection against rain	19/05/2020	OJ L 156 - 19/05/2020	-		-		-
2016/425	CEN	EN 343:2003+A1:2007, EN 343:2003+A1:2007/AC:2009	Protective clothing - Protection against rain	21/04/2018	OJ C 113 - 27/03/2018	-		-	19/11/2021	OJ L 156 - 19/05/2020
2016/425	CEN	EN 352-1:2002	Hearing protectors - General requirements - Part 1: Ear-Muffs	21/04/2018	OJ C 113 - 27/03/2018	-		-	21/01/2023	OJ L 259 - 21/07/2021
2016/425	CEN	EN 352-1:2020	Hearing protectors - General requirements - Part 1: Earmuffs		-	Notice: This standard does not require labelling indicating the noise attenuation level on the product. Compliance with this standard therefore does not confer a presumption of conformity with point 3.5., second paragraph, of Annex II to Regulation (EU) 2016/425.	21/07/2021	OJ L 259 - 21/07/2021		-

Spørgsmål?



DANSK STANDARD