

# ICH M7 (R2) Maintenance IWG/EWG Work Plan

## February 01, 2019

**Topic Adoption date:** *June 2017*

**Rapporteur:** *Dr. Masamitsu Honma – MHLW/PMDA, Japan*

**Regulatory Chair:** *N/A*

**Last Face-to-Face Meeting:** *Charlotte, NC, USA, November 2018*

### 1. Key milestones

#### 1.a. Current status of key milestones

<b>Past completion date</b>	<b>Milestone</b>
<b><i>Jun. 2014</i></b>	<i>ICH-M7 was issued as Step4.</i>
<b><i>Mar. 2017</i></b>	<i>ICH-M7 (R1) was issued as Step 4. It contains Appendix 3 (Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes).</i>
<b><i>Jul. 2018</i></b>	<i>The concept paper of ICH-M7 (R2) is proposed; Maintenance of ICH-M7 with the 2<sup>nd</sup> addendum (application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes) and Q&amp;A topics proposed based on experience through implementation of ICH-M7.</i>
<b><i>Nov. 2018</i></b>	<i>The Face-to Face meeting of ICH-M7 (R2) was held in Charlotte.</i>

## 1.b. Future anticipated key milestones

Expected future completion date	Milestone
<b>Jun. 2019</b>	<i>Revising M7 main document, and drafting guideline of addendum and Q&amp;A</i>
<b>Nov. 2019</b>	<i>Step 1 and 2a/b, revised M7 document, draft guideline of addendum and Q&amp;A</i>
<b>Jun. 2020</b>	<i>Step 3 Public Consultation.</i>
<b>Nov 2020</b>	<i>Discussions of public comments, if feasible, reach Step 4</i>

## 2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<b>Nov. 2018</b>	<b>Jan. 2019</b>	<i>Listing items for the 2<sup>nd</sup> addendum and the Q&amp;A by E-mail.</i>	<i>For the development of the 2<sup>nd</sup> addendum, additional compounds can be submitted. For the development of the Q&amp;A, additional questions can be submitted.</i>
<b>Feb. 2019</b>	<b>Feb. 2019</b>	<i>Whole EWG WebEx</i>	<i>Discussion about a list of compounds in the 2<sup>nd</sup> addendum and items in the Q&amp;A.</i>
<b>Mar. 2019</b>	<b>Mar. 2019</b>	<i>Safety EWG WebEx</i>	<i>Discussion about safety issues in the Q&amp;A.</i>
<b>Mar. 2019</b>	<b>Mar. 2019</b>	<i>Quality EWG WebEx</i>	<i>Discussion about quality issues in the Q&amp;A.</i>
<b>Apr. 2019</b>	<b>Apr. 2019</b>	<i>Whole EWG WebEx</i>	<i>Discussion about a list of compounds in the 2<sup>nd</sup> addendum and confirmation of the progress of Q&amp;A documents.</i>
<b>May. 2019</b>	<b>May. 2019</b>	<i>Safety EWG WebEx</i>	<i>Discussion about safety issues in the Q&amp;A (continued).</i>

<b>May. 2019</b>	<b>May. 2019</b>	<i>Quality EWG WebEx</i>	<i>Discussion about quality issues in the Q&amp;A (continued).</i>
<b>May. 2019</b>	<b>May. 2019</b>	<i>Whole EWG WebEx</i>	<i>Discussion about a list of compounds in the 2<sup>nd</sup> addendum and confirmation of the progress of Q&amp;A documents (continued).</i>
<b>Jun. 2019</b>	<b>Jun. 2019</b>	<i>EWG Face-to Face meeting / Drafting the 2<sup>nd</sup> addendum and Q&amp;A.</i>	<i>Drafting the 2nd addendum and Q&amp;A document. Finalizing M7 (R2) main text after confirmation in EWG.</i>