



VICH PROCEDURE FOR THE EXPERT WORKING GROUPS

INTRODUCTION

This document provides guidance to Expert Working Group (EWG) members on the operations of VICH. This document's objective is to explain the VICH procedures regarding the operations of the EWGs. Another document "Guidance for Members of VICH Expert Working Groups" (VICH/00/150) contains additional practical information regarding the functioning of the EWGs.

A. THE VICH ORGANISATIONAL CHARTER

The VICH Organisational Charter (*ref: VICH/96/002*) ([link](#)) is the basic document, i.e. the "constitution" of VICH. All participants in EWGs should read this document to be clear about the VICH objectives, the rules, the procedures of VICH as well as the status and the roles and responsibilities of each participant in the VICH process.

VICH achieves the technical development of guidelines through its EWGs. The Steering Committee decides if an EWG should be established once it has agreed on a guideline project.

The VICH process is facilitated by the World Animal Health Organisation (OIE), which as associate member of VICH, supports the VICH process and disseminates the VICH information at a world-wide level.

B. SUMMARY OF THE ROLES WITHIN VICH

1/ The Steering Committee (SC)

The SC drives the harmonisation process. The key tasks of the SC are to:

- determine the working procedures;
- determine the priority items based on concept papers prepared by its members, also taking recommendations from the VICH Outreach Forum into consideration;
- establish the appropriate Expert Working Groups (EWGs) and appoint topic leaders and EWG chairpersons;

- consider and resolve issues raised by the EWGs;
- approve the draft recommendations issued by EWGs before release for world-wide consultation and subsequently for approval by the regulatory authorities of the EU, Japan and the USA;
- implement a programme of monitoring, maintenance and review of Guidelines.

Information on the composition and structure of the SC can be found in the VICH Organisational Charter.

Coordinators: Each SC member has appointed a coordinator to act as contact point with the VICH secretariat. In addition to their roles in coordinating the distribution of documents and the preparation of their delegations for SC meetings, coordinators have the following role to play in assisting the effective functioning of EWGs:

- The coordinators must provide written feedback to EWG Chairpersons from their delegation and inform on actions arising from the SC meeting. For any actions arising from the SC meeting for an EWG, the coordinator for their delegation will provide such feedback to EWG Chairperson within 2 weeks of the meeting;
- The coordinator with a Chairperson of an EWG from his/her delegation liaises with other SC members from the same delegation and reviews the agendas for EWG meetings. The coordinator then liaises with the EWG Chairperson to provide any input from colleagues and feedback from SC meetings;
- The coordinator follows up with the EWG chair, reviews his/her written report, feeds back key issues to delegation members and takes required action on any points of dispute well in advance of the next SC.

Secretariat: IFAH provides the secretariat for VICH activities. It also maintains the VICH web site.

2/ Expert Working Groups (EWG)

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.

Operating procedures for the EWGs are detailed in specific VICH guidance documents.¹ The EWGs will work towards harmonisation of technical requirements by way of consensus in accordance with the established procedures.

¹ VICH/00/150 - Guidance for members of VICH Expert Working Groups
 VICH/00/152 - Guidance for the Steering Committee on the appointment of Experts and Chairpersons/topic Leaders to Expert Working Groups

The EWGs should undertake their work using electronic communications and only require physical meetings for exceptional circumstances. However, in order to increase the efficiency of the EWG, the number of physical meetings can be increased.

Particular attention should be paid to:

- any issues that are likely to be difficult to resolve should be brought to the attention of the SC,
- concentrating efforts on what can be achieved within the time provided.

If an EWG cannot reach agreement, the SC should consider publishing the main outcomes in a “status report” document. In such cases a document should be prepared by the EWG including the points on which an agreement could not be reached.

Membership of the Expert Working Groups

The membership is decided by the SC.

➤ Experts

- Limited number of members (typically 10 to 18, depending on needs) balanced between representatives from Authorities and from Industry as well as between the regions;
- 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 meeting.

➤ Topic Leaders / Chairperson of EWGs:

A Topic Leader is appointed for each EWG by the SC, on the basis of expertise and on geographical balance.

When establishing the work plan of the EWG, the Chair will make their best effort to ensure it is as timely as possible

One topic leader is responsible for each topic. He/She normally chairs the specific EWG and is therefore accountable to the SC with respect to the mandate and time frame given by the SC. He/She is also responsible for preparing the appropriate discussion documents for the EWG meetings.

In the case where several topics are related to each other, it may be cost-efficient to group them into one EWG chaired by one chairperson. This chairperson is appointed by the SC and is accountable to the SC with respect to the mandate and time frame given by the SC. In this instance, each topic is still under the leadership and responsibility of the topic leader.

At step 5 of the procedure the topic leader must be a representative of the regulatory authorities.

C. VICH PROCESSES FOR PRODUCING GUIDELINES

The 9 step procedure

The development of VICH guidelines follows a 9-step process described in the VICH Organisational Charter (*ref: VICH/96/002*)

D. PROCEDURE TO BE FOLLOWED BY THE SC AND EWG TO GAIN AGREEMENT FOR THE FIRST EWG MEETING

1

A VICH topic is selected by the SC from a concept paper (See Note to prepare of a VICH Topic Concept Paper VICH/97/037-Revision 3-FINAL

EWG members should obtain a copy of the concept paper for their particular topic from their coordinator. This paper (subject to any changes or decisions made by the SC) defines the scope of work of the EWG.

2

A Topic Leader, or Chairperson and Topic Leaders, is/are appointed at a Steering Committee meeting.

3 6 weeks

Each SC member/observer can appoint one expert for the topic selected.

Name, affiliation, mailing address, telephone number, telefax number and e-mail address of the experts are to be provided to the VICH Secretariat by the coordinator of the SC member or the observer.

4 1 week

The VICH Secretariat sends out a list of members of the EWG to the EWG, together with relevant documents:

- *Organisational charter of VICH (VICH/96/002) (link)*
- *VICH procedure for the Expert Working Groups (VICH/00/151) (link)*
- *Guidance for members of VICH Expert Working Groups (VICH/00/150) (link)*
- *Notes on the format and style of VICH guidelines (VICH/97/061) (link)*

and asks the Chairperson (if appointed) or the Topic Leader to initiate action on the specific topic.

5 6 weeks

The Topic Leader will write a **discussion document** and establish an action plan. The action plan must be presented and agreed by the EWG. Confirmation of the acceptance of the

action plan should be sent to the VICH secretariat. The plan should be updated as appropriate and any proposed amendments submitted to the SC by the Chairperson.

For EWG with multiple topics the chairperson will be responsible for establishing the action plan and the Topic Leader(s) would prepare the discussion documents under the Chairperson's direction.

In order to enable the start the work of the EWG by electronic procedure the experts need to receive from the Topic Leader a first outline of the draft guideline in which the issues that are to be discussed, the work plan with proposed timelines, and possibly first proposals should be outlined as follows:

- Purpose** : Initiate the work of the EWG
- To be elaborated by** : The Topic Leader (in consultation with the Chairperson in the case of an EWG with multiple topics)
- Outline** : Detailed description of all issues at stake on the topic concerned (i.e. differences in regulatory requirements and practices) using the concept paper prepared as a basis and taking into account the mandate outlined by the SC.

Proposal on ways to resolve issues, either as points for discussion, or even draft guidelines.

Proposed work plan and, if necessary, a tentative schedule of face to face meetings, and tentative target deadline for proposing guidelines text for submission to SC at step 3.

Suggested number of pages : 2 - 10

Suggested appendices : Tabulated comparison of specific requirements in the different VICH regions. Requirements in Outreach Forum countries as supplemental information in a separate table when needed.

Existing legal requirements and/or relevant national guidelines.

Relevant international guidelines (e.g. ICH, OECD, OIE, CODEX, JECFA).

This document should be concise and sent to the using the specific EWG e-mail address.

6 4 weeks

The EWG members to agree to the discussion document and action plan.

7

In parallel with the elaboration of this document, the Topic Leader or Chairperson should, as soon as he/she is appointed, contact all the EWG experts and tentatively schedule the necessary meeting(s) so that they can take place as soon as possible after the SC authorisation.

8 1 week

The VICH secretariat sends the document received from the Topic Leader and Chairperson to the SC for authorisation of the meeting schedule and the action plan.

9 4 weeks

The SC authorises (or not) by written procedure the meeting schedule and the action plan as drafted by the Topic Leader and Chairperson.

10 1 week

The VICH secretariat notifies the Topic Leader and Chairperson of the authorisation given by the SC.

Note: These timelines are deadlines that should if possible not be exceeded. All involved should endeavour to reduce these timelines to the minimum feasible.

E. SEEKING PERMISSION FOR SUBSEQUENT MEETINGS AND LOCATION OF MEETINGS

Authorisation needs to be obtained from the SC for **each** EWG meeting in order to consistently monitor the cost-efficiency of VICH. Authorisation is given at SC meetings or by a written procedure.

The frequency of EWG meetings is to be decided by the SC following a proposal of the Topic Leader/EWG Chairperson.

All EWG meetings are to be rotated among the three regions, starting in general with the region that holds the chair of the EWG.

F. CONSULTATION AT STEP 4

The procedures applied for consultation at step 4 are detailed in the document VICH/00/154. ([link](#))

G. CONDUCT OF MEETINGS

The working language is English. Any translation considered necessary by any expert or Topic Leader shall be provided by such experts and Topic Leaders at their own expense.

The Topic Leader/Chairperson of the EWG ensures that at all times, all members of the EWG are able to participate actively in the discussions and present their opinions and views to their colleagues. When necessary, adequate time should be allowed for simultaneous translation. Due to language and time-zone barriers telephone conferences should not be used without the prior agreement of all EWG members.

The Topic Leader/Chairperson of the EWG will ensure that minutes of the meetings are produced in a timely fashion and sent without delay to the secretariat for circulation to the SC members. The minutes should explain on which subjects an agreement was found, clarify the conclusions reached, and highlight the areas of disagreement, explaining the reasons for this.

H. PROCEDURE FOR EWG TELECONFERENCES

- 1/ The EWG Chair shall consider keeping the number of teleconferences to the minimum;
- 2/ The agenda and discussion documents shall be distributed to EWG members sufficiently in advance of the teleconference to enable a proper preparation of the discussions;

- 3/ The EWG members may submit comments before the teleconference;
- 4/ The EWG Chair shall lead the discussions taking the comments from absentees into consideration;
- 5/ No conclusive decisions shall be made during the teleconference without the attendance of all EWG members;
- 6/ The EWG Chair shall distribute the minutes of the teleconference to all EWG members including the absentees as soon as possible after the teleconference and shall reply to any questions from the absentees;
- 7/ Absentees may submit comments after the teleconference;
- 8/ Final decisions shall only be made by written procedure after the above steps from this procedure have been fulfilled.

I. ESTABLISHMENT OF A VICH TOPIC PROGRESS REPORT

Before each SC meeting, the SC members should receive a **progress report** on the progress and activities of each VICH topic.

Purpose : Report progress to SC

To be elaborated by : The EWG Chairperson/Topic Leader. Alternatively, if several topics are grouped under one EWG, this should be done by the Chairperson, with input from the topic leaders.

Outline : Summarise the status/progress of the work on the GL(s)

Describe the points agreed to by the EWG members, thereby reflecting the degree of consensus.

Provide a precise description of the points where there is no agreement with an indication of the different member's positions.

If needed, outline the areas where clarification or guidance from the SC is being sought. The questions should be asked in a clear and unambiguous way.

Proposal for the next steps with an estimate of the necessary time frame to complete the work.

Suggested number of pages : 2 – 4

J. PAYMENT OF EXPENSES

VICH does not provide any financial support for EWG members. Each SC member/observer who appoints an expert/advisor is responsible for making his/her own arrangements for funding the travel and accommodation expenses of their appointee.

K. DISBANDING OF EXPERT WORKING GROUP

(see document VICH/00/153) (link)