



European Standardization Organizations

HAS assessment update

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Your speakers today

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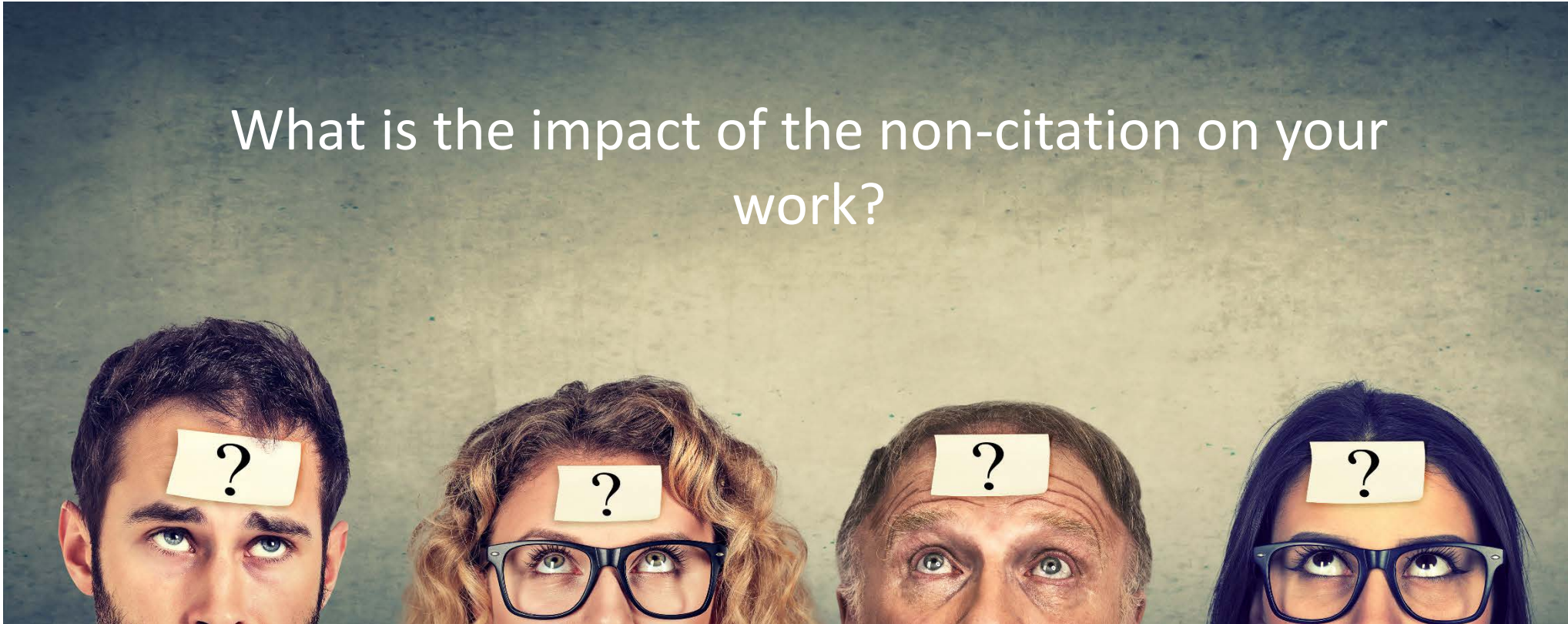
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How familiar are you with the topic presented today?



What is the impact of the non-citation on your work?



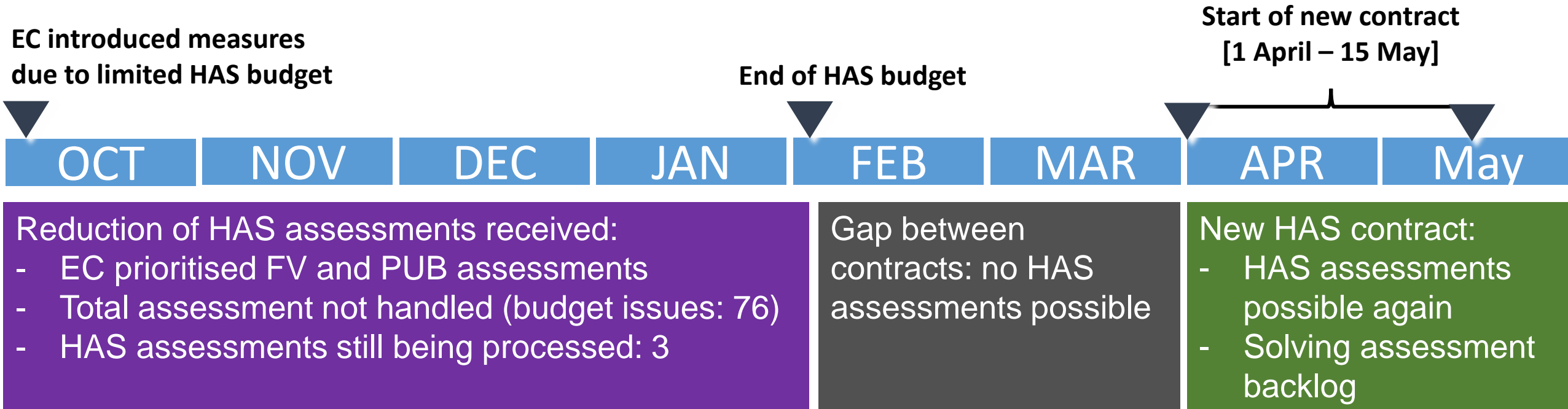
Background

- ▶ HAS contractor = EY
 - ▶ 1 April 2018 until 31 March 2022
- ▶ Issues with HAS budget:
 - ▶ March 2021: meetings between HAS consultants and TCs interrupted
 - ▶ October 2021: EC started prioritize FV and PUB assessments → many requests put on hold
- ▶ Causes for budget issues: new sectors (e.g. fertilizers, explosives), consultant management, etc

Where are we now?

- ▶ As of 2022-02-04, **ESOs can no longer request assessments** in the frame of current HAS contract
- ▶ HAS assessments reports still being processed: 3
- ▶ Total assessments requests not handled (due to budget issues): 76
 - ▶ Machinery: 32
 - ▶ LVD: 15
 - ▶ RCD: 5
 - ▶ Medical devices: 4
 - ▶ ...

HAS assessment: timeframe



Gap between contracts

What do we do now?

- ▶ CCMC will continue to request ENQ and FV HAS assessment via HAS platform on livelink → important to track assessments and follow up

Interim solution:

- ▶ CCMC to provide lists of draft hENs at ENQ and FV stages to:
 - ▶ DG GROW standardization unit
 - ▶ EC sectoral officers by sectoral CCMC PM
- ▶ EC desk officers might provide “assessments”
 - ▶ EC requests that TCs perform self-assessment of hEN against **EC checklist**
- ▶ CCMC PM: contact point with EC desk officer and coordinate with TCs for checklist completion

Verification of conditions for the publication of references of harmonised standards in the Official Journal

1. INTRODUCTION

The references of a harmonised standard¹ are not automatically published in the *Official Journal of the European Union (OJ)*. Before publication² can take place, the Commission must verify³ and, where relevant, assess various aspects to ascertain that the conditions in Article 10(6) of Regulation (EU) No 1025/2012 and in relevant sectorial provisions are met.

Article 10(6) of the Regulation

Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation,⁴ the Commission shall publish a reference of such harmonised standard without delay ...

The references of a harmonised standard are published in the *OJ* only where the standard actually satisfies the relevant legal requirements. Once they have been published, there is a **presumption of conformity**, but only with the legal requirements (e.g. ‘essential’ requirements) actually covered by the harmonised standard or parts thereof and set out in relevant legislation (see model in Article R8 of Decision No 768/2008/EC).⁵ Also, the presumption of conformity does not apply to other provisions of a standard that have nothing to do with those legal requirements. There is no presumption of conformity with requirements that are not set out in relevant legislation and the standard must not imply that there is.

Article R8 of Decision No 768/2008/EC (Presumption of conformity)

Products which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in ... [reference to the relevant part of the legislation]

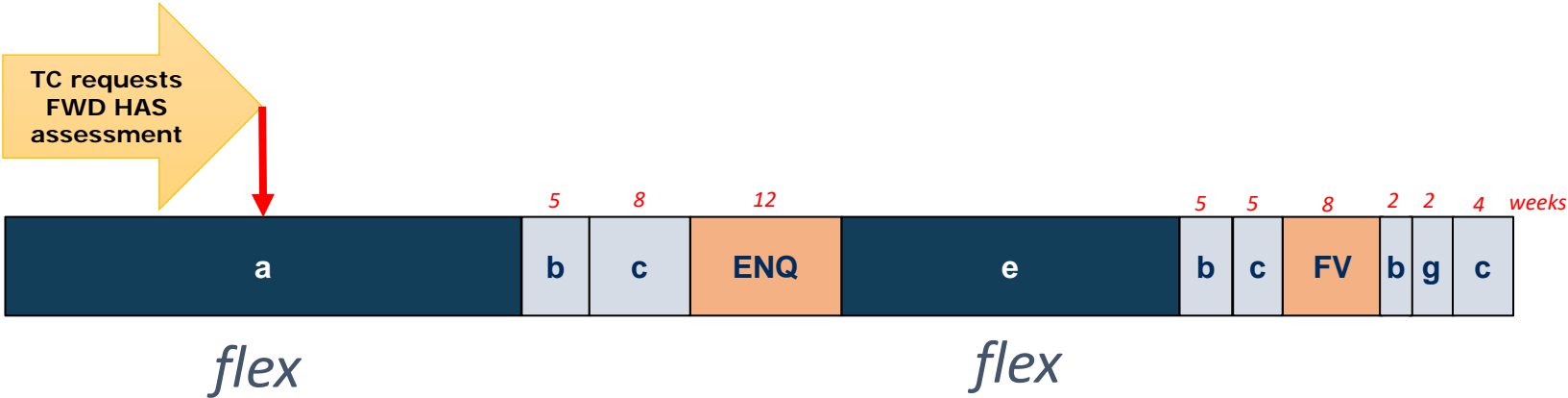
Table 1 — Procedure before deciding to publish references of a harmonised standard in the *OJ*

No	Verified issue	Remarks	Yes	No
Step I: Verification of procedural formalities				
1 Coverage by a relevant standardisation request and Union harmonisation legislation (Art. 2(1)(c), Art. 10(1))				
1.1	Is the standard covered by the requested-work programme of a relevant standardisation request made by the Commission?			
1.2	Does the subject matter deal (at least partly) with a product, service or other aspect regulated by relevant Union harmonisation legislation and/or can the standard, on the basis of its actual content, be used to support application of legal requirements under Union harmonisation legislation (e.g. terminology and definitions) alone cannot confer any presumption of conformity? (see also corresponding act)			
1.3	Is the title of the standard translated into all official languages?			
1.4	In cases of a family of standards or multiple parts only: Is there a meaningful set of different parts which could be cited in the <i>OJ</i> at the same time or is there absence of other reasons for citing only a single part?			
1.5	In cases of revised versions of harmonised standards already cited in the <i>OJ</i> only: Are significant changes clearly indicated in the revised or amended standard? (see SWD(2015) 205 Part 2, section 3.5; model Article 5 and the relevant request; SWD(2015) 205 Part 3, section 2.10.4)			
2 Transparency and inclusiveness during requested standardisation work (Art. 3(1)-(4), Art. 5, Art. 6)				
2.1	Was the work item for the standard included appropriately in the requested-work programme? (see SWD(2015) 205 Part 3, sections 2.3 to 2.5)			
2.2	Absence of any concerns as regards inclusiveness during drafting and adoption?			
3 Absence of a formal objection or any information on a possible objection (including other objected harmonised standards to which there are normative references, where relevant)? (Art. 11)				
4 Legal requirements aimed to be covered are indicated (Annex Z or equivalent informative element is available) and, where relevant, expressed separately for each relevant Union harmonisation act to be supported? (Art. 10(6); SWD(2015) 205 Part 2, section 3.6; Part 3, section 2.8.4)				
5 Normative references made in clauses or sub-clauses which support legal requirements (SWD(2015) 205 Part 3, section 2.8.3)				
5.1	Are all standards to which there are normative references publicly available, i.e. normative references have been adopted and/or standards are still valid, and are there no references to draft standards (relevant during the final assessment of an adopted standard only)?			
5.2	Is it possible to have access in all official EU languages to the most relevant standards to which there are normative references? [1]			
5.3	Is there an absence of undated normative references?			
5.4	Complete normative reference chains (i.e. further normative references contained in a normative reference) need to be followed and each level verified according to 5.1 to 5.3. Is there absence of any concerns on these other levels of normative references?			
Step II: Quantitative verification as regards the legal requirements aimed to be covered on the basis of the standardisation request (Art. 10(1), 10(6))				
6 Clarity and transparency of normative parts of the standard which aim to support the legal requirements aimed to be covered (SWD(2015) 205 Part 3, section 2.8.4)				
6.1	Are the legal requirements (e.g. ‘essential’ requirements) aimed to be covered indicated clearly, transparently and in a structured way, so that Step III qualitative assessment can be carried out for each (in the case of Annex Z or equivalent informative element, this includes legally sound statements, references only to normative elements of the relevant standard, no reference to other standards) and do the normative elements of the standard contain no references to legal acts [2]?			

Gap between contracts

Case 1: TC requests FWD/CD HAS assessment

- ▶ CCMC informs TC that no FWD/CD assessment is possible within the current contract
- ▶ TBs continues technical work



Gap between contracts

Case 2: Submission of draft to ENQ/DIS/CDV stage

- ▶ Homegrown: CCMC will request ENQ HAS assessment (for traceability)
- ▶ For parallel process → follow the same steps → CCMC to request assessment
- ▶ Enquiry will not stop (this is already the case today)



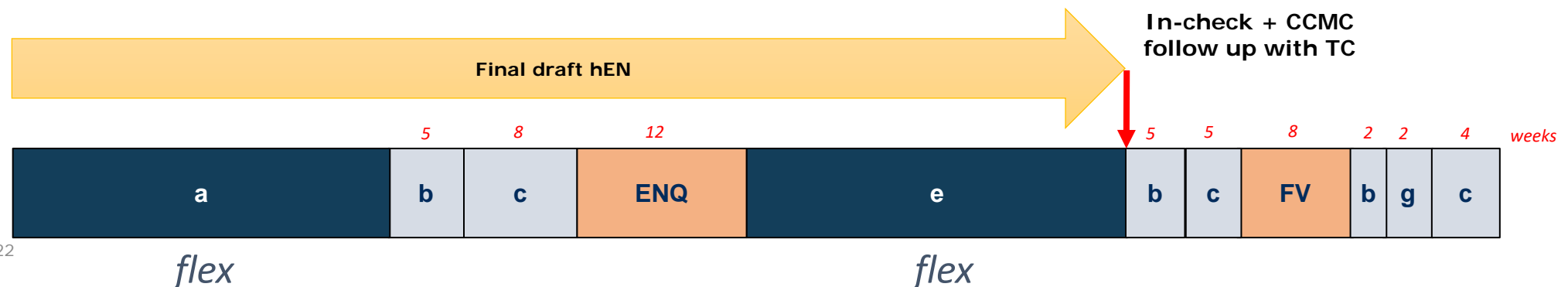
Gap between contracts

Case 3: Submission of draft hEN to CCMC for FV stage (homegrown)

(Option 0: TC decides not submit the documents to CCMC)

If CCMC receives a document, during in-check → CCMC to follow up with TC on way forward:

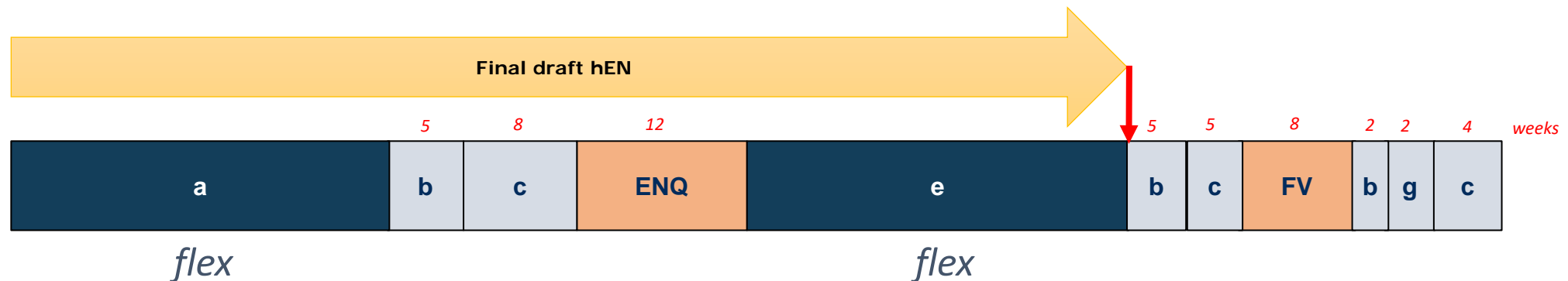
- ▶ **Option 1:** Proceed to FV
 - ▶ CCMC edits document and makes request on HAS platform (if intended to be harmonized) → traceability purposes
 - ▶ At the end of the translation FV starts
 - ▶ Lists of hENs to be submitted to EC (case-by-case)
- ▶ **Option 2:** TC wants to wait for FV HAS assessment
 - ▶ **Option 2a:** TC prefers to reject submission
 - ▶ CCMC returns the document to TB (not edited)
 - ▶ **Option 2b:** TC prefers to proceed with submission of document, but wait for FV HAS assessment
 - ▶ CCMC edits document and makes request on HAS platform → traceability purposes
 - ▶ Lists of hENs to be submitted to EC



Gap between contracts

Case 3: FV/FDIS stage (Parallel work)

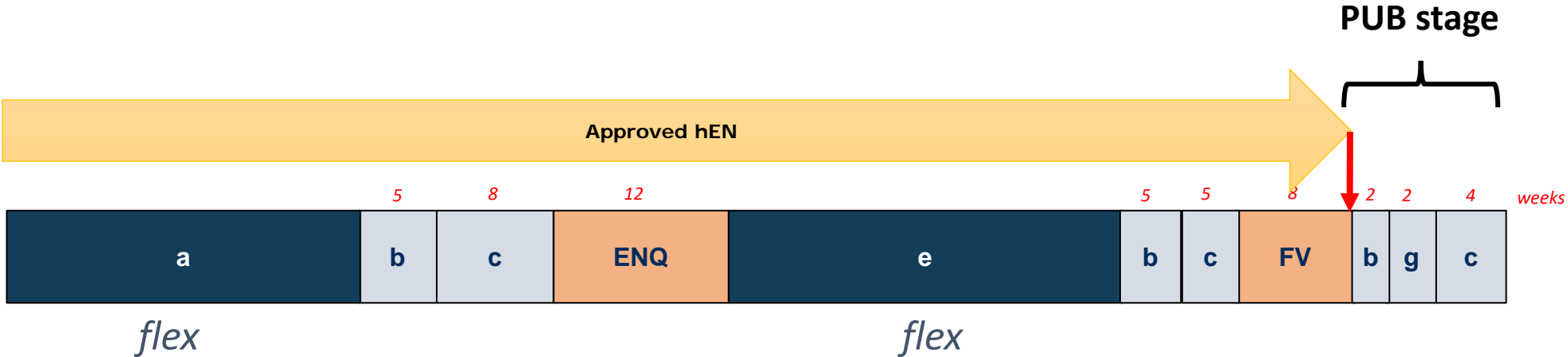
- ▶ For IEC parallel work, FDIS starts → CCMC to make request on HAS platform (for traceability)
- ▶ For ISO parallel work, ISO to decide if FDIS starts (ISO and CEN leadership together with TPMs to agree on way forward):
 - ▶ **Option 1:** Proceed to FDIS/FV
 - ▶ CCMC to make request on HAS platform (for traceability)
 - ▶ **Option 2:** wait for FDIS/FV HAS assessment
 - ▶ **Other options:** de-coupling, abandon, etc



Gap between contracts

Case 4: TC requests PUB (after FV/FDIS) HAS assessment

- ▶ **After FV**: CCMC to inform TCs that PUB HAS assessment is not possible



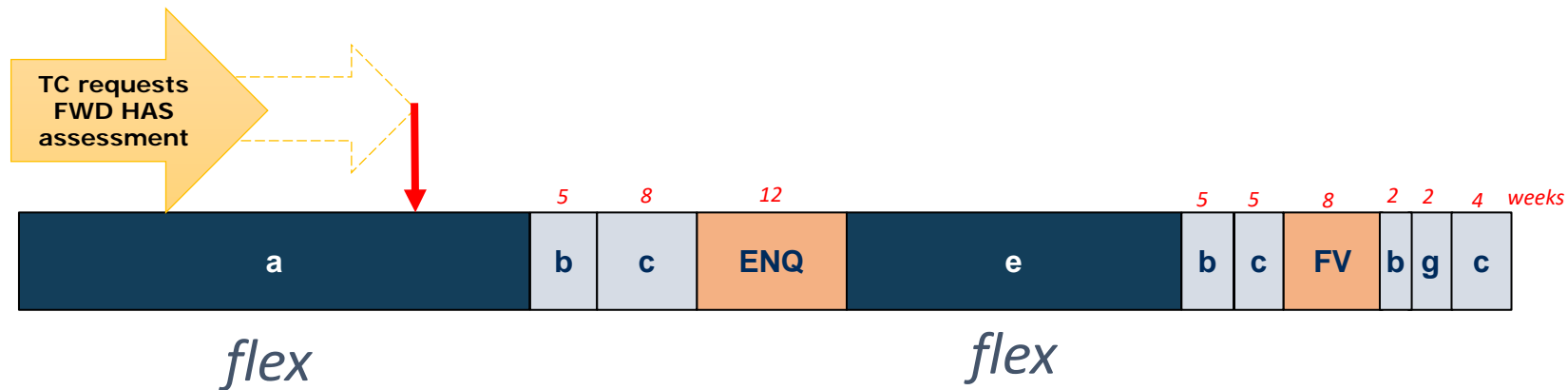
HAS assessment system restored

- ▶ **How do to deal with backlog of assessments?**
 - ▶ 1st working drafts and ENQ assessments still needed?
 - ▶ FV/FDIS assessments to be followed up
 - ▶ CCMC to support in identification of pending assessment

HAS assessment system restored

Case 5: TC requests FWD/CD HAS assessment

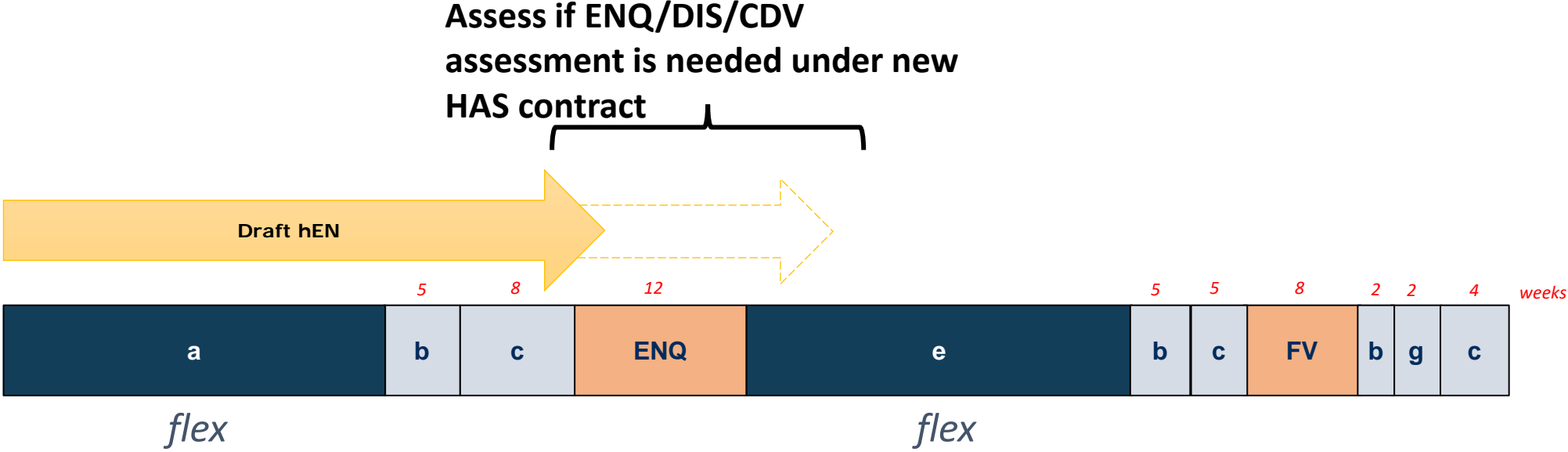
- ▶ If WI timeframe allows → TC may decide to request FWD/CD assessment



HAS assessment system restored

Case 6: ENQ/DIS/CDV ongoing or closed and system restored

- ▶ **During or after ENQ/DIS/CDV stage:** TC leadership to assess whether ENQ/DIS/CDV HAS assessment should be requested when new HAS contract is in place



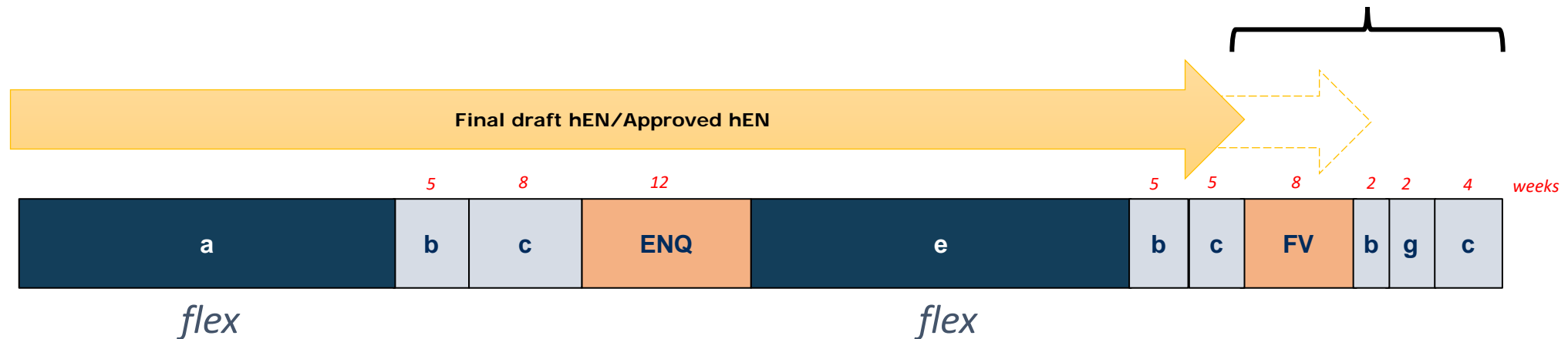
HAS assessment system restored

Case 7: FV/FDIS ongoing or closed and system restored (but before publication)

TC leadership to decide on the following options:

- ▶ **Option 1**: Proceed to publication
- ▶ **Option 2**: Request FV/FDIS HAS assessment

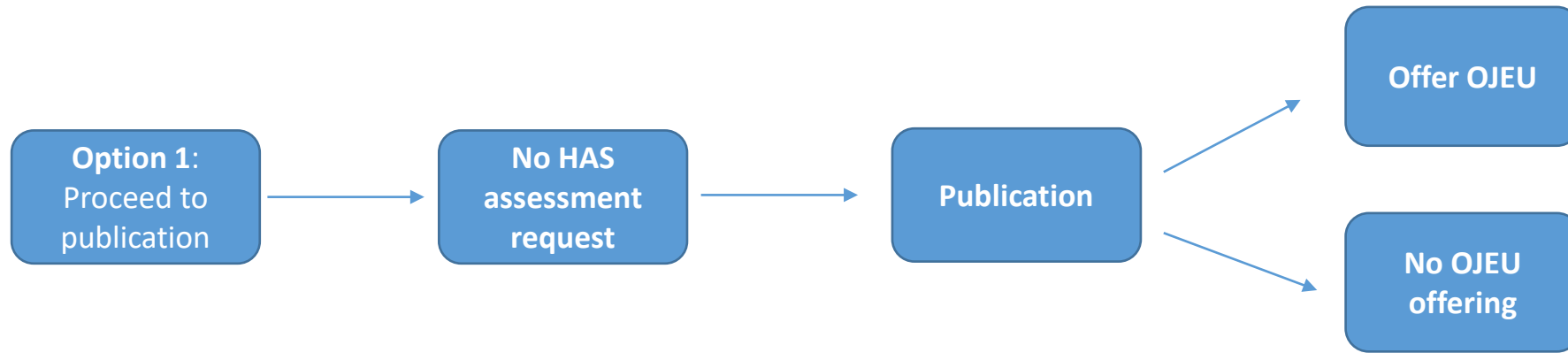
Assess if FV/FDIS assessment is needed under new HAS contract



HAS assessment system restored

Case 7.1: FV/FDIS ongoing or closed and system restored (but before publication)

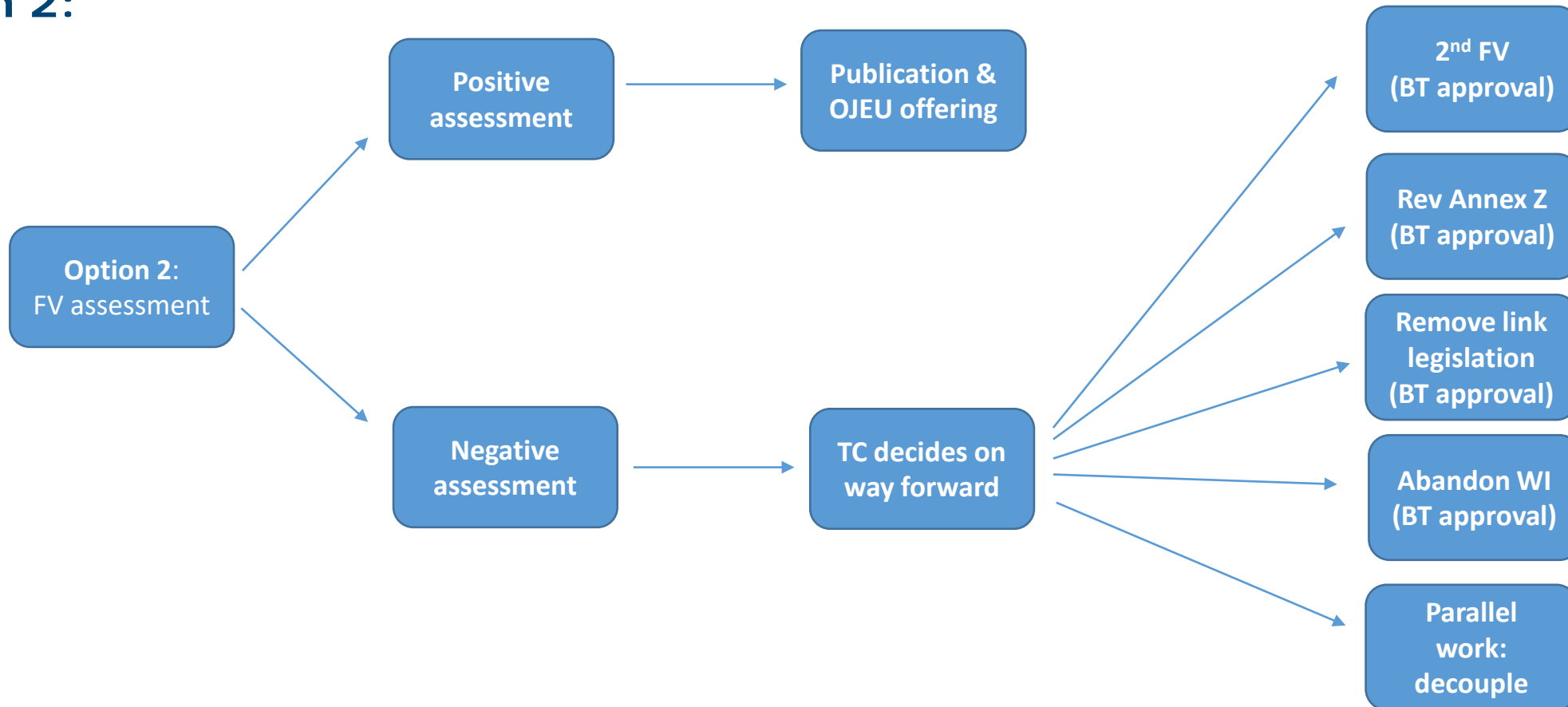
Option 1:



HAS assessment system restored

Case 7.2: FV/FDIS ongoing or closed and system restored (but before publication)

Option 2:



HAS assessment: new contract



- ▶ EC launched call for tenders [‘Technical Assistance to the Commission for the Assessment of Harmonised Standards’](#) on 2021-12-27
- ▶ Documents library → [link](#)
- ▶ Deadline for receipt of tenders: 2022-01-31
- ▶ Evaluation of tenders received is now ongoing
- ▶ HAS contractor = ?
- ▶ Starting new contract: officially between 2022-04-01 and 2022-05-15
- ▶ HAS budget: **10 800 000 EUR**

Tasks/duties of the Contractor

New tender specifications

Task 1: Administrative and logistical tasks to coordinate the tasks and work of the HAS Consultants including recruitment of the HAS Consultants; → maximum 380 person-days for 24 months

Task 2: Horizontal verifications and checks of non-technical nature with regard documents to be assessed by the HAS Consultants → maximum 460 person-days for 24 months

Task 3: Evaluation of the assessment results and the effectiveness of the assessment concept in order to make recommendations to the Commission → maximum 180 person-days for 24 months

Task 4: Communication and information to the Technical Bodies of the ESOs and to the Commission services, in order to train and explain the beneficiaries of the system on its functioning so that they use it in the most efficient manner; maximum 200 person-days for 24 months

Current contract

Task 1: Administrative and logistical tasks to coordinate the tasks and work of the HAS Consultants including recruitment of the HAS Consultants → maximum 340 person-days for 24 months

Task 2: Horizontal verifications and checks of non-technical nature with regard documents to be assessed by the HAS Consultants → maximum 440 person-days for 24 months period.

Task 3: Evaluation of the assessment results and the effectiveness of the assessment concept in order to make recommendations to the Commission → maximum 180 person-days for 24 months period

New tender specifications

Task 10: Assessment of compliance of the documents drafted by the ESOs with Commission's initial standardization requests (at least **75%** of the delivered person-days for each consultant), and

Task 20: Communication to the technical bodies of the ESOs to give clarifications and advice in order to contribute to the compliance of the drafted documents with the Commission's initial standardization requests (maximum **25%** of the delivered person-days for each consultant)



More communication and meeting participation: from 20% to 25% (maximum)

Current contract

Task 10: Assessment of compliance of the documents drafted by the ESOs with Commission's initial standardisation requests (at least 80% of the delivered person-days), and

Task 20: Communication to the technical bodies of the ESOs to give drafting advice in order to contribute compliance of the drafted documents with the Commission's initial standardization requests (maximum 20% of the delivered person-days)

New tender specifications

'Compliant' (if the same conclusion is done by the Commission the publication of the reference in the OJ is normally possible without any specific notice)

'Conditional compliance' (to be used only in case of problems related to the dates of normative references to other inter-linked standards and meaning that, if the identified issue(s) is positively addressed by the ESO after the assessment, and if the same conclusion is done by the Commission the publication of the reference in the OJ is normally possible without any specific notice)

'Lack of compliance' (if the same conclusion is done by the Commission the publication of the reference in the OJ is likely not possible before the document is revised – a publication of the reference in the OJ with a notice would also be a possible option in some cases)

Current contract

'Compliant' (if the same conclusion is done by the Commission the publication of the references in the OJ is normally possible without any specific notice)

~~**'Partial compliant'** (if the same conclusion is done by the Commission the publication of the references in the OJ could be possible with a notice; such a notice shall be outlined in the report for already adopted standards and for documents assessed before formal vote)~~

'Lack of compliance' (if the same conclusion is done by the Commission the publication in the OJ is likely not possible before the document is revised)

New tender specifications

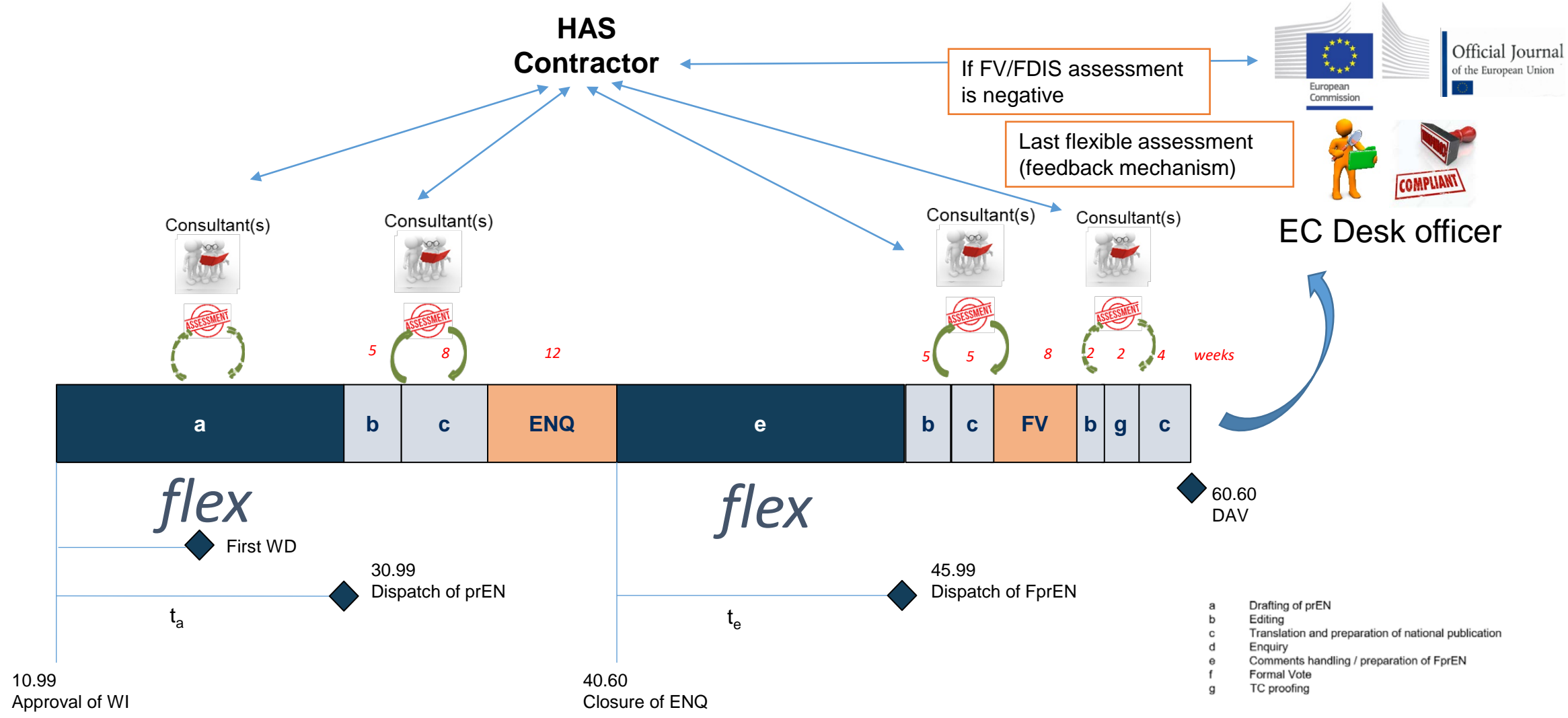
- ▶ At drafting stage (Optional)
- ▶ At Enquiry stage
- ▶ At Formal Vote stage
- ▶ **Last flexible assessment** can be requested if FV is lack of compliance → considered as **feedback mechanism**
 - ▶ **Either as second assessment at FV** or
 - ▶ After FV but before publication
- ▶ **Not allowed to request assessments of published standards**
- ▶ During citation, EC can request final assessment by HAS consultant → only for EC

Current contract

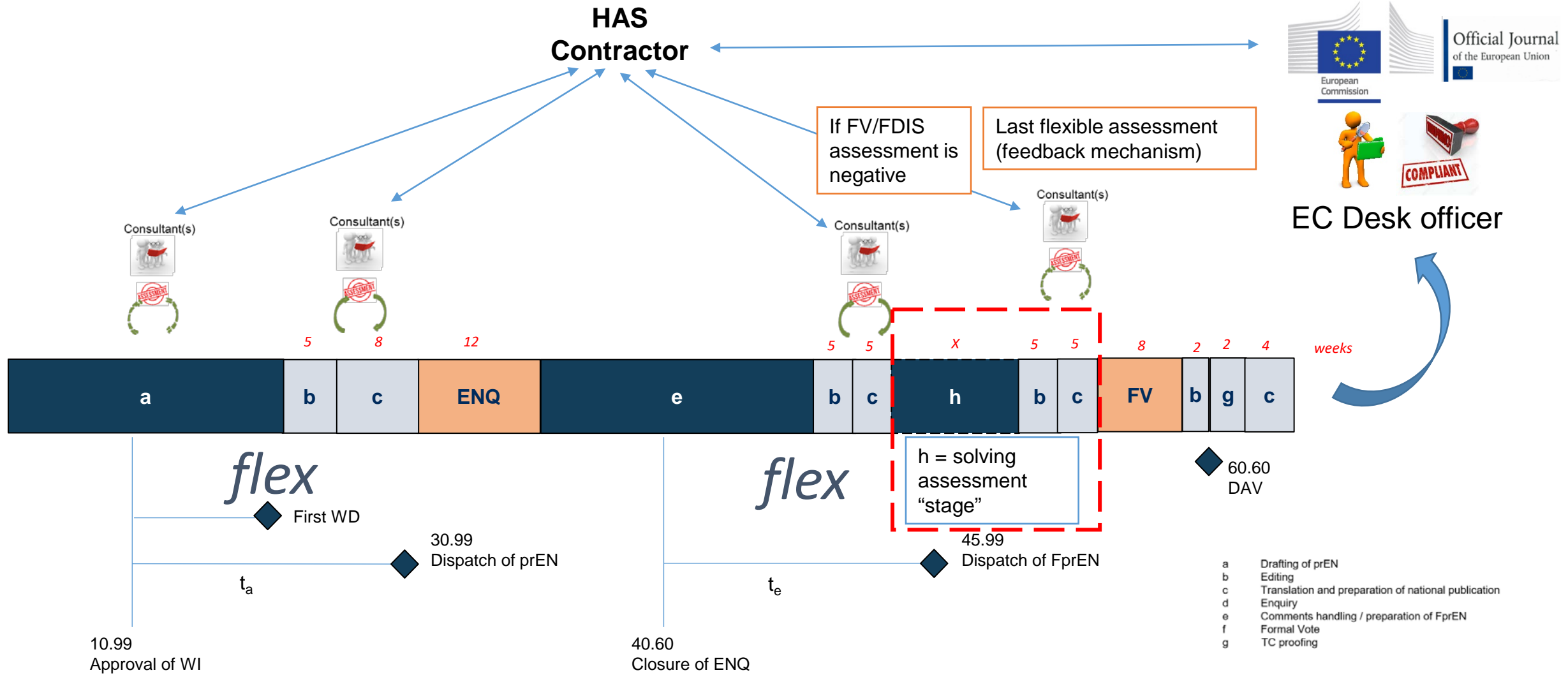
- ▶ At drafting stage (Optional)
- ▶ At Enquiry stage
- ▶ At Formal Vote stage
- ▶ On documents that have already been voted upon (Optional)

- ▶ One assessment per stage rule

Assessment of standards: new contract



Assessment of standards: new contract



Key learning points

- ▶ Current HAS contract: no more budget
- ▶ Gap between contracts:
 - ▶ Technical Bodies to assess options and remain responsible for decisions
 - ▶ EC desk officer might “assess” standards → EC checklist to be completed by Technical Bodies (Interim solution)
- ▶ New HAS assessment contract: 1 April – 15 May
 - ▶ Increase of budget
 - ▶ HAS consultants: more communication/meeting participation
 - ▶ Introduction of ‘conditional compliance’ outcome
 - ▶ Introduction of last flexible assessment (in case of negative assessment at FV)
- ▶ When HAS system is restored → FV/FDIS assessments to be followed up (with CCMC support)



European Standardization Organizations

Thank you! Any questions?

Next webinars

2022-03-08 – [Online celebration for the renewed collaboration between the JRC and CEN-CENELEC](#)

2022-03-10 – [Webinar 'How do standards benefit consumers?'](#)

2022-03-15 - [Cybersecurity Standardisation Conference 2022](#) (cooperation between ENISA, ETSI, CEN & CENELEC)

2022-03-22 - [Webinar "Together to make stronger Standards for Europe: How can you cooperate with CEN and CENELEC?"](#)

2022-04-21 – [Workshop 'Interoperability of security'](#)