

Consultation procedure for guidance

1. Purpose

This procedure document describes the general structure of the consultation procedure for Guidance documents which is part of the process “Provision of new guidance and guidance update” (PRO-0012).

The procedure includes the organisation and management of the consultation with ECHA partners which is intended to ensure a broad acceptance of the guidance.

This procedure applies when a new guidance or an update (fast-track or normal) to a guidance document needs to be developed.

2. Scope

The procedure begins when the Project Team has finalised and agreed on the draft of new or updated guidance document and has the Guidance roadmap (when foreseen; TEM-0005) approved (PRO-0012).

The procedure ends when the final guidance document (new or updated) is ready for publication on the ECHA website.

3. Description

The consultation process is organised and co-ordinated by the Project Manager (PM), who is nominated by the Team Leader of the Guidance Team as indicated, in the Guidance roadmap (when foreseen) and is supported by the Project Team. The Project Team consists of the PM, the Scientific Advisor to the Executive Director, a representative of the Legal Affairs Unit (LAU) and relevant ECHA staff.

The PM launches the Consultation Procedure as described in the approved Guidance roadmap. In the case of a fast-track update there may not be a Guidance roadmap so it is launched under the responsibility of the PM and subject to a Decision of the Executive Director (ED) or the ECHA Business Program Board (BuPB) according to the criteria defined in the “Second revision to the Consultation Procedure for Guidance” MB/63/2013.

The PM ensures that the draft documents sent for consultation at the different stages are published on the ECHA website in the section dedicated to the ECHA Consultation Procedure on guidance following the process “Handling requests for the ECHA website” (WIN-0034) in

Consultation procedure for guidance

order to keep the process open and transparent. This also allows stakeholders not directly involved, such as third countries and other interested parties, to follow the progress of work closely and to comment using the standard form on the website; answers to individual comments made via this standard form (i.e. outside the formal consultation procedure described in the rest of this document) are not provided.

Step 1: Consultation of the Partner Expert Group (PEG)

In case of a fast-track update for which it has been decided that a PEG consultation is not needed, this step is not performed. In such case the procedure either starts at step 2 or (in case also consultation of ECHA committees/Forum is not foreseen) 3.

According to what has been established in the Guidance roadmap, the consultation of the PEG can proceed in one of the following two ways:

Option A: Establishment of a new PEG

The PM, in collaboration with the Guidance Team assistant, invites Accredited Stakeholder Organisations and institutional interested parties to nominate experts and, if relevant, invites individual experts to participate in the PEG. Experts whose nomination or confirmation of individual willingness to participate is received by the specified deadline (circa 3 weeks from invitation) are included in the consultation of the PEG.

Option B: Reactivation of an existing PEG

The PM, in collaboration with the Guidance Team assistant, informs the members of a PEG previously established for the same Guidance document or topic, of the intention to reactivate the same PEG. Experts who confirm by the specific deadline (circa 3 weeks) their continued interest and affiliation with the organisation that nominated them are included in the consultation of the PEG.

In either case A or B the PEG and its respective mandate are established/reactivated by sending the confirmation of nomination to each expert by email. The PM, at the same time, informs the PEG members about the Consultation procedure for guidance, the timeline and the indicative date of the PEG meeting (if foreseen). The main task of a PEG is to comment and strive for consensus on the draft proposed by the Project Team, with a view to ensure that it should be acceptable to all interested parties. The outcome of the consultation of the PEG serves as the basis for ECHA's next draft version of the guidance text for further consultation steps.

The content of the draft guidance document is prepared by the PM, together with the Project Team. If needed, and foreseen in the Guidance roadmap, input from external service providers can be used to develop (part of) the content.

When the draft guidance update or new guidance is internally agreed, the PM sends it together with a cover note and a blank template for comments to the members of the PEG. The PEG is invited to submit comments on the guidance document within a specified timeframe of a minimum of four weeks.

The Guidance Team assistant with the support of the Communications Unit, ensures that the draft guidance document that has been sent to the PEG and the composition of PEG,

Consultation procedure for guidance

are published on the ECHA website (in the section dedicated to the ECHA Consultation Procedure on guidance).

After the deadline for comments has expired, the PM, with the support of the Project Team, analyses the comments received.

In the exceptional cases when a physical PEG meeting is not planned, the following activities are not performed and the process continues from outcome A or B.

On the basis of the analysis by the PM a proposal for a draft agenda of the PEG meeting is made.

Usually the PEG meeting takes place at ECHA but if any unforeseen situation arises or for logistic considerations, the venue of this meeting may be changed. The meeting is chaired by a representative of the ECHA Secretariat and the ECHA Secretariat, (or an appointed ECHA contractor) is/are also responsible for taking the minutes.

The draft minutes are prepared and sent to the PEG members after the meeting however the revisions to the draft guidance document take priority in order to comply with the timetable for the next consultation step. PEG members are given an appropriate time to provide comments (minimum 5 working days) and clarifications before finalising the minutes.

From the meeting, one of two outcomes may occur:

Outcome A: Consensus achieved

If consensus is achieved and a commonly agreed solution is found for all the main issues, the PM, in collaboration with the Project Team and LAU, assesses the comments received from the consultation round and decides on their relevance and implementation. The PM in collaboration with the Project Team, where necessary, prepares a consolidated text, seeking further advice from the PEG members if necessary. A brief response to all the comments is provided to the PEG members through a summary spreadsheet either indicating that the comment was accepted or specifying the reasons why comments are not implemented or are implemented in part through alternative changes. The PM also sends the revised draft guidance document and consolidated comments with responses to the PEG members to verify the correct understanding of the input received, giving the PEG members approximately 10 working days to indicate if their own comments have been misunderstood. No new (i.e not previously raised) comments from PEG members are to be expected to be submitted to ECHA at this point. The draft guidance document can be further modified by the PM, taking in consideration written communications received from PEG members that one or more comments have been misinterpreted or overlooked. In this case, the consolidated comments with responses as well as the draft text if appropriate are revised accordingly by the PM.

The final version of the consolidated draft guidance document and summary of the comments received from the PEG with the Project Team's reply are reviewed by the LAU representative.

Outcome B: Consensus is not achieved

If consensus on one or more main issues is not achieved during the meeting, the majority position of the PEG is taken. If there is no clear majority or in exceptional cases, such as a

Consultation procedure for guidance

large number of difficult, contentious or unforeseen issues, the PM in consultation with the Team Leader of the Guidance Team and the Head of Unit may decide that a second PEG consultation round and possibly a (second) PEG meeting needs to be organised. The PM (in consultation with the Team Leader and the Head of Unit) establishes new timelines for this second round and informs the PEG via email that a second consultation is foreseen and of the timelines for it.

Step 2: Consultation of the experts from the ECHA Committees and/or Forum

In case of a fast-track update for which a consultation of the ECHA Committees and/or Forum is not foreseen, this step is not applied. In this case the procedure continues or (in case step 1 did not apply) starts at step 3.

The PM launches the consultation with the relevant bodies. The consultation takes place via a written procedure with the PM sending the consolidated draft guidance document together with a blank template for comments and the consolidated summary of PEG comments to the members of the Committees and/or the Forum through the Forum Secretariat with a request to provide comments within a deadline of approximately four weeks.

The Guidance Team assistant, with the support of the Communications Unit, ensures that the consolidated draft guidance document sent to the Committees/Forum and the consolidated summary of PEG comments with ECHA responses to PEG comments, are published on the ECHA website (in the section dedicated to the ECHA Consultation Procedure on guidance).

The PM, in collaboration with the Project Team, assesses the comments received from the consultation round and decides on their relevance and implementation. The PM then prepares a consolidated text, seeking advice from the Project Team whenever necessary.

A summary of the responses to all the comments is provided to the Committees and/or the Forum members by way of the consolidated document indicating either that the comments were implemented or the reasons why ECHA disagrees with a proposed change where comments are not implemented. The PM sends the revised guidance document and consolidated comments with responses to the Committee members and/or the Forum members (through the Forum Secretariat) to inform about the implementation of the input received giving them approximately 10 working days to indicate if their own comments have been misunderstood. No new (i.e. not previously raised) comments from Committees/Forum members are to be expected to be submitted to ECHA at this point. The PM may further modify the draft guidance document to take into consideration written communications from Committees and/or the Forum members informing that one or more comments have been misinterpreted or overlooked. The consolidated comments with responses (and if appropriate the draft guidance document) are revised accordingly by the PM.

The final version of the further consolidated draft guidance document and the summary of the comments received from the Committees and/or Forum with the replies elaborated by the Project Team are reviewed by the LAU representative.

Step 3: Consultation of the European Commission and the Competent Authorities / Designated National Authorities

Consultation procedure for guidance

The consultation with the European Commission and the Competent Authorities (CAs) / Designated National Authorities (DNAs) constitutes the final step of every consultation procedure. It ensures that any new guidance, or updated guidance, will find as wide support as possible with harmonised implementation by all the authorities.

The PM launches the consultation via a written procedure by submitting a request to the Commission services to upload the final version of the consolidated draft guidance, a cover invitation letter, and a consolidated summary of PEG and Committee/Forum comments (if applicable) with the Project Team's replies to those comments, in CIRCABC or equivalent platform. The consultation is carried out according to the "silence gives consent" principle: parties that do not provide any comments by the deadline (approximately 4 weeks) will be deemed to have agreed with the proposed draft text.

The Guidance Team assistant, with the support of the Communications Unit, ensures that the final version of the consolidated draft guidance is sent to the CAs/DNAs and the consolidated summary of the Committee/Forum comments with ECHA responses to the comments, are published on the ECHA website (in the section dedicated to the ECHA Consultation Procedure on guidance).

From this consultation, one of two situations may occur:

Outcome A: The written consultation is conclusive

In this case, the PM, in collaboration with the Project Team, implements relevant comments and prepares a final version of the draft guidance document based on the outcome of the consultation.

A summary of the ECHA responses to all the comments is provided to the CAs/DNAs either indicating that they have been implemented or specifying the reasons why the proposed changes have not been made. The PM sends the request to Commission services to upload in CIRCABC or otherwise communicates via an agreed mechanism the final version of the guidance document as well as the consolidated comments received from the CAs/DNAs, giving them approximately 10 working days to check that their own comments have not been misinterpreted. No new (i.e. not previously raised) comments from CAs/DNAs are to be expected to be submitted to ECHA at this point.

The PM may further modify the draft guidance document to take into consideration written communications from CAs/DNAs or the Commission informing that one or more comments have been misinterpreted or overlooked. The consolidated comments with responses are aligned with the modified draft by the PM before publication and upload of the comments to the website.

Outcome B: A consensus cannot be achieved through a written procedure

In this case, the controversial issues are discussed at the first possible meeting of the CAs/DNAs. The PM coordinates the process, requesting to add a discussion point on those issues to the agenda of the meeting.

Option 1: If the consultation at the meeting is conclusive, the PM implements relevant comments and prepares a final version of the draft guidance document based on the outcome of the consultation.

Option 2: If a consensus at the meeting cannot be achieved, the majority and minority opinions and their justifications are recorded in the meeting minutes, which are made public. The PM in collaboration with the Project Team and LAU prepares a

Consultation procedure for guidance

note to be signed by the ED to make the reader of the guidance specifically aware of a lack of consensus and provide a cross-reference to the meeting minutes. This note is made as the new first page of the PDF-file containing the guidance.

The PM prepares a final version of the guidance document incorporating this page for publication on the ECHA website.

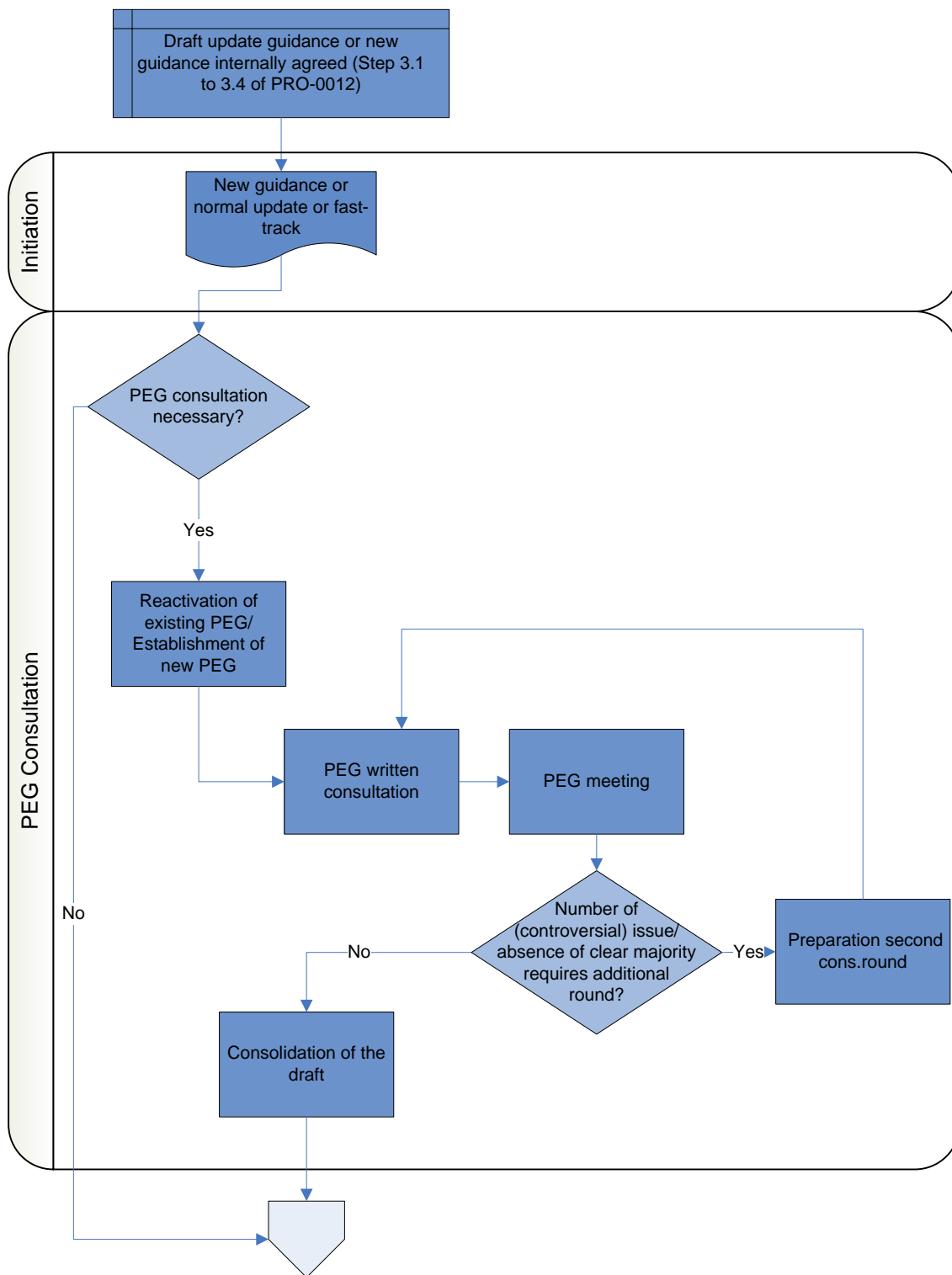
A summary of the ECHA responses to all the comments is provided to the CAs/DNAs either indicating that they have been implemented or specifying the reasons why the proposed changes have not been made. The PM sends the request to Commission services to upload in CIRCABC or otherwise communicates via an agreed mechanism the final version of the guidance document as well as the consolidated comments received from the CAs/DNAs, with the aim to inform them about the implementation of the input received before and during the meeting.

Step 4: Finalisation of the consultation procedure

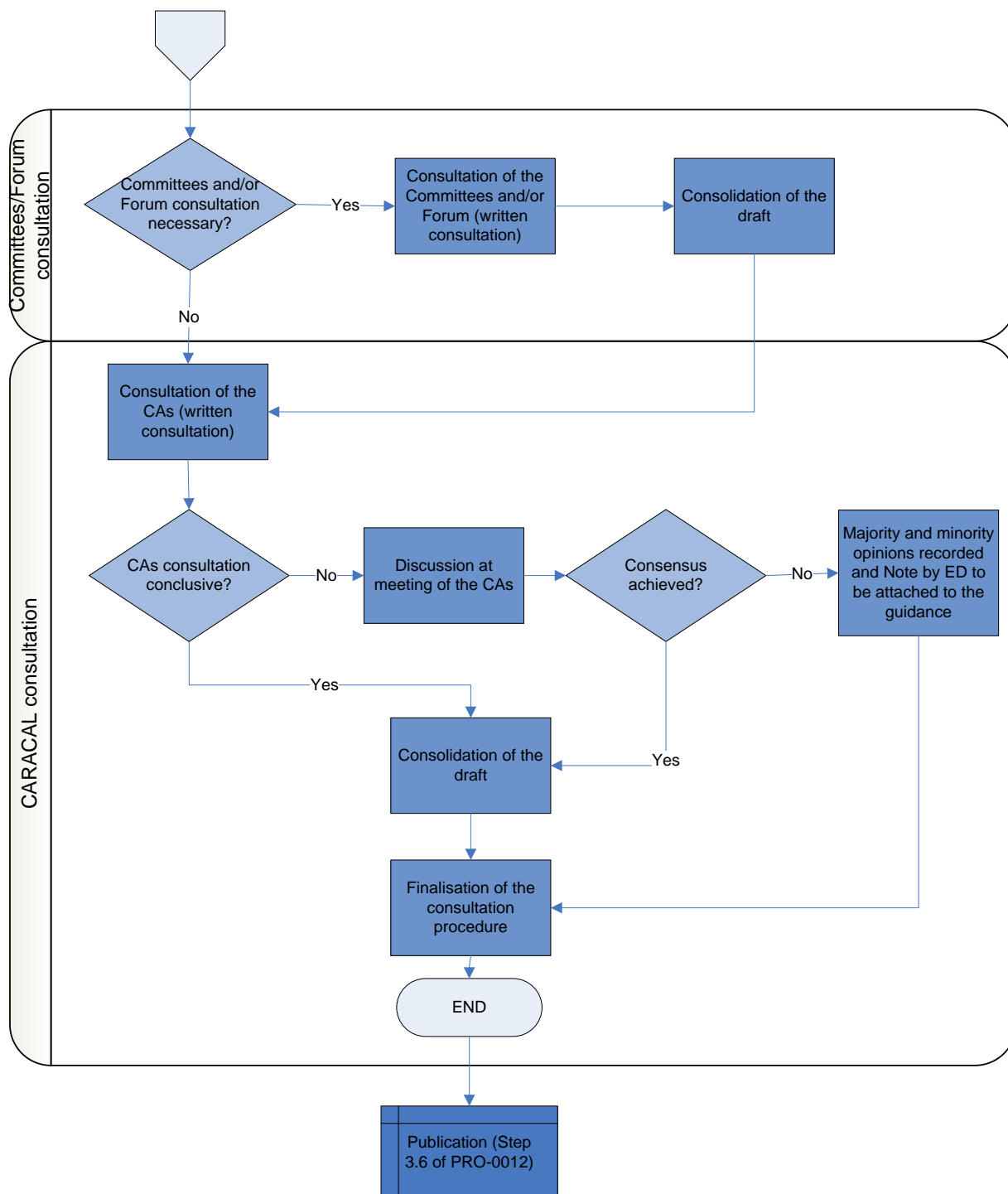
After review of the content by LAU and approval by the ECHA management, the final version of the guidance document and the consolidated comments received from the CAs/DNAs with ECHA responses to them are published on the ECHA website (this corresponds to step 3.6 of PRO-0012).

Consultation procedure for guidance

4. Flowchart



Consultation procedure for guidance



Consultation procedure for guidance

5. Definitions

Term or abbreviation	Definition
Accredited Stakeholder Organisations	Organisations with a legitimate interest in the work of ECHA who applied for the Accredited Stakeholder role and are selected based on eligibility criteria adopted by the Management Board
BuPB	Business Program Board
CA	Competent Authority
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
DNA	Designed National Authorities
Fast-track update	See Pro-0012 "Provision of new guidance and guidance update"
Guidance document	Formal documents of a highly technical nature which require interpretation of the underlying regulation(s) and a common understanding on how to fulfil the obligation that they place on industry and authorities. Therefore these documents when developed or updated will be the subject of consultation as described in this PRO.
ECHA partners	Combination of both "institutional interested parties" and "stakeholders" as defined in MB 2013/63.
Forum	Forum for Exchange of Information on Enforcement
LAU	Legal Affairs Unit
Normal update	See Pro-0012 "Provision of new guidance and guidance update"
PM	Project manager
PEG	Partner Expert Group
PRO	Procedure
Stakeholders	Non-institutional interested partners (industry, trade unions, environmental and consumer NGOs, academia, etc.)

Consultation procedure for guidance

6. Records

Record name	Security level	Comments
Invitation to nominate experts to the PEG	Public	
Expert nomination	Internal	
PEG establishment	Internal	
Final draft update/new guidance internally agreed and for PEG written procedure	Public	
Comments on draft guidance document	Internal	
PEG meeting minutes	Public	
Summary spreadsheet with PEG comments with ECHA's responses	Public	
Information about a second PEG consultation round and a possible PEG meeting when consensus is not achieved	Internal	
Draft update/new guidance to Committees/Forum for written procedure	Public	
Committees/ Forum comments	Internal	
Consolidated draft update/new guidance after Committees/Forum consultation	Public	
Summary spreadsheet with Committees/Forum comments with ECHA's responses	Public	
Draft update/new guidance to CAs/DNAs for written procedure	Public	
CAs'/DNA's comments	Internal	
Note to the reader by ED	Public	
Consolidated final update/new guidance after CAs/DNAs consultation	Public	
Summary spreadsheet with CAs'/DNAs' comments with ECHA's replies	Public	

7. References

Associated document code	Document name
MB/34/2011	Revised eligibility criteria for ECHA's Accredited Stakeholders
MB/63/2013	Second revised consultation procedure on guidance
	List of ECHA's Accredited Stakeholder Organisations: ECHA's webpage

8. Annexes

N/A