



Criteria for participation of VICH Outreach Forum members in VICH Expert Working Groups

Introduction:

This paper summarises the criteria used by the VICH Steering Committee (SC) when deciding on participation from VICH Outreach Forum members in a VICH Expert Working Group (EWG). A key aspect in taking those decisions is the need to maintain a workable and efficient EWG structure, while allowing adequate participation of experts from VICH Outreach Forum member countries or regional organisations.

Background:

(a) Providing input into the VICH work:

Parties or countries can provide input during different stages of the process through:

- submitting needs/ideas for harmonised technical requirements to the VICH SC in the form of a concept paper and providing further explanation as appropriate for discussion and consideration prior to decision-making at a VICH SC meeting,
- commenting on published concept papers for VICH SC-approved harmonisation topics,
- commenting on the published draft guidelines at Step 4 of the guideline development or revision process.

In addition, there is the possibility for VICH Outreach Forum members to actively participate in the EWGs elaborating new harmonised guidelines or revising existing ones.

(b) Expectations from EWGs and experts:

The process for establishment of EWGs by the VICH SC, the roles and responsibilities of each actor as well as the rules for the functioning of the groups are described in detail in a number of VICH-internal procedural guidances. These are listed in the Annex where for ease of reference the key points of these procedural documents have been summarised. Some aspects of the procedures may require further modification in the future in order to ensure appropriate participation by experts nominated by VICH Outreach Forum members.

Criteria for participation of experts from VICH Outreach Forum members in VICH EWGs:

The VICH Outreach Forum members in question should have demonstrated an interest in actively participating in the elaboration of new/revision of existing VICH guidelines (e.g. during the phase of new topic submission or through comments on published concept papers).

Expert(s) proposed to represent VICH Outreach Forum members in VICH EWGs should fulfil the following criteria:

- Relevant expertise
- Sufficient resources and time to contribute and to attend meetings
- Commitment for the duration of the EWG work plan for the topic of interest
- Ability to participate in a meeting conducted in English

Taking into account the objectives and scope for the new topic or guideline revision as agreed in the concept paper, the VICH SC determines the appropriate number of experts that should be appointed to the EWG from VICH-members/observers and VICH Outreach Forum members. The final EWG size should not compromise the efficient functioning of the group (N.B.: ideally between 10 to 18 members) and should maintain the balance between representatives from Authorities and from Industry as well as geographical balance.

If necessary (e.g. to maintain a workable VICH EWG size) VICH Outreach Forum members may organise themselves on a regional basis and appoint one expert per region.

Annex

Listing of existing VICH-internal procedures relating to EWGs:

- VICH/00/150: Guidance for Members of VICH Expert Working Groups
- VICH/00/151: VICH Procedure for the Expert Working Groups
- VICH/00/152: Guidance for the Steering Committee on the Appointment of Experts and Chairpersons/Topic Leaders to Working Groups
- VICH/00/153: Policy for Disbanding Expert Working Groups
- VICH/00/154: Policy on Consultation at Step 4
- VICH/00/155: Policy on Appreciation and Recognition of the Chairs and Expert Working Group Members

Key expectations from VICH EWGs and experts as laid down in the above procedures:

The EWGs are task-oriented and their aims are to:

- develop a comprehensive discussion paper based on the SC concept paper;
- elaborate recommendations and draft guidelines based on a concept paper adopted by the SC for the priority items determined by the SC;
- report regularly on progress and issues for resolution to the SC;
- submit these recommendations and draft guidelines to the SC;
- produce minutes in a timely fashion.

The EWGs will work towards harmonisation of technical requirements by way of consensus in accordance with the established procedures.

The membership of EWGs is decided by the SC considering the following:

- Limited number of members;
- Each SC member and observer member has the right to appoint one expert;
- If necessary, and unless otherwise specified by the SC, each expert may be accompanied by one advisor. The chairperson, the topic leaders and the secretariat should be notified of this;
- Additional experts from other regions could be appointed by the SC particularly in response to proposals from VICH Outreach Forum members;

- Unless otherwise decided by the SC, no other observers are allowed in the EWG meetings.

Most EWG members are expected to have three roles i.e.

- to be a topic expert,
- to represent the views of their sponsoring organisation,
- to communicate the outcomes of the EWG discussions back to their sponsoring organisation.