

ICH M9 EWG Work Plan

23 August 2017

Topic Adopted: 14 June 2016

Last Face-to-Face Meeting: Montreal, Canada – May/June 2017

1. Anticipated Milestones

Completion Date	Deliverable
4 th Q 2017	Endorsement of <i>Step 2 a/b</i> document
1 st Q 2019	Adoption of <i>Step 4</i> document

2. Timelines

Date	Task / Activity	Details
June 2016 - November 2016	E-mail consultation within WG/ EWG	<ul style="list-style-type: none">➤ Concept paper and Business plan were established.➤ Agenda and possible documents for Osaka meeting were prepared.
7-10 November 2016	Face-to-face meeting (Osaka)	<ul style="list-style-type: none">➤ In depth discussion on criteria for BCS classification and biowaiving.➤ Preparation of draft version guideline.➤ Preparation/consensus on next steps towards face-to face meeting Montreal May 2017.
November-February 2017	Submission by e-mail: Collecting of supporting documents	<ul style="list-style-type: none">➤ Tasks have been distributed among members (action plan) to collect supporting documents on open issues as identified during the face to face meeting.
January 2017	Submission by e-mail: new draft version of the guideline	<ul style="list-style-type: none">➤ The Rapporteur will prepare a (new) draft version of the guideline based upon the discussions so far.
February 13, 2017	EWG teleconference	<ul style="list-style-type: none">➤ Discussion of open issues based upon the collected supportive documents by members.➤ Drafting new version of guideline.
May 10, 2017	EWG teleconference	<ul style="list-style-type: none">➤ Update of progress.➤ Discussion open/controversial issues identified during February 2017 teleconference.

		<ul style="list-style-type: none"> ➤ Drafting new version of guideline. ➤ Preparation second EWG meeting.
May 29 - June 01, 2017	Face-to-face meeting (Montreal)	<ul style="list-style-type: none"> ➤ Finding consensus on controversial issues. ➤ Update of the draft guideline through face-to-face discussion.
June 2017	Submission by e-mail: new draft version of the guideline	<ul style="list-style-type: none"> ➤ The Rapporteur will prepare a new draft version of the guideline based upon the discussions of the face-to face meeting Montreal. Annex I (outline Caco2 experimental conditions) will be attached/forwarded at a later stage. ➤ Members/experts will discuss this draft versions with there regional experts.
August 2017	Planning EWG teleconference	<ul style="list-style-type: none"> ➤ Feed back from the experts on the draft guideline. ➤ Discussion controversial issues and identifying the need for additional data to resolve issues if necessary. ➤ Drafting new version guideline.
September/ October 2017	Planning EWG teleconference	<ul style="list-style-type: none"> ➤ Discussion of open issues based upon the additional collected supportive documents by members. ➤ Drafting new version of guideline.
November 2017	Face-to-face meeting (Geneva)	<ul style="list-style-type: none"> ➤ Final discussion draft guideline. ➤ Resolving the last issues by consensus. ➤ Finalization guideline.