

**Helsinki, 18 December 2013**

**Doc: MB/63/2013 (final)**

## **Second revision to the Consultation Procedure for Guidance**

(Document endorsed by the Management Board)

## 1. Introduction

Guidance<sup>1</sup> that has to be made available by ECHA according to the provisions of the corresponding legislation<sup>2</sup> provides industry and authorities (ECHA, the European Commission, the relevant Competent Authority<sup>3</sup> (or other equivalent authorities specified according to the regulation in question<sup>4</sup>, which will be collectively referred to as “Competent Authorities” henceforth in this document)), with a common understanding on how to fulfil the obligations that the Regulations place on them.

Although it is not legally binding, guidance should, insofar as possible, provide its user with a high certainty that any action that is in line with the guidance will be acceptable to all other concerned actors. It is therefore very important that guidance be agreed, as far as practicable, by the concerned parties; this consideration is equally valid for new guidance and updates to existing guidance.

To this end, during the start-up phase of ECHA, the ECHA Secretariat developed a Guidance Consultation Procedure which was endorsed by ECHA’s Management Board<sup>5</sup>. A revision of this original procedure was subsequently published<sup>6</sup>. The procedure, as revised, aimed to allow any shortcomings in the existing guidance to be dealt with, to minimise the period that guidance containing identified shortcomings would be publicly available on the ECHA website and to retain the best practices concerning stakeholder (and other ECHA partners<sup>7</sup>) involvement and still relevant elements of working structures developed by the European Commission. Furthermore, the process for updating the

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<sup>1</sup> Guidance documents may be of a highly technical nature and require interpretation of the underlying regulation(s). Therefore these documents when initially developed or subsequently updated should be the subject of an appropriate degree of consultation as described in the present procedure. The term “Guidance” is reserved within this document for use for this “high level” or “formal” guidance that addresses the requirements of the relevant Articles of the corresponding Regulations quoted below to generate the specified guidance and on which formal consultation is required. Other documents, on which formal consultation is not required, such as guidance fact sheets, “guidance in a nutshell” documents, Questions & Answers (Q&As), Frequently Asked Questions by Industry (FAQs), the Navigator tool, Practical Guides and REACH factsheets as well as IUCLID and other software manuals are so-called “Quasi Guidance” or simply manuals and are out of the scope of this consultation procedure (as is text that is directly posted on the ECHA web pages rather than uploaded as documents) at all stages of their development.

<sup>2</sup> For the REACH Regulation: Articles 77(2) (g), (h) and (i) and 123 and Annex XI point 1.5; for the CLP Regulation Article 50(2) (a) and (b); for the Biocidal Products Regulation (BPR) Article 76 (1) (d), (e), and (f); for the Prior Informed Consent (PIC) Regulation Article 6(1) (c) and (d).

<sup>3</sup> The relevant Competent Authorities are as follows: Member State Competent Authorities (MSCAs); Competent Authority for Biocides and Designated National Authorities (DNAs) for PIC.

<sup>4</sup> It should be noted that the consultation procedure for guidance on biocides already initiated before December 2013 under either the previous Biocidal Products Directive (BPD) or the new BPR is outside the scope of this document.

<sup>5</sup> Document MB/30/2007 final dated 29/02/2008.

<sup>6</sup> Document MB/14/2011 final dated 25/03/2011.

<sup>7</sup> In the REACH Regulation text, usage of the term “stakeholder” is restricted to non-institutional interested partners (industry, trade unions, environmental and consumer NGOs, academia etc). In this document the term “institutional interested partners” refers to the Competent Authorities (as listed in above footnote) and to the European Commission. The term “ECHA partners” is used in this document to refer to the combination of **both** “institutional interested parties” and “stakeholders” (see fuller definition of “ECHA partners” later).

guidance documents themselves must be kept transparent and open to participation by relevant ECHA partners<sup>8</sup>.

This process starts with ECHA identifying a need for either new guidance or an update to existing guidance. ECHA then drafts the document and consults with the appropriate ECHA partners<sup>9</sup> (including the European Commission, Competent Authorities, stakeholder organisations) on the draft before it finally publishes the new or updated guidance.

## **2. Initiation of the procedure for the consultation of interested parties in relation to scientific and technical guidance for industry and authorities**

The ECHA Secretariat systematically collects information about the use of the existing guidance with a view to identifying any difficulties that have arisen. The main sources of this information are questions from industry received by the ECHA helpdesk, issues arising from the national helpdesks for the relevant regulation(s) in question, and issues highlighted by relevant bodies and/or authorities during the use of the guidance documents (the ECHA Secretariat and Committees, the Competent Authorities and the European Commission). In addition, feedback concerning guidance documents can be communicated by any party to ECHA via a standard web feedback form on ECHA's website<sup>10</sup>.

The result of this feedback can indicate:

- The need for new guidance on one or more aspects of a Regulation within ECHA's remit;
- The need for further clarification within an existing document (e.g. with regard to its technical content, changes in the legal text of the pertinent Regulation, clarifications by the European Commission or a ruling by the Court of Justice of relevance to the guidance document);
- A lack of sufficient information on a specific aspect (e.g. a technical issue that is not covered by the guidance);
- Inconsistencies (e.g. as a consequence of conflicting statements in different guidance documents, or within the same document);

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<sup>8</sup> ECHA should be central to ensuring that chemicals legislation and the decision-making processes and scientific basis underlying it have credibility with all stakeholders, other ECHA partners and the public. ECHA should also play a pivotal role in coordinating communication concerning this Regulation and in its implementation. The confidence in ECHA of the Community institutions, the Member States, other ECHA partners, the general public and other interested parties is therefore essential. For this reason, it is vital to ensure its independence, high scientific, technical and regulatory capacities, as well as transparency, efficiency and effectiveness.

<sup>9</sup> The term "**ECHA partners**" is newly defined in this version of the present document for added clarity and precision as follows: "the combination of the European Commission (including relevant directorate generals for the regulation in question), the relevant Member State Competent Authorities/Designated National Authorities (or other relevant equivalent body) and the full range of relevant stakeholder organisations (where appropriate specifically including Non-Governmental organisations (NGOs)) for the regulation in question" i.e. the combination of "institutional interested partners" with "non-institutional interested partners" **that are relevant for the regulation in question.**

<sup>10</sup> See: [https://comments.echa.europa.eu/comments\\_cms/FeedbackGuidance.aspx](https://comments.echa.europa.eu/comments_cms/FeedbackGuidance.aspx)

- Workability issues (e.g. a procedure described in the guidance could work more effectively if amended);
- Information (particularly examples on how to conform with duties in practice) in the guidance is outdated by comparison with current real-world working practices as a consequence of changes in e.g. ECHA's internal procedures/MSCA procedures, industry best practice, evolving IT tools, etc.).

The ECHA Secretariat will analyse the information to prioritise and categorise issues and, whenever warranted, subsequently generate one of the following **three** types of documents:

1. New guidance;
2. A **guidance update**<sup>11</sup>. This can be either:
  - A normal update: Involving a full consultation in (the normal) three steps of the PEG, the relevant Committees/Forum<sup>12</sup> or equivalent, (which will be collectively referred to as "Committees/Forum" henceforth in this document), and concluding consultation of the European Commission and Competent Authorities with "normal" deadlines for feedback on each consultation step;
  - A fast-track update: time pressure (or potentially other considerations) requires setting short deadlines and/or streamlining the consultation process. The choice of the fast-track procedure needs to be confirmed by either the ECHA business programme board for foreseeable justifications as listed in 3.1 below or by the Executive Director in other cases<sup>13</sup>. The ECHA Secretariat shall in all cases provide a written justification for using the fast track procedure.

**Both** a normal and a fast-track update will result in the generation of a revised guidance document within which the version number will increase to the next whole integer to indicate a new (significant) revision, as is currently the ECHA practice when publishing revised guidance documents<sup>14</sup>.

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<sup>11</sup> The term "guidance update" is newly defined in this version of the present document to include generation of **either** the type of document previously termed an "amendment" (i.e. one involving a less extensive "update" and no re-structuring) as well as that previously termed "revision" (i.e. more extensive update and/or re-structuring) since this distinction is no longer felt to be as significant as that needed to differentiate between guidance aimed primarily at industry and that aimed primarily at ECHA itself/MSCAs/DNAs or other authorities.

<sup>12</sup> The list of "ECHA Committees/Forum" components that can be consulted is as follows: the Member State Committee (MSC); the Committee for Risk Assessment (RAC); the Committee Socio-economic Analysis (SEAC); the Biocidal Products Committee (BPC); the Forum for Exchange of Information on Enforcement (Forum) and the Customs authorities (for the PIC Regulation only).

<sup>13</sup> Such a situation may for example arise e.g. when a deadline is imminent and guidance appears to be incorrect or unworkable e.g. the guidance is not in line with the final version of the IT-software to be used to conform with the requirements in advance of the relevant deadline.

<sup>14</sup> For example a current Version 1.3 would become 2.0; by contrast, current practice when publishing a **corrigendum** is to indicate its difference from the previous version *inter alia* by increasing only the decimal of a version number as published by 0.1 e.g. change from Version 2.3 to 2.4; the next **update** in this case would then be 3.0. This is already normally explained in

3. A Corrigendum: a new document version with one or more relatively simple editorial changes or corrections.

For simple editorial changes to a document (including update to references to legislation or other cross-referenced documents) and corrections for obvious (or less obvious but still unambiguously evident) mistakes, e.g. of linguistic errors, the ECHA Secretariat will issue a corrigendum. No specific stakeholder consultation will be carried out for corrigenda. Comments on the corrigendum can always be provided via the standard form on the website referred to above.

When the change in the guidance affects its content (an update) or where new guidance is required, a specific stakeholder consultation process will be initiated and implemented as described hereafter. This process will aim to achieve the broadest possible acceptance of the final output document among relevant actors and to ensure that the necessary guidance of required quality is published as quickly as is practicable.

### **3. Consultation of ECHA partners**

After the ECHA Secretariat concludes that there is sufficient justification for resources to be allocated to draft new or update existing guidance it will, where appropriate, call upon the assistance of external experts. Whenever the document requires legal interpretation of the relevant regulation text, the ECHA Secretariat will normally consult the European Commission before it makes the draft available to wider consultation. This may prolong the drafting process. The outcome of any such pre-consultation will be reported in the introduction of the draft document concerned.

The subsequent consultation process is organised and co-ordinated by the ECHA Secretariat and consists of up to three consultation steps:

- Consultation of a Partner Expert Group (PEG);
- Where considered appropriate, consultation of the ECHA Committees/Forum;
- Concluding consultation of the European Commission and Competent Authorities.

The timeline and the main interim documents prepared at the different steps of the consultation process will be published on the ECHA website in order to keep the process transparent. This also allows those stakeholders not directly involved, third countries and other interested parties, to follow the progress of work closely and to comment using the standard form on the ECHA website referred to above.

#### **3.1 Selection of the consultation steps to be implemented and ECHA Partners to be involved in specific steps of the consultation on a new guidance or guidance update**

ECHA will record, in writing any justification not to take all three consultation steps. Otherwise, by default, all three steps will be taken, with at least one Committee/Forum being consulted. In addition, if the fast-track update involves reduced commenting periods the reason for this must also be recorded.

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the document history of the guidance as published for new and updated guidance according to current practice.

The following three foreseeable justifications for not carrying out the full three-step consultation require no additional justification or decision of the Executive Director before implementation:

1. Fast-track updates **concerning only legal issues**<sup>15</sup> with no major technical implications; the European Commission and Competent Authorities **only** may be consulted without need for further justification for excluding the PEG and Committees/Forum consultation step.
2. Fast-track updates to guidance **targeted mainly at industry**, which include technical and other non-legal issues; the PEG and European Commission and Competent Authorities consultation steps **only** may be carried out without further justification for excluding the Committees/Forum consultation step.
3. Fast-track updates to guidance **targeted mainly at ECHA itself and/or the Competent Authorities**; the Committees/Forum and European Commission and Competent Authorities consultation steps **only** may be carried out without further justification for excluding the PEG consultation step.

For any new guidance or guidance update, a decision on the consultation of the Committees/Forum will be made on a case-by case basis. Elements to be considered in such a decision are the relevance of a guidance update or new guidance for the Committees/Forum tasks as foreseen in the relevant regulation(s), the priority compared to other activities in their work programme and the urgency of the matter. For similar reasons, the ECHA Secretariat may decide to consult the Committees/Forum on only certain parts of an update or new guidance.

The European Commission and Competent Authorities will be consulted on all new guidance or guidance updates<sup>16</sup>.

### **3.2 Partner Expert Group (PEG) consultation**

In cases of new guidance or a guidance update (for which a PEG step has not been excluded according to the provisions of 3.1 above), a PEG will be established composed of experts from the various stakeholders and institutional interested parties<sup>17</sup>. Those organisations or persons to be invited to either nominate a participant or personally participate in a PEG will be selected from ECHA's Accredited Stakeholder Organisations (ASOs) or (in the case of individual expert persons) may be invited to participate as nominees of either ECHA or the European Commission. To this end, experts whose nominations have been received or who have accepted a personal nomination by a specified deadline will be included in the PEG. This group will be consulted on technical content issues. The same PEG may be consulted on future updates to the same document, after confirming their continued interest and affiliation with the organisation that nominated them – especially if there is a long time between updates. Information on

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<sup>15</sup> Including results of a court case which leave no ambiguity with respect to technical issues or concern only legal issues, even if these have consequences for other stakeholders.

<sup>16</sup> Where "guidance update" as previously defined specifically excludes corrigenda on which there is no consultation.

<sup>17</sup> The term "institutional interested partners" refers to the appropriate national authorities for the relevant regulation e.g. Member State Competent Authorities (MSCAs); Competent Authority for Biocides; Designated National Authorities (DNAs) and Customs authorities and to the European Commission.

the general mandate of a PEG, nomination and selection of its members, its operating procedures and the role of the experts within it, is given in Appendices A, B, C and D of this document respectively.

A PEG consultation normally includes the following steps:

- The PEG is established and receives its mandate by e-mail from the ECHA secretariat (see Appendix A);
- The draft new guidance or draft guidance update is circulated to the members of the PEG with a deadline for comments well in advance of the PEG meeting;
- A PEG meeting is held to discuss (a selection of the) comments made and in particular any contentious (technical) issues on which agreement is difficult to arrive at;
- After the meeting the written comments made in advance of the meeting and the discussions during the meeting are taken into account in a new draft text and a table of comments and ECHA's responses to them. The new draft text is sent to the PEG for a short period (approximately ten working days) to allow the PEG members to comment **only** on any misinterpretation of their comments.

Based on the outcome of the PEG consultation, the ECHA Secretariat will prepare a further draft of new guidance or guidance update for the next consultation step.

In very exceptional cases (e.g. a large number of difficult and/or contentious issues, completely new guidance on a new aspect of a regulation or on a regulation new to ECHA for which many unforeseen issues arise), organising additional PEG meetings may be considered; in which case the process according to the last three of the four bullet points above is repeated for each new meeting held.

### 3.3 Consultation of experts from the ECHA Committees and/or the Forum

The ECHA Secretariat will decide whether the expertise of members of all or any of the Committees/Forum needs to be sought on a specific guidance document (see 3.1 above). This will give the members of the Committees/Forum the opportunity to provide comments '*à titre personnel*' to make best use of the available 'in-house' expertise at the disposal of the ECHA Secretariat.

This consultation will normally take place via a written procedure. The ECHA Secretariat will ask the Chair of the relevant ECHA Committee/Forum for the advice of its members on the draft guidance within a specified deadline. In practice, in the interest of speed and efficiency and to maximise the time available to make the comments, the ECHA secretariat may forward the request for comments directly to the members with a template for feedback. The feedback received within the deadline set is then used to generate a new draft text in an analogous manner to that described for the PEG consultation above.

### 3.4 Consultation of the European Commission and the Competent Authorities

The final step in the external consultation process is the concluding consultation with the European Commission and the Competent Authorities to ensure that the guidance update or new guidance will find the widest possible support and the greatest degree of harmonisation of implementation by all relevant authorities. This consultation will normally take place as follows:

- It will always start with a written procedure on the basis of the consolidated final draft;
- The outcome of the written procedure will be recorded;
- The consultation will be carried out according to the "silence gives consent" principle: parties that do not provide any comments will be deemed to agree with the proposed draft text;
- If comments are received<sup>18</sup> and the written procedure is conclusive, the ECHA Secretariat will prepare a final text based on the outcome of the consultation and re-present it for a short period (approximately ten working days) to allow the European Commission / Competent Authorities to comment **only** on any misinterpretation of their comments before publication;
- If a consensus cannot be achieved via a written procedure a meeting<sup>19</sup> will be convened. The purpose of this meeting is to seek a consensus and to seek the advice of the European Commission and Competent Authorities. Where a consensus is not possible, the majority opinion<sup>20</sup> as well as the minority opinions and their justifications will be recorded in the meeting minutes; these minutes will be made public. In such cases, a note from the Executive Director of ECHA will make the reader specifically aware of the lack of consensus, and provide a cross-

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<sup>18</sup> If no comments at all are received from this consultation step, the ECHA Secretariat will proceed directly to the preparation of the final document for publication.

<sup>19</sup> This will normally take place via the meeting of the relevant Competent Authorities.

<sup>20</sup> With regard to the majority opinion the "silence gives consent" principle will be applied.



reference to these minutes; this note to the reader shall be printed/downloaded automatically whenever the guidance document is printed/downloaded; to this end, it shall make up the first page of the PDF-file containing the guidance document.

- o A final version of the guidance document will be prepared by the ECHA Secretariat.

#### **4. Publication**

The ECHA Secretariat will publish the final guidance document in the English language on the ECHA website without undue delay and this will be communicated to all stakeholders by ECHA's normal communication channels.

Those guidance documents that are of a general nature and touch upon many downstream user sectors and/or a high proportion of SMEs will be translated from their original into all of the additional official EU languages in order to improve the accessibility of guidance to all stakeholders. The translated versions of the documents will be published on the ECHA website as soon as practicable after they become available.

#### **5. Withdrawing documents as obsolete**

When the ECHA Secretariat considers that a document has become obsolete it will, by definition, clearly no longer be current. If a decision has been taken by the ECHA Secretariat not to update it, then there must also be good reasons documented for not doing so. Under these circumstances it is sufficient for a formal "pre-warning" to be sent only to the last stage of the consultation (i.e. the European Commission/ Competent Authorities) and for other stakeholders to be warned either in advance of the formal communication or during it (for example via a note on the ECHA website entry for the guidance in question and/or other normal mechanism for ECHA to communicate with stakeholders such as a news item) that the document is considered as obsolete and may eventually be removed from the website. In the absence of feedback indicating unforeseen strong reasons not to implement the planned obsolescence the document will be removed from the ECHA website and a short explanation of the reasons (and date) of removal will be given at its previous location. This procedure **does not** need to be applied for cases where the content of one document is simply being transferred to another guidance document (potentially including update of content) **if** the new document into which it is being incorporated is itself the subject of a formal guidance consultation.

## **Appendix A: General mandate of a Partner Expert Group (PEG)**

A PEG is set up to endeavour to ensure that a new guidance or guidance update is scientific/technically discussed, taking due account of the particularities of all ECHA partners consulted at the PEG step. In addition to scientific technical aspects, a PEG may provisionally address issues such as workability, enforceability, efficiency and proportionality in order to prepare for the necessary buy-in from all ECHA partners.

- For both new guidance and guidance updates<sup>21</sup> a guidance-specific PEG will be set up (unless, in the case of an update, a sufficiently recently set-up one for the original guidance can be re-activated) consisting of experts in the specific subject area and who are affiliated to stakeholder organisations or interested institutional partners, or are otherwise knowledgeable about certain concerned stakeholder populations or the needs of specific interested institutional partners and have been identified and nominated by ECHA or the European Commission.
- The task of a PEG is to comment on the draft new guidance or guidance update proposed by the ECHA Secretariat with a view to ensuring that this should be acceptable to all interested parties. The outcome of the consultation of the PEG serves as the basis for ECHA's next draft of the guidance text to be consulted upon in the subsequent step of the guidance consultation procedure.
- The PEG should strive for consensus. Any controversial issues will be clearly highlighted in the summary of comments and ECHA's responses and/or the PEG meeting minutes. For issues on which there is no consensus the majority and minority positions will be recorded and explained in the summary/minutes for consideration during drafting of the text for the next step.

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<sup>21</sup> With the exception of those for which the PEG step is being missed according to the provisions of 3.1 above.

## **Appendix B: Nomination and selection of members of the PEG**

The ECHA Secretariat invites stakeholder organisations that are eligible to collaborate with ECHA<sup>22</sup> and institutional interested partners to nominate experts. The criteria for selecting accredited stakeholder organisations (ASOs) are themselves the subject of a separate document endorsed by the Management Board<sup>23</sup>. Members of the PEG should have expertise or relevant experience in the field to be addressed by the group. Experts proposed by stakeholder organisations and institutional interested partners whose nominations have been received by the ECHA Secretariat by the specified deadline will become members of the PEG. They may be invited on the basis of proposals made by:

1. Concerned institutional interested partners:
  - o The ECHA Secretariat;
  - o The European Commission;
  - o Competent Authorities<sup>24</sup>;
2. Accredited Stakeholder Organisations conforming to the Management Board endorsed criteria cited above.

In order to get the most appropriate scientific and technical input and stakeholder involvement in the PEG, stakeholder organisations and institutional interested partners are recommended to take due account of following general criteria for nominating individual members of the PEG:

- o The required scientific and technical expertise to address the subject matter of the new guidance or guidance update;
- o The required scientific and technical expertise or relevant experience in the field(s) covered by the nominating organisation to be able to represent its interests;
- o Experience from similar regulatory processes or cross cutting issues of relevance such as other legislation and different scientific disciplines;

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<sup>22</sup> Further explanation is available at: [http://echa.europa.eu/stakeholders\\_en.asp](http://echa.europa.eu/stakeholders_en.asp)

<sup>23</sup> MB/34/2011 (final) 21 June 2011.

<sup>24</sup> The ECHA Secretariat will notify the Competent Authorities whenever it invites a person nominated by them to become a PEG member.

## Appendix C: PEG Operating procedures

### Meeting(s) of a PEG

- A PEG will normally have at least one physical meeting, normally held at ECHA's premises in Helsinki, Finland.
- In the interests of good financial and personnel resource management (on the part of both the ECHA Secretariat and the nominating organisations) ECHA may decide at an early stage in the development of planning for a new guidance or guidance update (ideally as early as the roadmap stage) that for a particular consultation a physical PEG meeting is **not** required. These "planned" absences of physical PEG meetings may be deemed appropriate for example when a guidance update concerns either only a relatively small part of a guidance document (for example update of one or more annexes/appendices and/or selected chapters only) or when there is already a basis to assume that the scope of the update does not include contentious issues. If it turns out that major issues arise, a PEG meeting can be convened by mechanisms analogous to those implemented for a second PEG meeting when unforeseen issues arise during a normal consultation.
- In exceptional circumstances (e.g. no substantial comments received from the PEG on a new guidance or guidance update, unforeseen logistical event (airline strike, ash cloud due to volcanic eruption, etc.)) it may be decided at relatively short notice not to have a PEG meeting in cases where re-scheduling would endanger the timetable for the whole consultation and publication of a final document in advance of a registration/notification deadline, guidance publication moratorium or other pre-defined unmovable fixed target date.
- Invited experts attending meetings will be reimbursed according to ECHA's rules as mentioned in the ECHA document "*Guide for the reimbursement of travel, hotel and subsistence expenses for Board members, Committee members and any other experts attending meetings of the European Chemicals Agency (ECHA)*" or any document that may replace these rules in future.

### Working procedure of the PEG

- In all cases, the ECHA Secretariat will generate a first draft of the new guidance or guidance update as the basis for the work of the PEG.
- The nominating stakeholder organisations and institutional interested parties will be informed on the procedure and timelines when calls for nominations are made.
- The PEG members will be informed of the timelines and feedback procedures when their feedback is requested.
- Formal invitations to any PEG meeting will be sent only when a financial commitment for it has been made; any informal pre-information on likely meeting dates **must not** be used as the basis for booking flights etc.
- The draft document for consultation will be sent to the PEG members with a minimum of four weeks to make their feedback.
- Except in exceptional circumstances, any PEG meeting to be held will not be held less than two weeks after the closing date of the consultation in order to allow time for the ECHA Secretariat to identify, prioritise and prepare discussion points arising from the feedback to be discussed at the meeting.

- After the deadline for feedback on the draft document has passed, the ECHA Secretariat will analyse the comments received and on that basis draft an agenda for the PEG meeting. In particular, the ECHA Secretariat may decide to focus discussions on selected priority issues where the number and complexity of comments mean that it is impracticable to discuss all of them during the finite duration of the physical PEG meeting. The PEG meeting will be chaired by one or more representative(s) from ECHA and minutes of the meeting will be taken by one or more representative(s) from ECHA (or by an appointed ECHA contractor). It should be noted that, since any delay in implementing comments into a new draft for the next consultation step may endanger the target date for the next consultation step and eventual publication of a guidance document, it is the generation of this next draft which will be given priority by the ECHA Secretariat. Thus, although draft meeting minutes will be prepared as soon as practicable re-drafting of the text for the next consultation stage to take into account both comments made in advance of the PEG meeting and discussions during it will take precedence over finalisation of meeting minutes. The ECHA Secretariat will therefore prepare a version of the guidance document taking into account the feedback and discussion as soon as practicable after the PEG meeting and send it to PEG members to confirm that their comments have not been misinterpreted. The next draft may therefore be finalised before the meeting minutes.

## **Appendix D: Role of the Experts**

As a core element of the PEG consultation exercise, ECHA seeks to ensure that PEGs are composed not only of individual experts who provide the best possible scientific advice to ECHA in the Guidance Consultation Procedure, but also of representatives acting on behalf of their nominating organisation or Member State. The nomination of PEG members according to predefined criteria aims at ensuring its well-balanced composition. The ECHA Secretariat expects that comments from the PEG members also reflect their professional background and environment and will therefore, in most cases, coincide with the views of the party that has nominated them rather than acting solely as individual experts. However, the detail of the relationship between a PEG expert and the nominating organisation is an internal matter left to the discretion of the nominating organisation.