

ICH E6(R3) EWG Work Plan

February 22, 2024

Topic Adoption date: *June, 2019*

Rapporteur: *Dr. Khair ElZarrad, FDA, United States*

Regulatory Chair: *Mr. Peter Twomey, EC, Europe*

Last Face-to-Face Meeting: *Prague, Czech Republic, November 2023 (Annex 2 Subgroup)*
Basel, Switzerland, March 2024 (Principles and Annex 1)

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Apr. 2023</i>	<i>MC endorsement/approval of updated Concept Paper for Annex 2</i>
<i>May. 2023</i>	<i>Step 1 Sign-off of Technical Document (Principles and Annex 1) Complete</i>
<i>May. 2023</i>	<i>Step 2a/2b Endorsement of Technical Document (Principles and Annex 1)</i>
<i>May. 2023</i>	<i>Began Step 3 Public Consultation (Principles and Annex 1)</i>
<i>Jun. 2023</i>	<i>Began drafting Annex 2</i>
<i>Nov. 2023</i>	<i>Step 3 End of Public Consultation (Principles and Annex 1)</i>
<i>Nov. 2023</i>	<i>Begin review of public comments for Principles and Annex 1</i>
<i>Dec. 2023</i>	<i>Complete initial draft – Consensus Version of Annex 2</i>
<i>Dec. 2023</i>	<i>Begin Caucus Review for Annex 2</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jan. 2024</i>	<i>End of Caucus Review for Annex 2</i>
<i>Feb. 2024</i>	<i>Begin review of caucus comments for Annex 2</i>
<i>Mar. 2024</i>	<i>Interim Meeting to Incorporate Public Comments for Final Version (Principles and Annex 1)</i>
<i>Apr. 2024</i>	<i>Plenary Working Party (PWP) Consultation Period prior to Step 1 Sign-off of Technical Document (Annex 2)</i>

Jun. 2024	<i>Complete Annex 2 caucus review comments with final consensus version for Annex 2</i>
Jun. – Jul. 2024	<i>Step 1 Sign-off of Technical Document (Annex 2)</i>
Jun. – Jul. 2024	<i>Develop Step 2 Presentation (Annex 2)</i>
Jul. – Aug. 2024	<i>Step 2a/2b Endorsement of Technical Document (Annex 2)</i>
Jul. – Aug. 2024	<i>Step 3 Begin Public Consultation (Annex 2)</i>
Jul. – Aug. 2024	<i>Complete review of public comments for Final Consensus Version for Principles and Annex 1</i>
Jul. – Aug. 2024	<i>Final Agency clearance for Principles and Annex 1</i>
Aug. 2024	<i>PWP Consultation Period prior to Step 3 Sign-off of draft Guideline(Principles and Annex 1)</i>
Aug. – Sep. 2024	<i>Develop Step 4 Presentation (Principles and Annex 1)</i>
Sep. 2024	<i>Step 3 Sign-off of draft Guideline (Principles and Annex 1)</i>
Oct. 2024	<i>Step 4 Adoption of draft Guideline (Principles and Annex 1)</i>
Dec. 2024	<i>PWP Consultation Period prior to Step 3 Sign-off of draft Guideline (Annex 2)</i>
Jan. 2025	<i>Step 3 End of Public Consultation (Annex 2)</i>
Apr. – May. 2025	<i>Step 3 Sign-off and Step 4 Adoption of draft Guideline (Annex 2)</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Jan. 2024	<i>Jun. 2024</i>	<i>E6(R3) EWG meeting every 1 or 2 days a week</i>	<i>Review public comments for draft E6(R3) document (Principles and Annex 1)</i>
Feb. 2024	<i>Jun. 2024</i>	<i>E6(R3) Small group meeting once a week</i>	<i>E6(R3) small group will meet to review public comments for draft E6(R3) document (Principles and Annex 1)</i>
Feb. 2024	<i>Jun. 2024</i>	<i>Annex 2 Sub-Group Meeting every week</i>	<i>Review caucus comments for Annex 2</i>

Mar. 2024	<i>Mar. 2024</i>	<i>E6(R3) EWG interim meeting (March 4 – 8 Basel, Switzerland</i>	<i>In person and virtual meeting to review public comments for draft E6(R3) Guideline (Principles and Annex 1)</i>
Mar. 2024	<i>Mar. 2024</i>	<i>Annex 2 Stakeholder Engagement (March 28, 2024)</i>	<i>Meet with E6 Stakeholder Representatives to discuss Draft Annex 2 Document</i>
May. 2024	<i>May. 2024</i>	<i>E6 Stakeholder Engagement for Principles and Annex 1</i>	<i>Meet with E6 Stakeholder Representatives to discuss Principles and Annex 1 document. Plan to have 2 virtual meeting for 2-hours each day.</i>