Accredited Stakeholder Workshop

Cooperating with ECHA through the Committees

Background document

Accredited Stakeholder Workshop 2012

Cooperating with ECHA through the Committees

ECHA's three Committees and their functions

ECHA has three Committees which provide essential scientific opinions to ECHA and the Commission in support of the REACH and CLP processes.

According to REACH (Recital 103) "*Through a Member State Committee (MSC), the Agency should aim to reach agreement amongst Member States' authorities on specific issues which require a harmonised approach".* Similarly, REACH specifies (Recital 102) that "*Through a Committee for Risk Assessment (RAC) and a Committee for Socio-economic Analysis (SEAC), the Agency should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence".*

Committee for Risk Assessment

RAC is responsible for preparing opinions of the Agency for the European Commission on:
- Applications for **authorisation** under REACH.
- Proposals for **restrictions** under REACH.
- Proposals for **harmonised classification and labelling** under the CLP Regulation.
- Any other questions that arise from the operation of REACH relating to **risks to human health or the environment.**

Committee for Socio-economic Analysis

SEAC is responsible for preparing opinions of the Agency for the European Commission on:
- Applications for **authorisation** under REACH.
- Proposals for **restrictions** under REACH.
- Any other questions that arise from the operation of REACH relating to the **socio-economic impact of possible legislative action on substances.**

The European Commission uses the opinions when granting authorisations, adding substances to Annex XVII (restrictions) of REACH and when approving harmonised classification and labelling requirements for substances in Annex VI of the CLP Regulation.

Member State Committee

Under the **authorisation** process of REACH, MSC is responsible for:
- seeking unanimous agreement on substances of very high concern (SVHCs) to be included in the 'candidate list' when it is stated in the public consultation that the substance does not fulfil the criteria of Article 57 for SVHCs or that the substance identity is not clear,
- providing opinion to ECHA on ECHA's draft recommendation on inclusion of priority substances in Annex XIV (authorisation list).

Under the **evaluation** process of REACH, MSC is responsible for:
- seeking unanimous agreement on ECHA's draft decisions on dossier evaluation when the Member State competent authorities (MSCAs) have made proposals for amendment on them,
- seeking unanimous agreement on Member States draft decisions on substance evaluation when MSCAs or ECHA have made proposals for amendments on them,

- providing opinion on ECHA's draft Community Rolling Action Plan (CoRAP).

When the MSC has reached unanimous agreement, ECHA shall make the final decision accordingly. ECHA shall take MSC opinions into account.

Concept of stakeholder participation

ECHA's values of openness and transparency help shape its policy, as adopted by the Management Board towards the participation of stakeholders in its work. According to REACH, stakeholders may be invited to attend Committee meetings as observers, as appropriate, at the request of the Committee members or the Management Board. To facilitate dialogue and engagement with their stakeholders, the Committees have been encouraged to actively involve and inform stakeholders from the very beginning. Stakeholders are regularly invited to provide input on scientific and technical matters to further support the work of the Committees.

The Committees themselves may decide on inviting representatives from the Accredited Stakeholder Organisations (ASO). However, in order to provide equal and fair treatment, the selection is done according to established criteria and expressions of interest. One of the preconditions is also that the interested organisation has provided their registration number in the European Union Transparency Register to ECHA.

Each of the three Committees have further defined in their Rules of Procedure (RoPs) the types of meeting participants, besides the members, advisers or invited experts, as well as the kind of access to the documentation of the meetings and other practicalities. In line with those RoPs nominated representatives of stakeholder organisations may be admitted by the Committee as regular observers to the meeting of the Committee or its working groups. These stakeholder observers are expected to conform to the ECHA Code of Conduct for Stakeholder Observers at ECHA meetings (link to ECHA website).

Principles for stakeholder participation agreed by the Committees

Defined maximum number of observers

Since 2008, all three Committees have followed the principle that there is a maximum number of observers to be allowed per meeting as well as the possibility of rotation among the stakeholder organisations. Limitations to the numbers derive mainly from practical and organisational reasons, thus the number should not account for more than half of the number of Committee members. This allows a balanced approach where the number of observers is proportionate to the number of members of the Committee.

The current mechanism is based on continuity (i.e. *persons* are appointed by the Stakeholder Observers following an invitation from the Committee, with a possible replacement). As the participation is very much based on trust, certain confidentiality requirements are respected and put in place.

Balance between industry and NGOs

As much as feasible the Committees follow a principle that a similar number of observer seats are allocated to industry/marketing associations and NGOs (and trade unions). Academies' representatives have been allocated only a few seats due to the limited requests until now.

Sector specific observers

Mainly due to the high number of different sectoral organisations having interest in the Committees work, the participation of sectoral stakeholder organisations is arranged somewhat differently than for the organisations representing more general interests. In the case of the MSC, the Committee has established a system whereby the sectoral stakeholder organisations that have shown interest in the Committees' work can be invited on a case-by-case basis, depending on the items on the agenda. This is done at the discretion of the Chair and/or the Committee. Similarly, for RAC and SEAC the sector-specific stakeholders are invited for a particular item on the agenda. Any sector-specific stakeholder organisation, provided it is registered in the above mentioned Transparency Register, should indicate its interest in a particular agenda item to the Chair, at least 10 days in advance of the meeting.

Transparency

The dates for the coming **Committee meetings** as well as the agendas and minutes can be found on the web pages of each body:

RAC - SEAC - MSC

Full meeting minutes are published immediately after adoption and contain information about the substances and more general topics addressed during the different meetings. Outcomes of the Committee processes are made available on the ECHA website including publication of all opinions (CLH, restrictions, authorisation applications, ECHA's draft recommendation for priority substances for Annex XIV and draft Community Rolling Action Plan as well as any other opinions following specific requests) and agreements on the identification of SVHCs.

Despite the aim of having maximum transparency, including transparent decision-making, there are possible limitations to the participation of Stakeholder Observers in some of the discussions. Some of the sessions may need to be closed from observers, primarily to protect confidential business information (CBI). The Committee RoPs provide more details on this, sometimes specific to a process or a Committee, and always leave a possibility for the Chair to close a session if such a need is flagged. Reasons for closed sessions may be due to:

- The meeting formulates policy or interprets legislation.
- Request from a member.
- Request from a registrant (evaluation work) or case holder (applications for authorisation).
- Discussion on CBI-related matters (specific uses, manufacturing details, impurities and other details for which confidentiality has been requested and accepted).

To allow maximum participation possibilities to the regular Stakeholder Observers in the work of the Committees the basic rule that is applied is that Committee documents and meetings are always open for Stakeholder Observers when possible. Main conclusions and action points from each plenary meeting are made available to all meeting participants, including the representatives of the Stakeholder Observers of the respective Committee after each meeting allowing easy reference to those who were not able to attend the meeting.

Currently, some further refinement of the participation of Stakeholder Observers is ongoing for sessions where Committees will be discussing applications for authorisation and their opinions on them. There, the attendance of Stakeholder Observers to open (where CBI is not essential) sessions is foreseen to be in a strictly observation capacity with no speaking rights in order to ensure that the rights of case-owners are not affected. Case-owners and other active interested parties will be heart at an earlier stage through hearings.

Procedures and practical arrangements

Each Committee may review the list of Stakeholder Observers annually to accommodate for any additions or changes in the ASO lists. Stakeholder organisations may be removed from the list of invitees e.g. if the level of participation has been low. As specified in the ECHA Code of Conduct for Stakeholder Observers, the appointed representatives should not have a direct interest in cases dealt with by any Committee. In other words the intention is not just to have individual companies as observers in order to provide a level playing field to all interested parties but also to be able to have wider industry perspective represented. In justified cases, the regular observer may be accompanied by one other person possessing specific expertise that is required during a targeted discussion, if needed.

Depending on the topics on the agendas of a meeting, there is sometimes a need for the regular Stakeholder Observers to be on standby due to the closed sessions. The timing of the agendas aims to minimise inefficient periods of the regular Stakeholder Observers between open and closed sessions. Non-confidential briefing to the observers is regularly provided from any closed sessions.

Possibilities for ASOs who do not participate in the Committee meetings

Accredited Stakeholder Organisations, as well as other interested and third parties are encouraged to participate in public consultations to provide their input. For several processes public consultations are organised, such as on:

- Work programme and Multi-annual Work Programme.
- Testing proposals.
- Harmonised classification and labelling.
- Identification of substances of very high concern.
- Draft recommendations of substance for the Authorisation List.
- Restrictions.
- Applications for authorisation.

For organisations not attending meetings as regular Stakeholder Observers, input to the REACH processes is primarily via different public consultation processes. Input from these public consultations feeds directly into the Committees' work in each case where one of the Committees is involved. As a matter of fact, for most of the processes a *precondition* for an issue to be addressed by the Committee is that it was actually raised in the public consultation or that the possibly missing data was received during such consultation. Comments and the input are carefully reviewed by the Committees during the process, and Stakeholder Observers present at the meeting may also highlight some aspects of the submitted comments for further discussion. Responses to those comments are also published either in general or individually, depending on the nature or stage of the process.

Representatives from ASOs who do not participate in the Committee meetings may also provide their input directly to the representatives of the Committees' regular Stakeholder Observers who then in return may bring forward such contributions during the meetings.

Ongoing consultations can be found on the main page of the ECHA website.