

ICH M7(R2) Maintenance EWG Work Plan

9 February 2018

Topic Adoption date: *June 2017*

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Regulatory Chair: *N/A*

Last Face-to-Face Meeting: *Fukuoka, Japan – June 2014*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2014</i>	<i>ICH-M7 were issued as Step4.</i>
<i>Mar. 2107</i>	<i>ICH-M7 (R1) were 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>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Mar. 2018</i>	<i>A concept paper will be released, and then discussion about 2nd addendum will start.</i>
<i>Nov. 2018</i>	<i>Step 1 sign-off & continue discussions on the concept paper</i>
<i>Jun. 2019</i>	<i>Step 2 a/b endorsement</i>
<i>Nov. 2019</i>	<i>Public consultation</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Apr. 2018</i>	<i>May. 2018</i>	EWG 1st WebEx / Discussion of 2nd addendum work plan	<ul style="list-style-type: none">➤ Discussion for work plan to develop the 2nd addendum➤ Review of the concept paper➤ Development of a list of compounds in the 2nd addendum
<i>Jun. 2018</i>	<i>Jul. 2018</i>	EWG 2nd WebEx / Discussion of 2nd addendum	<ul style="list-style-type: none">➤ Development of a list of compounds in the 2nd addendum (continued)
<i>Aug. 2018</i>	<i>Sep. 2018</i>	EWG 3rd WebEx / Discussion of 2nd addendum	<ul style="list-style-type: none">➤ Development of a list of compounds in the 2nd addendum (continued)
<i>Nov. 2018</i>	<i>Nov. 2018</i>	EWG f2f meeting/ Discussion of 2nd addendum	<ul style="list-style-type: none">➤ Development of a list of compounds in the 2nd addendum (finalize list)