ICH M7 Sub-Group Work Plan
17 February 2026

Topic Adoption Date: *June 2024*
Rapporteur/s: *Dr. Krista Dobo, PhRMA*
Regulatory Chair: *Dr. Alisa Vespa, Health Canada, Canada*
Last Face-to-Face Meeting: *Singapore, November 2025*

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
Jun. 2024	*Outline of Concept Paper "3 June 2024"* *Endorsed by the Assembly on 4 June 2024*
May. 2025	*Final Concept Paper dated 24 April 2025* *Endorsed by the Management Committee on 7 May 2025*

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
May. 2025	*ICH M7 Addendum on Risk Assessment and Control of N-Nitrosamine Impurities*
May. 2025	*Compound specific monographs for some N-nitrosamines*
May. 2025	*Training materials*

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
Jun. 2028	*Step 1 sign-off - Consensus reached on Draft Technical Document*
Jun. 2028	*Develop Step 2 Presentation*

Aug. 2028	*Step 2a/b sign-off - Confirmation of Technical Document by Assembly, Adoption of draft Addendum by Regulatory Members, and Step 2 Presentation*
Aug. 2028	*Initiate Development of Training Materials*
Dec. 2029	*Step 3 completed - Public consultation and address comments*
Dec. 2029	*Develop Step 4 Presentation*
Mar. 2030	*Step 3 Expert Sign-off and Step 4 Adoption by ICH Assembly Regulatory Members of Final Addendum Document and Step 4 Presentation*
Mar. 2030	*Finalize Training Materials*

2. Timeline for Specific Tasks

*Please provide in the table below short-term high-level specific tasks for work to be done within the Working Group **between now and the next ICH meeting** (recommended 4 – 10 tasks).*

Beginning date	End date	Task / Activity	Details
Nov.2025	*March, 2026*	Establish acceptable intakes (AIs) and develop draft monographs for 6 key nitrosamines	Achieve alignment on methodology for deriving AIs from carcinogenicity data for 6 key nitrosamines, and align on established AIs by March 2026
Nov. 2025	*April, 2026*	Draft text for enhanced Ames test (EAT) protocol	Draft text to be reviewed by EWG in advance of Brazil meeting. At Brazil meeting, will work towards consensus text
Nov. 2025	*April, 2026*	Negative *in vivo* mutation assay outcomes and establishing an acceptable limit	Achieve alignment on recommendation for an acceptable limit for *N*-nitrosamines that are negative in an in vivo mutation assay
Nov. 2025	*June, 2026*	Data analyses, discussions related to less-than-lifetime (LTL) framework	Achieve alignment on LTL framework
Nov. 2025	*June, 2026*	Interpretation of EAT assay for establishing acceptable intakes	Achieve alignment on EAT interpretation and if EAT can be used as a stand-alone assay for hazard identification
Nov. 2025	*June, 2026*	Assess OECD 488 *in vivo* mutation study design for nitrosamine hazard identification	At Brazil meeting, review and agree on study design recommendations for nitrosamines, beyond those provided in OECD 488

Nov. 2025	*June, 2026*	Data gathering and analyses to validate the use of in vivo mutation data as a surrogate for carcinogenicity data for nitrosamines	Advance discussions and alignment on this topic within the EWG
Nov. 2025	*June, 2026*	Develop methodology options for deriving AIs using in vivo mutation as a point of departure	At Brazil meeting, discuss methodology options to advance this topic and agree on next steps