



SOP for Annual Workshop Planning of APEC Harmonization Center

2016

APEC Harmonization Center

Table of Contents

1. Background	1
2. Objective	1
3. Process	1
4. Workflow	2
4.1. (Step 1) Workshop Survey	2
4.2. (Step 2) Circulating Workshop Application	2
4.3. (Step 3) Teleconference for Workshop Proposal Selection	2
4.4. (Step 4) Circulating the Meeting Result and Developing Plan for the Next Year	2
4.5. (Step 5) Announcing Workshop Plan	2
Appendix 1.	3
Appendix 2.	4
Appendix 3.	5

List of Figures

Figure 1. The Process of the AHC Workshop Planning

Figure 2. The Organizational Chart of the AHC

List of Appendices

Appendix 1. AHC Organization

Appendix 2. Criteria for Workshop Selection

Appendix 3. Workshop Application Form

1. Background

The APEC Harmonization Center(AHC) was established in 2009 after the endorsement of the APEC ministerial-level talks and summit as an official and permanent organization, specialized in training. The AHC is in pursuit of APEC’s trade facilitation and regional economic integration by promoting a higher level of international regulatory harmonization in the APEC region.

The scope of the AHC’s activities includes: 1) conducting surveys and research, 2) providing training such as workshops, 3) establishing network, 4) e-publication and managing website, and 5) cooperation with other organizations. (See the Appendix 1 for the organizational chart of the AHC)

This Standard Operating Procedure(SOP) focuses on organizing workshop, as one of AHC’s activities to contribute to regional regulatory harmonization. The SOP is intended to describe specific procedure of annual workshop planning which will be shared with APEC member economies while ensuring transparency of the process.

2. Objective

This SOP defines the process of workshop planning of the AHC from application submission to announcement of plan.

3. Process

AHC Workshop plan is developed according to the following process.

Step	When	What	By Whom	Details
1	By Sept. (Previous year)	Workshop Survey (Application Submission)	Applicant	Workshop application indicating specific topic, time, and other information is submitted to the AHC (Refer to Appendix 3. Workshop Application Form)
↓				
2	Early Oct. – Early Nov.	Circulating the Workshop Application	AHC Secretariat	Submitted applications are reviewed by AHC Advisory Board(AB), and RHSC ¹ for comments.
↓				
3	Mid Nov.	Teleconference for Workshop Topic Selection	AHC	Discussion on AHC workshop plan
↓				
4	Late Nov.	Circulating the TC Result and Establishing Plan for the Next Year	AHC Secretariat	After circulating the result of teleconference and public consultation, workshop plan is established for the next year
↓				
5	Jan. – Feb.	Announcing Workshop Plan	AHC	Workshop plan is presented for sharing and requesting support from RHSC members at SOM1 RHSC meeting

Figure 1. The Process of the AHC Workshop Planning

¹ Regulatory Harmonization Steering Committee(RHSC)

4. Workflow

4.1. (Step 1) Workshop Survey

1) The AHC informs survey period through AHC's website, e-mails and RHSC meeting before collecting workshop proposals via its website.

2) Applicants (including international organizations, associations and others) of workshops submit the form of the Appendix 3 within the application period through the AHC's website.

* A list of submitted application will be shared but application itself could either be publicly opened through the website or not, depending on the decisions of applicants.

4.2. (Step 2) Circulating Workshop Application

1) The AHC circulates submitted applications among AHC Advisory Board(AB) and RHSC members for comments and review.

2) If the number of proposed workshop is less than that of the AHC could host within a year, additional application submission can be made after carrying out additional workshop survey.

4.3. (Step 3) Teleconference for Workshop Proposal Selection

The AHC organizes teleconference to develop workshop plan for the following year as below:

1) Teleconference is held when as many stakeholders could participate in as possible. RHSC co-chairs, workshop applicants and the AHC must attend the meeting. Date, time and other related information for the meeting is notified to the relevant parties including AHC AB and RHSC members.

2) Both of RHSC co-chairs should join the meeting in principle. If one of co-chairs is not available to call in, teleconference will proceed only when the co-chair who cannot participate in TC delegates his/her authority to the other co-chair.

3) AHC's workshops have to be selected according to Appendix 2. "Criteria for Workshop Selection" among submitted application of the year but priority of workshop selection can be adjusted, when necessary, with the agreement of RHSC members.

Workshop proposals are not accepted if they do not meet the workshop selection criteria and not endorsed at the teleconference, even if the number of proposed workshop is below the number of workshop that the AHC could cover within a year. In that case, the AHC is able to propose and select workshop topic according to Appendix 2.

4) AHC's workshop plan should be finalized through consultation of the meeting participants.

4.4. (Step 4) Circulating the Meeting Result and Developing Plan for the Next Year

1) The result of teleconference is circulated among RHSC members for comments. AHC workshop plan, developed on the basis of the meeting result, is posted on AHC's website.

4.5. (Step 5) Announcing Workshop Plan

1) The AHC presents its workshop plan and seeks support of the plan at a RHSC meeting during the first APEC Senior Officials' Meeting.

2) If it is necessary to modify timeline, plan, and other factors of workshop, the AHC notifies them through its website (when significant changes are made, workshop plan could be re-circulated) and share information at the next RHSC meeting.

Appendix 1. AHC Organization

• Organizational Chart

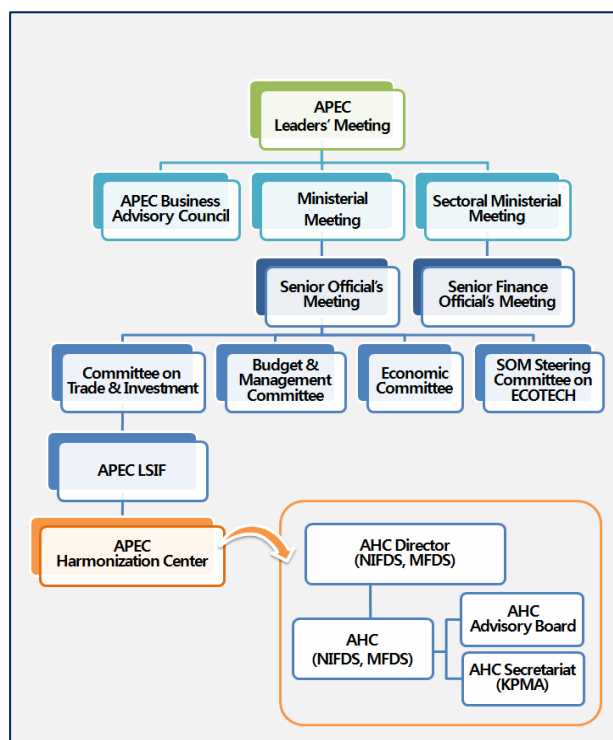


Figure.2 The Organization Chart of AHC

In partnership with Regulatory Harmonization Steering Committee(RHSC), the AHC operates under aegis of Life Sciences Innovation Forum(LSIF) in order to provide platform for regulatory priorities among APEC member economies. The AHC is operated and supported by the National Institute of Food and Drug Safety Evaluation(NIFDS), the Ministry of Food and Drug Safety(MFDS), Korea.

• AHC Director

Responsible for overseeing activities and events and leading coordination among LSIF, RHSC, AHC Secretariat, and the AHC Advisory Board. The Director of AHC is performed by the Director General of the NIFDS, MFDS, Korea.

• AHC Advisory Board

Responsible for providing technical input and professional expertise on the strategic direction of AHC's events. They may participate in the process of development of training modules and recommendation of appropriate trainers who could be a resource to strengthen the AHC and its specific projects.

• AHC Secretariat

Responsible for administrative point of contact and organization of AHC's day to day activities. The Secretary General will be an overseer of the Secretariat activities and assist the AHC Director. AHC Secretariat duties are performed by a contract service provider.

Appendix 2. Criteria for Workshop Selection

1. Workshops are selected on the basis of the following criteria and priorities.

- 1) Topics related to RHSC Priority Work Areas(PWAs)
- 2) Topics possible to hold back-to-back workshop with international harmonization initiatives or regulatory authorities meetings with high demand for now and in the future
- 3) Topics with high demand in the APEC region (if necessary, survey can be conducted to identify demand)

2. If the AHC can host workshops more than the number of submitted applications, the AHC could organize additional workshop besides the selected applications according to the following standard:

- 1) The AHC may consider additional workshop topics given the result of survey or previous research. In this case, considered topics for workshop will be circulated among AHC Advisory Board and RHSC for review and their endorsement.

Appendix 3. Workshop Application Form

Application Form: Support for the AHC Workshop Program

Applicant (Person in charge)	Name:	
	Position:	
	Organization:	
	Economy:	
	Telephone:	
	E-mail:	
Topic		
Objective (Summary) (Roadmap (if necessary))		
Date	DD/MM/YY to DD/MM/YY (Total ** Days)	
Venue (Economy)		
Expected No. of Guests	(# of participants)	<input type="checkbox"/> Open (incl. industry and academia)
		<input type="checkbox"/> Closed (regulators only)
Expected Total Cost of the Event		
Requested Support Areas from the AHC (See the attachment)		
Others		

Attachment. Possible support areas from the AHC (depending on the venue of the event)

○ Note: Support areas from the AHC would vary depending on economies where the event is held (Refer to the table below)

Eligibility	Possible Support Area from the AHC
<p>Allowable</p>	<p>[Online (The AHC Website, etc.)]</p> <ol style="list-style-type: none"> 1) Promotion of the event through the AHC website 2) Online registration for the event on the AHC website 3) Posting presentations and video clips of the event on the AHC website <p>[Funding/Budget] *PLEASE refer to the Internal Guidance for APEC Harmonization Center Project Expenses for the details.</p> <ol style="list-style-type: none"> 1) Photocopying and communication costs (including the costs of teleconference) 2) Conference room and secretariat room rental (MUST have AHC's agreement in advance) 3) Specialized materials or equipment needed for the event 4) Banners (used for advertisement of the project event but not for promotion of products/services/organizations/ideas and the like) 5) Conference kit (presentation materials, notepad, etc.) 6) Expenses to develop teaching and training materials 7) Others (i.e. visit to related organizations/facilities) <p>[Administrative Works]</p> <ol style="list-style-type: none"> 1) Program committee (PC) meeting related duties (i.e. organizing PC, notification of the PC meetings, minutes, etc.) 2) Trainee/Speaker invitation and related duties (i.e. invitation letters, reservation of accommodation, flight tickets, etc.) 3) Event preparation proceedings (i.e. banners, conference kit, equipments, etc.) 4) On-site support during an event (i.e. operating registration desk, etc.) 5) Conducting 'Training Evaluation Survey' and analyzing the results 6) Other administrative works (visit of related organizations, follow-ups, etc.)

Non-allowable

[Funding/Budget]

- 1) Promotional items and gifts
- 2) Conference registration fees
- 3) Ground transportation, including airport transfers, or costs of sightseeing
- 4) Meals (including reception)

*** The exceptions to non-allowable expenses are provided on the Internal Guidance for APEC Harmonization Center Project Expenses.**