CONSULTATION PROCEDURE ON GUIDANCE[1]

Procedure for the consultation of interested parties in relation to scientific and technical guidance for industry and authorities

1 Introduction

Guidance, that has to be made available by ECHA[2] provides industry and authorities (ECHA, the European Commission, MSCAs) with a commonly agreed view on how to fulfil the requirements the REACH Regulation puts 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 hence very important that guidance is agreed by the concerned parties – and this consideration is equally valid for new guidance as well as for updates or amendments of existing guidance.

The European Commission, when developing the existing guidance in REACH Implementation Projects (RIPs) developed a process which involved relevant parties in the guidance process from an early stage. In the vast majority of the cases this process led to general endorsement, ensuring that the final documents would be acceptable to all.

ECHA is now taking over the responsibility for providing scientific/technical guidance, including the need to finalise some and to clarify other existing guidance documents[3]. In the future it can also be asked to develop new guidance. The challenge is to devise a process that enables ECHA to quickly deal with any shortcomings of the existing guidance, given that stakeholders[4] are basing their actions on the publicly available guidance. At the same time

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1 Endorsed by the ECHA Management Board on 29 February 2008.

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

3 Examples of guidance requiring further development are RIP 3.1 handling Registration, RIP 3.2 dealing with Exposure Scenarios and RIP 3.8 on Substances in Articles.

4 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.

there is a need to keep the best practices from previous stakeholder involvement and the working structures developed by the European Commission.

This paper describes the consultation process foreseen by ECHA to minimise the period that guidance containing identified shortcomings would be publicly available on the ECHA website, while ensuring adequate buy-in of the relevant actors. The guidance updating process will be kept transparent and open to participation by relevant partners[5].

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 will systematically collect information about the use of the existing guidance with a view to identifying any difficulties that have arisen. Main sources of this information are the questions from industry received by the ECHA helpdesk, issues arising from the national REACH helpdesks, and issues highlighted by authorities during the use of the guidance documents (ECHA Secretariat and ECHA Committees, MSCAs or the European Commission)[6]. In addition, issues can be communicated by any party to ECHA via a standard form on its website.

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 Legal Service of 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 consequence of conflicting statements in different guidance documents);
- Workability issues (e.g. a procedure described in the guidance could work more efficiently if altered).

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;

[5] 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.

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

- 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 that 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[7]. 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 that is 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 possible.

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. These experts will be selected on account of their specific expertise, including their knowledge of the concerns of different parties, but not to represent the views of any specific party. Whenever an amendment, revision or new guidance requires legal interpretation of the REACH regulation, 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 this consultation will be reported in the introduction of the concerned draft document.

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

- Consultation of a Partners Expert Group (PEG);
- Consultation of 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, normally via the REACH Competent Authorities Meeting.

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

[7] 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.

parties, to follow the progress of work closely and to comment, using the standard form on the website.

ECHA may decide that a restricted consultation is necessary for a fast-track amendment. For example, 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 or the relevant ECHA Committee, as well as the European Commission and MSCAs will be consulted but would in any case receive short deadlines.

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 partner expert group (PEG, see section 3.1), 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.

3.1 Partners 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, interested parties, the European Commission and MSCAs. This group will be consulted on technical content issues regarding draft amendments, revisions or new guidance. A standing PEG consisting of a network of experts that may be consulted on a short notice at any time will be installed. Information on the general mandate, nomination and selection of members of the PEG and an outline of the operating procedure for a PEG is given in the Appendices A, B and C.

The PEG consultation includes the following steps:

- The PEG is established and receives its mandate by e-mail from the ECHA secretariat (see annex A);
- The draft amendment, revision or new guidance is circulated to the members of the PEG;
- A meeting will be convened only if necessary to resolve issues that cannot be solved in writing;

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.

3.2 Consultation of the ECHA Committees and/or the Forum

For any amendment, revision or new guidance related to the operations of the ECHA Committees[8] and/or the Forum, the Executive Director will consult the body concerned. .

In case of a consultation, the Chair of the relevant ECHA Committee/Forum will put the issue on the agenda and ask the concerned ECHA Committee/Forum for advice on the draft text.

[8] Art. 77(3) (c): "The Committees shall undertake the following tasks: (c) at the Executive Director's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles". For the Forum this clause does not exist. Consequently, its consultation remains voluntary.

The ECHA Committee will deliver this advice, as much as possible within the deadline set, in accordance with its own working procedures. After a concluding discussion in the plenary or after the conclusive written consultation, the ECHA Secretariat will redraft the text, taking into account the comments provided by the(se) ECHA Committees. The guidance document will contain the disclaimer text given in Appendix D.

3.3 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 agreement and harmonised implementation by all authorities. This consultation will normally take place at the REACH CA Meeting 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 ECHA Secretariat will prepare a final text based on the outcome of the written procedure;
- If the written procedure is conclusive, the final text will be published without delay and communicated to the next REACH CA Meeting for information;
- Issues that cannot be resolved via a written procedure will be tabled at the plenary of the REACH CA Meeting with the purpose to seek consensus at that meeting. Where consensus is not possible, the majority opinion[9] as well as the minority opinions and their justifications will be recorded in the meeting minutes; These minutes will be made public by the Commission.
- A final version will be prepared by the ECHA Secretariat on the basis of the consensus or, where necessary, on the majority opinion recorded in the minutes. When no consensus is reached with the MSCA and the Commission due to differences in views on legal interpretation of the Regulation, the Executive Director will seek advice of the Management Board before concluding.

The Executive Director will publish the final guidance on the ECHA website, together with any dissenting positions notified in writing by the Commission or concerned Member States to the Agency. The guidance documents will include a reference to existing dissenting positions, where relevant.

[9] 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, it 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 which are affiliated to stakeholder organisations or interested institutional partners, or knowledgeable about certain concerned stakeholder populations or the need of certain 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 consolidated opinion of the PEG serves as basis for ECHA's final draft version of the guidance text.
- The PEG should strive for consensus. If a consensus cannot be achieved within the available time frame, the majority view position of the concerned PEG should be taken. 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, and the Executive Director will decide on the need to further consultation.

Appendix B: Nomination and selection of members of the PEG

The ECHA Secretariat defines the number of members and the required expertise or experience in its invitation to nominate experts. The selection by the ECHA Secretariat of experts proposed by stakeholder organisations and institutional interested partners will be from the list of expert nominations received by the ECHA Secretariat at a given deadline. In doing so the ECHA Secretariat will apply the criteria defined hereafter which will be published on the ECHA website.

Members of the PEG must have a proven expertise or relevant experience in the field to be addressed by the group. They will be invited on the basis of proposals made by:

1. Concerned institutional interested partners:
   - ECHA including its Committees;
   - The European Commission;
   - MSCAs;
   - Third countries invited by the MB to participate in the work of the agency.

2. Stakeholder organisations (non-institutional interested partners) with a 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, the following general selection criteria will be applied for 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;
- The balance between scientific and technical expert-knowledge and practical knowledge of the field and industrial sectors;
- The balance between experts nominated by MSCA and stakeholder organisations.

In order to ensure a workable size of the PEG, there will be a need to balance the membership of the group by applying the following criteria in order of priority:

- Overall competency of the PEG, covering all key aspects of the issue at stake;
- Relevance of the individual's expertise or experience for the overall competency of the PEG;
- Geographical distribution;
- Gender.

Appendix C: Operating procedure of the PEG

Meetings of the PEG

- The PEG will meet only if necessary, and normally in Helsinki.
- Invited experts will be reimbursed according to ECHA's rules as mentioned in "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 for the amendment, revision or new guidance as the basis for the work of the PEG.
- Together with the formal invitation to participate, the ECHA Secretariat will send the initial draft to all confirmed members, asking for written comments within a specified deadline.
- The outcome of the written procedure will be recorded;
- The ECHA Secretariat will then analyse the comments received and decide if a meeting is necessary to deal with remaining issues. If this is the case, the PEG will be convened at a workshop in Helsinki at the earliest date possible to finalise its position. The PEG meeting will be chaired and minuted by representatives from ECHA. If no meeting takes place, the ECHA Secretariat will prepare a consolidated text and circulate it for written approval to the group members. A deadline will be set in relation to the urgency of the matter.
- If a consensus cannot be reached, the position of the majority of the group will be the position of the PEG. All unsolved or open issues will be clearly documented as well as the majority and minority positions on them. Together they constitute the output from the PEG that is the basis for the subsequent consultation process.

Appendix D: Disclaimer for guidance documents

The scientific and technical guidance documents available on the website of the European Chemicals Agency provide explanatory and supplementary information to the text of the REACH Regulation. Its objective is to assist industry, especially SMEs, the Member States Competent Authorities, the European Commission and the Agency to fulfil their respective duties under REACH and to enhance coherence of the activities of the parties concerned.

The European Commission has been developing the initial guidance documents which are the result of close cooperation between authorities in the EU, the Member States and the relevant stakeholder organisations. ECHA has put these guidance documents on its website and will also update and further develop the guidance by applying a similar working method. In order to achieve the largest possible acceptance, it will endeavour to reach consensus among the different EU and national authorities on any changes to the guidance. When publishing new or revised guidance documents it will indicate whether consensus was reached.

It is important to note that guidance documents are not subject to formal adoption or approval through legislative processes. The ECHA does not accept any liability with regard to the content of the guidance.