

TOPIC: AIF Support Series #14:

The ISO/CEN Vienna Agreement, HAS Consultants and Recent European Commission Policy Concerns

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OPENING OF THE MEETING

- A presentation (see AIF N426-2021) was given on the intention and implementation of the ISO/CEN Vienna Agreement, concerns regarding the interventions of EC HAS Consultants, and recent concerns regarding EC policies that are negatively impacting ISO standards development. The presentation was followed by an open question and answer session, and the questions and answers are presented below.
- We want to hear from you to learn how we can best support you throughout your U.S. TAG and committee work. Submit any inquiries or comments to ANSI's ISO Team (isot@ansi.org).

QUESTIONS AND ANSWERS

1. ISO/CEN Vienna Agreement (General)

- 1.1 If an ISO document being developed under the VA is disapproved on the ISO "side" but approved on the CEN "side," is CEN allowed to move forward with the publication of that document as an EN standard?

Answer:

Yes, if it is mutually agreed not to continue working together toward a common solution.

- 1.2 Why is each country in the European Union allowed to be represented when that is considered one market while other countries or markets are allowed only one vote in the ISO committees?

Answer:

ISO membership from the countries of Europe was established long before the unification of the European market. This is not likely to change as review of voting patterns has not shown widespread European bloc voting as a problem in ISO. There may be isolated cases of European bloc voting and the ISO/TMB has recourse under the ISO Global Relevance Policy to address such cases. More often than not, the European countries may not be unified in their voting, or the USA and other non-European countries will agree with the European countries.

- 1.3 How can one find out which standards within an ISO committee are being developed under the Vienna Agreement?

Answer:

This information should be readily available from the ISO committee manager. ANSI staff can assist in seeking such information from ISO committee managers.

- 1.4 How does one become aware that a CEN standard is open for comment?

Answer:

CEN and CENELEC maintain an online site that lists their draft standards that are open for commenting at the following location:

<https://www.cencenelec.eu/societal/interests/environment/comments/Pages/default.aspx>

1.5 How many Vienna Agreement standards are under CEN led?

Answer:

There are currently 6,741 Vienna Agreement projects (published standards and standards under development), of which 689 are under CEN lead.

1.6 Why does the ISO committee have to provide Annex ZA and ZB for the DIS vote?

Answer:

The ISO committee manager is expected to upload to ISO all documents and supporting materials for a DIS vote. This includes the texts for Annex ZA and ZB, which are presented in the DIS but are removed before publication of the ISO version of the standard. The ISO CM is not expected to produce these Annexes; it is the responsibility of the CEN committee to provide these texts. However, it is the responsibility of the ISO CM to obtain these texts from the CEN committee and submit them to ISO.

1.7 When parallel standards are being developed in ISO and CEN, outside the Vienna Agreement, how do the P members obtain awareness of the CEN activities?

Answer:

ANSI staff is not aware that ISO committees are developing any standards with CEN outside of the Vienna Agreement.

1.8 How does one make sure that the ISO committee is notified that CEN is working on a standard?

Answer:

If an ISO committee is working regularly in cooperation with a CEN committee on standards under the Vienna Agreement, the ISO committee should expect regular reports from the CEN committee on its work program and any new work projects. A US/TAG may decide that ANSI request the ISO CM to obtain such reports regularly from the CEN committee.

1.9 Why doesn't ANSI have an agreement similar to the Vienna Agreement for the US?

Answer:

The Vienna Agreement is an agreement that leads to the joint development of standards between ISO and CEN. ANSI is the US member of ISO but ANSI is not a standards developer. Standards development in the USA exists within hundreds of organizations accredited by ANSI. A Vienna Agreement for the USA would not make sense as not all US-based SDOs may be interested in working cooperatively toward joint standards with ISO. Furthermore, such an agreement would require the US-based SDOs to withdraw their own versions of the standard when the joint standard is published, which some SDOs may not wish to do.

1.10 What would influence a US initiated new work item proposal to decide to have a document developed under Vienna Agreement?

Answer:

A US/TAG may decide to propose in its new work item proposal that the project be advanced under the Vienna Agreement. US stakeholders may see a business/trade benefit in having the

same standard globally rather than more than one standard on the same subject that may differ. Furthermore, even if not proposed in a US new work item proposal, other ISO members may suggest when voting on the proposal that the project take place under the Vienna Agreement. The ISO committee will then need to decide on whether it wishes to develop the standard with CEN under the Vienna Agreement.

1.11 When we have a representative in a CEN working group, are they representing our US/TAG or ISO?

Answer:

Under the Vienna Agreement, for projects under CEN lead, the ISO committee may name up to 4 non-European experts to represent the ISO committee in the work of the CEN committee. If US persons are so named, they represent the ISO committee and not the US/TAG.

1.12 Aren't Vienna Agreement projects noted on the ISO form 4?

Answer:

Yes, they may be so noted (see question 1.10 above).

1.13 Does the ISO committee have to agree to break away from a VA standard?

Answer:

Yes, if the ISO committee and the CEN committee cannot agree, the P members of the ISO committee must decide to break away.

1.14 Does ISO have a definition of a "harmonized standard?"

Answer:

"Harmonized standard" refers to an ISO/CEN or CEN standard that is developed to support an EC directive or regulation. ISO does not have a definitive definition.

1.15 When the ISO approved document is published, does CEN have to withdraw their version of the document?

Answer:

Yes, if the ISO approved standard is a joint ISO/CEN standard under the Vienna Agreement. Furthermore, any joint ISO/CEN standard requires all European national standards organizations to withdraw their related national standards on the same subject.

2. HAS Consultants

2.1 Why aren't the HAS Consultants held to the same response deadline as P members in order to be able to address their comments in a timely manner with all others?

Answer:

While this has been expected, it has not been enforced in the past. Recent concerns about the negative impact of late HAS Consultant comments has been raised in ISO and IEC and with CEN and CENELEC and this will soon be addressed with the EC that oversees Ernst & Young's management of the HAS Consultants. It is expected that this will be favorably resolved.

2.2 Are HAS Consultants "paid" or volunteers

Answer:

Yes, HAS Consultants are financially compensated for their time and effort. Ernst & Young has the contract to manage the HAS Consultants, the process of their selection and the disbursement of money which comes from the European Commission.

- 2.3 In our committee, the HAS Consultant won't accept undated normative references, and this creates problems.

Answer:

This is an additional EC policy concern that ISO, IEC, CEN and CENELEC will soon discuss with the EC. ISO, IEC, CEN and CENELEC all allow undated references, but the EC does not in order to have greater assurance as to the specific technical content being normatively referenced.

- 2.4 What does HAS stand for?

Answer:

Harmonized Standard

- 2.5 Is it typical for the HAS Consultant to make technical comments during the FDIS ballot?

Answer:

The HAS Consultant comments on draft Harmonized Standards, either CEN or ISO/CEN that are intended to support an EC directive or regulation, may only comment on whether the draft standard's content will support the EC directive or regulation. The HAS Consultant should not comment on other content of the draft standard that does not relate to the EC directive or regulation, even though the HAS Consultant is presumably an expert in the subject of the standard.

- 2.6 It can be challenging to gain "early and continuous engagement" between technical bodies and the HAS Consultant. How does one go about requesting this involvement?

Answer:

An ISO or CEN committee may request early and continuous engagement, typically through the leadership of the CEN committee and the CEN central office to Ernst & Young that manages the HAS Consultants.

- 2.7 Are HAS Consultants required or a "nice to have"?

Answer:

At present, HAS Consultants are required for any CEN or ISO/CEN standard that is being developed with the intent to support an EC directive or regulation.

- 2.8 Can a HAS Consultant kill a document?

Answer:

A HAS Consultant cannot kill a document. More often, when a HAS Consultant gives a negative assessment that the draft standard does not meet the EC directive or regulation, the ISO committee must decide if it wishes to revise the ISO/CEN standard to comply with the HAS Consultant assessment. If the ISO committee does not agree to do so, then usually the ISO and CEN committees will decide to decouple their cooperation under the Vienna Agreement, and both ISO and CEN will proceed separately, each with its own document.

3. Recent EC Policy Concerns

- 3.1 Under the described proposal to allow HAS Consultants a 5 week review/comment period in advance of FDIS ballot - does the proposal then prohibit HAS consultant voting/comments during the formal FDIS ballot?

Answer:

There should be no need for the HAS Consultant to comment during the formal FDIS ballot period as presumably they would be looking at the same text before and during. Therefore, commenting during the formal FDIS ballot would be repetitive. However, if the FDIS is revised based on the HAS Consultant input before the formal ballot is issued, then it may be appropriate for the HAS Consultant to review and comment on the FDIS during its formal ballot.

- 3.2 ISO Directives Part 2, clause 10.2 first sentence gives strong preference to ISO references. Is there any movement to soften that clause?

Answer:

There is no movement to soften clause 10.2 that gives strong preference to normatively referencing ISO standards. However, that same clause does provide guidance on normatively referencing standards from external sources if the committee so wishes. The recent concerns regarding EC policies do include a concern relating to the EC seeking to require that normative references must be to ISO, IEC, CEN and CENELEC standards in any standards to be cited in the OJEU that they support EC directives or regulations.

AIF SUPPORT SERIES

ISO/CEN VIENNA AGREEMENT, HAS CONSULTANTS & EC POLICY CONCERNS

November 20, 2020



Housekeeping Items

- All participants will be muted until the end of the presentation
- Use the Q&A function to “All Panelists” / Raise Your Hand to ask questions
- If we don’t get to your question today, reach out via email isot@ansi.org
- Follow-up/repeat sessions will be held if necessary
- Slides and one-page summary to be circulated after the call
- Keep us informed of your experiences!

ISO/CEN VIENNA AGREEMENT

WHY DOES IT EXIST?

- To make the best use of available standardization resources at the international and European regional levels.
- To avoid duplicative standards development efforts.
- To realize the same standard for ISO and Europe for the benefit of companies doing business in Europe and the rest of the world.
- To help ISO and CEN exchange information to increase the transparency of work.

The WTO Code of Conduct states that international standardization takes precedence over national or regional standardization to help harmonize national standards, and therefore technical regulations, which helps reduce technical barriers to trade.

CEN members must give all European Standards the status of national standards and withdraw any pre-existing conflicting national standards.

ISO/CEN VIENNA AGREEMENT

- **Not all ISO committees are developing projects under the ISO/CEN Vienna Agreement.**
- **Some CEN standards projects are mandated by the European Commission in order to support EC Directives or regulations.**
- **Not all ISO/CEN Vienna Agreement projects are mandated or harmonized standards.**
- **ISO committees may take the lead on developing mandated standards provided that the European Commission target dates are met.**
- **Only ISO/CEN mandated standards engage New Approach Consultants (more about them later).**

KEY FIGURES

ISO currently has about 22,000 deliverables (published and under development).

Of these, 5704 are published or are in development under the VA, among which 896 are mandated standards requiring engagement with HAS consultants.

There are currently 25 projects that are delayed due to a missing or negative HAS consultant assessments at the publication stage.

64% of the projects requiring a HAS consultant review receive a negative assessment and require extra time and discussions.

ISO/CEN VA COOPERATION BY CORRESPONDENCE

- **Contributions by correspondence are accepted by both ISO and CEN.**
- **Individual ISO member bodies may submit their national comments on CEN draft standards only at the enquiry stage (prEN).**
- **CEN has agreed to consider and respond to all comments it receives, including comments on draft European Standards which are not being processed under the ISO/CEN Vienna Agreement.**
- **ISO committees and CEN committees are under obligation to respond appropriately to each and every comment submitted.**

STOPPAGE OF WORK IN ISO OR CEN

- **There are no provisions in the ISO/CEN Vienna Agreement that either the ISO or the CEN committee must cease work due to the existence of the same project in the other organization.**
- **ISO or CEN committee chairs or secretary cannot stop work unilaterally due to the existence of related work in the other organization.**
- **Stoppage of work only happens when one committee decides to apply the ISO/CEN Vienna Agreement and there is agreement to assign the work to the other organization.**

ISO/CEN STANDARDS DEVELOPMENT UNDER THE VA

- Under ISO lead – the standard is developed in the ISO committee through the close of the CD stage.
- Under CEN lead – the standard is developed in the CEN committee through the close of the CD stage.
- The draft standard is balloted in both ISO and CEN in parallel at the DIS and FDIS stages.
- If the ISO and CEN DIS or FDIS voting results do not agree, the committees discuss how to resolve disagreements.
- If disagreements are not resolved, the standard decouples from the ISO/CEN Vienna Agreement and each organization publishes its own standard.

DECISIONS ON ASSIGNMENT OF LEAD

- **ISO lead is the preferred – and default – option.**
- **Exceptional CEN lead is only possible if the non-European P-members of the ISO committee agree by simple majority to allow the CEN committee to lead.**
- **CEN national members are never at any disadvantage as they have the right to participate actively in both ISO and CEN.**
- **Therefore, there is no need for all P-members of the ISO committee to decide on CEN lead.**
- **Availability of European Commission funding should not be a factor in taking decisions on lead assignment.**
- **A European Commission mandated standard does not mean it is mandatory that the lead to develop the standard be assigned to CEN.**

CEN LEAD – COMMENTING PRIOR TO DIS/prEN STAGE

- **The ISO committee may review and comment on all relevant drafts, documents and information from the CEN committee at any stage.**
- **The P-members of the ISO committee should instruct their committee secretary to circulate all such materials and establish mechanisms for developing the committee's consensus positions/ comments in a timely manner.**
- **The deadlines of the CEN committee for commenting must be respected.**

CEN LEAD – PARTICIPATION IN CEN MEETINGS PRIOR TO DIS/prEN STAGE

- **ISO committees may nominate up to four representatives to attend relevant CEN meetings to represent the ISO committee's consensus positions/comments.**

- **Preference should be given to persons from non-European countries to serve as these representatives.**

- **It is important to note that these representatives:**
 - **may attend the CEN meetings without the requirement for special invitations to be issued**
 - **do not have voting powers in the CEN meetings**
 - **may comment and be actively engaged in the discussion**
 - **are expected to represent the ISO committee - not their individual countries.**

MEETINGS

- **Joint ISO/CEN committee meetings are not allowed – non-European members of the ISO committee do not have rights within the CEN committee.**
- **The ISO/CEN Vienna Agreement Guidelines encourage ISO and CEN committees to meet in *conjunction* with each other, for example on consecutive days in the same location.**
- **CEN has a policy that meetings of CEN committees, including meetings in conjunction with ISO committees, are to be held in Europe.**
- **Exceptions to this policy may be considered on a case-by-case basis – the non-European host of the meetings must bear the cost of hosting both the ISO and CEN meetings held in conjunction.**

ANNEX Z

- **When CEN standards are mandated to support European Commission Directives, the foreword of the standard shall indicate this.**
- **Annex Z is also required in the CEN standard to give more detailed information on how the standard supports the EC Directive.**
- **Drafts of Annex Z must be included in the CEN enquiry and formal vote drafts.**
- **The CEN committee shall provide the Annex Z text.**
- **While Annex Z will be included in the ISO DIS and FDIS versions, Annex Z is not included in the published International Standard.**

CEN/CENELEC GUIDE 15 – TASKS AND RESPONSIBILITIES OF HAS CONSULTANTS

- **Addresses details regarding the competence, roles and responsibilities, and processes for selection, regular review, complaints and dispute resolution.**

ROLES OF HAS CONSULTANTS

- **To assist in the preparation of mandated or harmonized standards, providing recommendations and information in relation to the relevant European Commission directive(s)/regulation(s) and their essential/basic requirements**
- **To obtain clarification on the scope of the EC directive(s)/regulation(s) from the European Commission, when requested by a committee secretariat**
- **To advise the committee/secretariat on the essential/basic requirements of the European Commission relevant directive(s)/regulation(s) to be addressed**
- **To inform the committee/secretariat on compliance of a draft standard with the relevant directive(s)/regulation(s)**

WORKING WITH HAS CONSULTANTS

- **Committees are free to agree by consensus whether they wish to reach compromise on revisions to the standards to address the HAS consultant assessment, or those committees may choose to ignore this assessment.**
- **There are cases where multiple HAS Consultants are providing multiple and conflicting inputs.**
 - **Europe has committed to look into establishing the means to ensure in such cases the multiple HAS Consultants work together to provide one coordinated input.**
- **HAS Consultants are only authorized to comment on text in the draft standards in relation to EC directives/regulations – Their assessments shall not comment on any other text in the draft standards that is not related to the EC directives/regulations.**

ISO COMMITTEE OPTIONS

- **Do not incorporate the HAS Consultant assessment input via revisions to the draft standard.**
 - **Note: This may likely lead to the ISO and CEN committees decoupling from VA cooperation, resulting in separate ISO and CEN standards on the same subject, as the resulting ISO/EN standard will not be cited in the EC Official Journal under the relevant EC directive(s)/regulation(s).**

- **Develop committee consensus on revisions to incorporate the HAS Consultant assessment in the normative requirements of the draft standard.**

- **In accordance with the ISO Global Relevance Policy (accepted by both the ISO/TMB and the CEN BT):**
 - **Reflect the input from the HAS Consultant assessment in optional normative requirements for the European market in the main body text and/or normative annexes.**

 - **Reflect the input from the HAS Consultant to provide normative requirements for the European market in a Technical Specification (TS) related to the general ISO/EN standard.**

RECENT ANSI CONCERNS

Some recent European Commission policies and requests seem to be contrary to the important standardization concepts of global relevance and consensus as established by the WTO and supported by ISO and CEN policy:

- **Not allowing optional clauses or annexes for specific regions or markets**
- **Requiring strict use of terms and definitions as presented in EC Directives and regulations – recent clarification**
- **Not allowing normative reference to standards from organizations other than ISO, IEC, CEN and CENELEC**
- **The negative impact on document progress and the resource burden of late HAS consultant inputs**

ANSI has raised these concerns with the ISO Technical Management Board in 2019 and 2020 and the ISO/TMB has unanimously agreed that ISO senior management should seek resolution of these concerns with IEC, CEN, CENELEC and the EC

ISO will pursue setting up a meeting of the relevant parties to address these concerns

ISO/TMB PROPOSED SOLUTIONS FOR THE MEETING

Recognition that mandated ISO/ENs are subject to the same development rules and concepts as all other ISO/ENs including:

- **expressing regional differences via parallel clauses or annexes or in alternative deliverables**
- **allowing committees to determine their terms and definitions by consensus**
- **allowing normative references to standards from organizations other than ISO, IEC, CEN and CENELEC**
- **allowing undated references**

Suggesting that the process for citing standards in the Official Journal of the European Union should be reviewed and improved, noting the lengthy time this process takes

Early and continuous engagement between technical bodies and HAS consultants from WD stage onward to ensure common understanding and increase the likelihood of a positive assessment

Allow a 5 week period before launch of FDIS for HAS consultant review, following which the ISO committee leadership could decide to launch the FDIS vote and potentially decouple from the VA or postpone the FDIS vote for up to 12 weeks to resolve issue (but this is not a substitute for early and continuous engagement)

Development of guidance and training on drafting mandated standards

PENDING THE RESULTS OF THE MEETING

ISO/TMB may decide to communicate to ISO committee leaders about the EC policy practices of concern so that they may be alerted to them. ISO/TMB may direct ISO committees that they cannot take any decision on the development or content of ISO standards that compromises the concepts of global relevance and consensus in order to comply with these EC policy practices.

If necessary, the ISO/TMB may decide to block the publication of any ISO standard that can be shown to compromise these principles to comply with the EC policy practices.

HELPFUL HINTS TO REMEMBER

- **A globally relevant ISO standard must also meet the needs of Europe – but the WTO and the ISO Global Relevance Policy state that an international standard should not impose any specific regional or national approach on the world.**
- **If it doesn't sound fair, it probably isn't. Trust your instincts.**
- **Rely on your ISO committee leaders and the ISO TPM to help, even if they are from Europe.**
- **Do not accept actions at meetings that were not announced before the meeting.**
- **Read and know the ISO Directives, the ISO/CEN Vienna Agreement and the ISO/CEN Vienna Agreement Implementation Guidelines.**
- **Let ANSI know. We can and will help.**

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