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(Revised) Consultation Procedure on Guidance

(document endorsed by the Management Board)

1. Introduction

Guidance[1] that has to be made available by ECHA[2] provides industry and authorities (ECHA, the European Commission, MSCAs) with a common understanding on how to fulfil the obligations that the REACH and CLP Regulations[3] place on them. Although it is not legally binding, guidance should, as far 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 actors. It is therefore very important that guidance is agreed, as far as possible, by the concerned parties – this consideration is equally valid for new guidance as well as for updates or amendments of existing guidance.

For that purpose, during the start-up phase of the Agency, the ECHA Secretariat developed a Guidance Consultation Procedure endorsed by ECHA's Management Board[4]. This procedure allowed any shortcomings in the existing guidance to be dealt with, minimise the period that guidance containing identified shortcomings would be publicly available on the ECHA website as well as best practices concerning stakeholder[5] involvement and working structures developed by the European Commission to be retained. Furthermore, the guidance updating process will be kept transparent and open to participation by relevant partners[6].

This process will start with ECHA identifying a need for, and subsequently drafting improvements to existing or new guidance. ECHA will then consult with stakeholders (including the European Commission, Member State Competent authorities, stakeholder organisations) on the draft before it finally publishes the revised or new 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 the questions from industry received by the ECHA helpdesk, issues arising from the national REACH and CLP helpdesks, and issues highlighted by authorities during the use of the guidance documents (ECHA Secretariat and ECHA Committees, MSCAs or the European Commission)[7]. In addition, issues can be communicated by any party to ECHA via a standard form on ECHA's website.

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[1] Guidance documents are of a highly technical nature and require interpretation of the underlying regulation(s). Therefore these documents when developed or updated will be the subject of consultation as described in the procedure as described hereafter. Other documents such as fact sheets, "guidance in a nutshell" documents, Questions & Answers (Q&As), Frequently Asked Questions by Industry (FAQs), the Navigator, Practical Guides are so-called "Quasi Guidance" and are out of the scope of this consultation procedure at any stage.

[2] Article 77(2)(g) and Article 77(2)(h).

[3] Or any other future Regulation in which ECHA will be given such a role e.g. the Biocides Regulation.

[4] Document MB/30/2007 final dd. 29/02/2008.

[5] In the REACH Regulation, the term "stakeholder" is restricted to non-institutional interested partners (industry, trade unions, environmental and consumer NGOs, academia etc). For the sake of simplicity, in this paper the term "institutional interested partners" refers to the Member State Competent Authorities (MSCAs) and to the European Commission as well as to third country representatives.

[6] The Agency should be central to ensuring that chemicals legislation and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public. The Agency should also play a pivotal role in coordinating communication around this Regulation and in its implementation. The confidence in the Agency of the Community institutions, the Member States, the general public and 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 and efficiency.

[7] The combination of industry and authorities is later referred to as ECHA partners

The result of this feedback can indicate:

- The need for clarification (e.g. with regard to the technical content, changes in the legal text, clarifications by the European Commission or a ruling by the Court of Justice);
- Insufficient information (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);
- Workability issues (e.g. a procedure described in the guidance could work more efficiently if altered or the information in the guidance is outdated as a consequence of changes in ECHA's internal procedures or IT tools,…);.

The ECHA Secretariat will analyse the information to prioritise and categorise issues and propose any of the four possible actions:

1. Corrigendum: one or more simple editorial changes and corrections;
2. Amendment: a change in substance to (part of) the existing guidance for technical or scientific issues that are not sufficiently covered or clear; this may include providing additional explanatory examples such as borderline cases
    - A normal amendment: Enough time to carry out a comprehensive stakeholder consultation process with "normal" deadlines;
    - A fast-track amendment: Time pressure requires setting short deadlines and/or streamlining the consultation process. The fast track procedure will be chosen only when the ECHA Secretariat considers that action must be undertaken as quickly as possible in order to minimise the period during which incorrect or inaccurate guidance leads to potentially wrong activities under REACH. This view needs to be confirmed by the Executive Director and may cover legal as well as non-legal issues[8]. The Secretariat shall provide a written justification for using the fast track procedure.
3. Revision: a more extensive update that addresses a combination of technical, legal, and/or administrative problems, possibly requiring significant restructuring of existing guidance;
4. New guidance.

For simple editorial changes and corrections for obvious mistakes, e.g. of linguistic errors, the ECHA Secretariat will issue corrigenda. No specific stakeholder consultation efforts will be necessary but comments can always be provided via the standard form on the website.

When the change in the guidance affects its content (amendment or revision) or where new guidance is required, a specific stakeholder consultation process will be initiated and implemented as described hereafter. It will aim at the broadest possible acceptance among relevant actors and at ensuring that the necessary guidance is published as quickly as is practicable.

[8]Such a situation may for example arise:

a. as a consequence of a Court case e.g. with regard to the handling of confidentiality claims by ECHA;
b. when a deadline will be approached in near time for any actor and the guidance appears to be incorrect or unworkable e.g. the guidance is not in line with the final IT-system.

3. Consultation of ECHA partners

Whenever the ECHA Secretariat realises that comprehensive work is required, it will initially draft a change of the guidance, where appropriate with the assistance of external experts. Whenever an amendment, revision or new guidance requires legal interpretation of the REACH and CLP Regulations, the ECHA Secretariat will normally consult the European Commission before it makes the draft available to wider consultation[9]. This may prolong the drafting process. The outcome of this 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 experts from the ECHA Committees (Member State Committee and/or the Committees for Risk Assessment and/or the Committee for Socio-economic Analysis) and/or the Forum;
- Concluding consultation of the European Commission and MSCAs.

The timeline and the main interim documents prepared at different stages of the consultation process will be published on the ECHA website in order to keep the process transparent. This also allows 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 website.

3.1 Assessment of the ECHA Partners to be involved in the consultation

The ECHA Secretariat will carry out an assessment of the ECHA Partners that need to be consulted with a view to streamlining the consultation process.

For fast-track amendments concerning legal issues with no major technical implications, only the European Commission and MSCAs will be consulted, whereas for non-legal issues the PEG, as well as the European Commission and MSCAs will be consulted but would in any case receive short deadlines.

For any amendment, revision or new guidance, 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 an amendment, revision or new guidance for the Committees/Forum tasks as foreseen in the REACH and the CLP Regulations, the priority compared to other activities on 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 amendment, revision or new guidance.

The European Commission and MSCAs will be consulted on any amendment, revision or new guidance.

In certain cases, in particular for entirely new guidance, it may be decided to launch a general Internet consultation. In this case it will be made clear that no formal responses can be given to individual contributions, but that either the PEG, or the ECHA Secretariat will take note of all relevant comments and take them into account when discussing and finalising the revised or new guidance.

[9] The ECHA Secretariat will inform MSCAs of the launch of any such consultation.

3.2 Partner Expert Group (PEG) consultation

In cases of an amendment, a revision or new guidance, a PEG will be established composed of experts from the various stakeholders and institutional interested parties[10]. To this end, experts whose nominations have been received by a specified deadline will be included in the consultation of the PEG. This group will be consulted on technical content issues. A standing PEG consisting of a network of experts that may be consulted at any time will be created. Information on the general mandate, nomination of members of the PEG, an outline of the operating procedure for a PEG and the role of the experts in the PEG is given in Appendices A, B, C and D.

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 amendment, revision or new guidance is circulated to the members of the PEG;
- A meeting is convened and is a standard part of the consultation of the PEG;

Based on the outcome of this consultation, the ECHA Secretariat will prepare a consolidated final draft of the amendment, revision or new guidance and inform the PEG members accordingly. In exceptional cases (e.g. difficult and/or contentious issues, new guidance), it may be considered to organise additional meetings.

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 or the Forum needs to be sought on a specific guidance document (see section 3.1). This will give the members of the Committees and/or the Forum the opportunity to provide comments *'á 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 written procedure. The ECHA Secretariat will ask the Chair of the relevant ECHA Committee/Forum for advice on the draft guidance and will redraft the text, taking into account the comments provided by members of the ECHA Committees/Forum within a specified deadline.

3.4 Consultation of the European Commission and the MSCAs

The final step in the external consultation process is the concluding consultation with the European Commission and the MSCAs to ensure that the amendment, revision or new guidance will find as wide as possible support and harmonised implementation by all 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 the written procedure is conclusive, the ECHA Secretariat will prepare a final text based on the outcome of the consultation;

[10]The term "institutional interested partners" refers to the Member State Competent Authorities (MSCAs) and to the European Commission as well as to third country representative.

- If a consensus cannot be achieved via a written procedure a meeting[11] will be convened. The purpose of this meeting is to seek a consensus and to seek the advice of the European Commission and MSCAs. Where a consensus is not possible, the majority opinion[12] 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-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.
- A final version of the guidance document will be prepared by the ECHA Secretariat.

4. Publication

The ECHA Secretariat will publish the final guidance in English on the ECHA website without undue delay and this will be communicated to the MSCAs and the European Commission.

Those guidance documents that are of a general nature and touch upon many down-stream user sectors and/or a high proportion of SMEs will be translated from their original into 21 further official EU languages in order to improve the accessibility of guidance to all stakeholders. The translated documents will be published on the ECHA website as soon as available.

[11]This will normally take place via the meeting of the Competent Authorities for REACH and CLP.
[12]With regard to the majority opinion the "silence gives consent" principle will be applied.

Appendix A: General mandate of the PEG

PEGs will be set up to ensure that an amendment, revision or new guidance is scientific/technically discussed, taking due account of the particularities of all concerned stakeholders and other partners of ECHA. In addition to scientific technical aspects, they may address issues such as workability, enforceability, efficiency and proportionality in order to ensure the necessary buy-in from all ECHA partners.

- For an amendment, a revision or new guidance, a guidance-specific PEG will be set up consisting of experts in the specific subject area and who are affiliated to stakeholder organisations or interested institutional partners, or are knowledgeable about certain concerned stakeholder populations or the needs of specific interested institutional partners.
- The task of a PEG is to comment on the draft 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 final draft version of the guidance text.
- The PEG should strive for consensus. Any controversial issues will be clearly outlined and the majority and minority positions explained and transmitted to the ECHA Secretariat.
- The ECHA Secretariat will revise, if needed, its initial text in the light of the PEG's work.
- The ECHA Secretariat will decide on the need for further consultation.

Appendix B: Nomination and selection of members of the PEG

The ECHA Secretariat invites stakeholder organisations that are eligible to collaborate with ECHA[13] and institutional interested partners to nominate experts. Members of the PEG must have a proven 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 participate in the consultation of the PEG. They will be invited on the basis of proposals made by:

1. Concerned institutional interested partners:
   - ECHA Secretariat;
   - The European Commission;
   - MSCAs[14];
   - Third countries invited by the Management Board to participate in the work of the Agency.

2. Stakeholder organisations (non-institutional interested partners) with an EU-wide membership and mandate:
   - Industry, including associations representing manufacturers, distributors, importers, or downstream users of chemical substances and in particular SMEs;
   - Environmental NGOs;
   - Social partners;
   - Consumer organisations;
   - Human health NGOs.

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:

- The required scientific and technical expertise to be addressed in the amendments, revision or new guidance;
- The required scientific and technical expertise or relevant experience in the field covered by the nominating organisation;
- Experience from similar regulatory processes or cross cutting issues of relevance such as other relevant legislation and different scientific disciplines;

[13] Further explanation is available on http://echa.europa.eu/stakeholders_en.asp

[14] The ECHA Secretariat will notify the MSCAs whenever it invites a PEG member nominated by them

Appendix C: Operating procedure of the PEG

Meetings of the PEG

- The PEG will have physical meetings, normally in Helsinki.
- In exceptional circumstances (e.g. no substantial comments received on the amendment, revision or new guidance, ash cloud due to volcanic eruption,…) it may be decided not to have a PEG meeting.
- Invited experts 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)."*

Working procedure of the PEG

- In all cases, the ECHA Secretariat will generate a first draft of the amendment, revision or new guidance 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. Documents will be sent out six weeks at the latest before the PEG-meeting with a deadline to provide comments two weeks before the meeting.
- Together with the formal invitation to participate and information on the date of the PEG meeting, the ECHA Secretariat will send the first draft to all members of the PEG, asking for written comments within a specified deadline.
- The ECHA Secretariat will then analyse the comments received and on that basis make a draft proposal for the agenda of the PEG meeting. The PEG meeting will be chaired by representatives from ECHA and the minutes of the meeting will be taken by a representative from ECHA. The ECHA Secretariat will prepare a consolidated text and seek the advice of the PEG members. A deadline will be set in relation to the urgency of the matter.

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[15]. The relevance in the PEG member nomination process of ensuring an overall balance between the different parties involved in the process and a fair representation of their interests and views also results from the mandate of the PEG[16].

[15]See Appendix B, Nomination and selection of members of the PEG.
[16]See Appendix A, General mandate of the PEG.