Nanomaterials Expert Group (NMEG) Manual

Last update: 11 January 2021 (version 3)

This document contains the links to all relevant administrative forms (declaration of interest and declaration of confidentiality) that should be filled in by NMEG members or supporting experts before the meetings. General provisions such as mandate of the group and working procedures and instructions for assignment of agenda items to open or closed sessions are also documented.

This NMEG manual replaces the NMEG mandate adopted on 25.3.2019.

Version	**Changes**	**Date**
Version 1	First version of the NMEG[1] mandate.	February 2017
Version 2	The NMEG mandate is restructured and renamed 'manual', in line with the manual of other Expert Groups hosted by ECHA (PBT and ED expert groups).	March 2019
Version 3	The NMEG mandate is further aligned with ECHA PBT and ED expert groups, and in particular: - the frequency of NMEG meetings is guided by the need expressed by its members to raise discussions on critical scientific issues and/or operational issues (individual cases) and by the availability of robust documentation. Dates for two meetings per year will be set, but they may be cancelled in case no specific scientific/operational issue is raised and ready for discussion. - the maximum number of experts for Observers is set to 4 for industry ASOs and 4 for non-industry ASOs; - for next meetings, a 'Summary report' will be published on the NMEG webpage (i.e. a concise 2-3-page document that will replace the 'minutes' published for previous meetings). Moreover, the practicalities (e.g. travel instructions, security information) are removed, and some sections are shortened.	January 2021

[1] In 2017, the name of the group was changed from Nanomaterial Working group (NMWG) to Nanomaterials Expert Group (NMEG). The NMWG was originally created in 2012.

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1. Mandate of the ECHA Nanomaterials Expert Group (NMEG)

The following text is the mandate of the ECHA NanoMaterials Expert Group (NMEG) as adopted by CARACAL by written procedure (document CA/54/2020).

The mandate of the NMEG is to provide informal and non-binding scientific and technical advice on questions related to nanomaterials[2] or nanoforms[3] of substances in the frame of the implementation of REACH, CLP, BPR, EUON[4] and other issues of relevance to ECHA's work[5]. For instance the NMEG can provide recommendations on complex (specific/generic) scientific issues related to the assessment of nanomaterials.

The activity of the NMEG will not interfere with REACH, CLP or BPR formal regulatory processes. The NMEG improves the understanding of specific issues concerning nanomaterials/nanoforms of substances which leads to more informed and efficient discussions in ECHA Committees, i.e. Member State Committee (MSC), Committee for Risk Assessment (RAC), Committee for Socio-Economic Analysis (SEAC) and Biocidal Products Committee (BPC). This may hence improve Member State Competent Authorities' (MSCA) capacity to evaluate nanomaterials and accelerate the decision-making process relating to dossiers concerning nanomaterials.

In order to ensure that the NMEG delivers the most efficient and effective support to decision making, a NMEG meeting will be organised only when 1) critical scientific issues or operational issues (individual cases from e.g. REACH or BPR) have been proposed by any of the NMEG members, and 2) robust documentation (clear, comprehensive and mature enough to allow a conclusive discussion) is provided. Dates for two meetings per year will be set, but they may be cancelled in case no specific scientific/operational issue is raised and ready for discussion. Moreover, the NMEG outcomes should be as precise as possible, and the connection between the NMEG, the MSCAs and ECHA Committees should be ensured.

The mandate and functioning of the NMEG is reviewed at least every four years, with inputs from NMEG members, and may be revised by ECHA, and modifications proposed to CARACAL.

2. Participation

2.1. Members

The NMEG consists of experts from EU Member State Competent Authorities (MSCAs), the European Commission (relevant DGs), ECHA, other relevant EU Agencies, and eligible Accredited Stakeholder Organisations (ASOs).

Nominations for participation are requested through CARACAL.

Participation to the NMEG is limited to one permanent expert nominated per MSCA, per European Commission service and per relevant EU Agency. These institutions may appoint auxiliary expert(s) to the permanent nominated expert member. The list of permanent and auxiliary experts nominated at the NMEG is published on ECHA website.

Experts from industry and non-industry ASOs that fulfil the eligibility criteria defined in

[2] The term 'nanomaterial' is associated with the size and particle size distribution of a substance, according to the European Commission recommendation on the definition of nanomaterial 2011/696/EU.

[3] The term nanoform is defined in accordance with section 2.4 of Annex VI of REACH 2018/1881/EU.

[4] European Union Observatory for Nanomaterials

[5] the NMEG will in particular address questions on Substance identity, Data sharing and supply chain communication, Dossier and substance evaluation, Risk management dossiers for nanoforms of substances, Development of tests and assessment methods for nanoforms, Guidance.

the NMEG Procedure for admission of Observers may participate in the NMEG as Observers[6]. NMEG Observers are appointed for a minimum period of one year.

A maximum of four nominated experts representing industry ASOs and four nominated experts representing non-industry ASOs may participate in the NMEG meetings.

ECHA will reimburse the travel expenses of one permanent expert per MSCA and of up to four experts representing the non-industry ASOs.

2.2. Supporting experts

Requests for supporting experts can be made by a NMEG member informally to the functional e-mail box of the NMEG (nanomaterials@echa.europa.eu) at least 2 weeks before the meeting. The request must list the name, affiliation and contact details (email, phone) and the topics or agenda items to which the expert will contribute.

The NMEG member having made the request must ensure that the supporting expert follows the instructions and work procedures of the NMEG, described in Sections 5, 6 and 7 of this document. Prior to the meeting, the supporting expert also needs to sign the 'Declaration of Confidentiality'. The link to the form is available in section 7.2.

Supporting experts may be employees of chemicals companies registering under REACH or BPR. However, they are not expected to intervene in the NMEG meetings as representatives of registrants. Registrants should instead channel their contribution to the discussions of the NMEG through their industry association, e.g. CEFIC.

3. Declaration of conflict of interest

ECHA has a policy on the prevention and managing of potential conflicts of interest[7,8] which also applies to the NMEG.

Permanent and auxiliary NMEG members nominated by MSCAs and by the EU Commission and other agencies are requested to complete and sign a declaration of interest[9] and submit it to ECHA before attending their first meeting. This declaration is to be revised annually upon invitation by the NMEG secretariat. The declarations are published on ECHA's website, together with the declaration of the ECHA NMEG Chair. Declarations of interest of members nominated by Accredited Stakeholder Organisations will not be requested as potential conflict of interest is considered obvious.

Furthermore:

- All participants of a NMEG meeting are asked at the beginning of the sessions to declare any potential conflicts of interest to the items on the agenda.
- Industry representatives and supporting experts are expected to declare conflict of interest if they are employed by or providing consultancy services to a commercial entity placing on the market or using a substance on the agenda.
- Independent of their affiliation, NMEG members and supporting experts receiving research funding from such commercial entities are requested to declare potential conflict of interest.

[6] ECHA may appoint permanent representatives at the meetings among the representatives of the NMEG ASOs who may then act as a contact point for the wider industry or non-industry group.
[7] ECHA Procedure: https://echa.europa.eu/documents/10162/13608/pro_0067_04_coi_management_en.pdf/c4082b12-5830-4647-abf7-47c4a0879c86
[8] General: https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/conflicts-of-interest
[9] Declaration of interest form: https://echa.europa.eu/documents/10162/13576/doi_commitment_form-0039.docx/edfe0ee6-3bfb-047d-b516-107449a3a04b

- All participants are further requested to declare any conflicting interests that may arise from the private sphere, e.g. from investments in commercial entities dealing with a substance up for discussion.

All declarations are recorded in the meeting minutes.

When, on the basis of the above declarations, a potential conflict of interest is identified, the chair of the NMEG decides on possible mitigating measures, as defined in chapters 3.2.2 and 3.2.3 of the ECHA procedure for Prevention and Management of potential Conflicts of Interest (PRO-0067.04[10]).

4. Communication between the experts and ECHA

4.1. S-CIRCABC

S-CIRCABC is the platform to exchange documents such as general documentation (procedures, instructions, templates), organisation of meetings (NMEG working list, rolling plan, follow-up monitoring, etc.), specific meeting documents (agenda, presentations, background documents, minutes) and documents related to guidance and scientific development.

Two interest groups have been created:

- one specific to MSCAs and European Commission members (S-CIRCABC/ECHA - Nanomaterials Expert Group (MSCA/COM))
- one specific to the Stakeholder members (S-CIRCABC/ECHA - Nanomaterials Expert Group (ASO/IND)).

The documentation related to the NMEG meetings is stored by default on the S-CIRCABC ECHA-NMEG interest group. As a rule, confidential information[11] is not disclosed to the stakeholders.

4.2. NMEG functional e-mail box

The functional e-mail box is mainly used for **non-confidential** communication between ECHA and NMEG members. It can be used for e.g. announcement and of invitation to meetings, workshops, travel documents, reminders, etc.

5. Working Procedures

5.1. Organisation of the meetings

ECHA provides the chair for the meeting, develops the agenda in consultation with the NMEG members, and prepares and distributes the draft minutes for commenting.

Proposals for agenda items may be submitted by all NMEG members.

The meetings are usually held in open session. However, based on the confidentiality of the items for discussion, ECHA may decide to have closed sessions restricted to MSCAs, European Commission and EU Agencies (see section 6 for details). NMEG ASOs Observers have access to a non-confidential version of meeting documentation.

Final minutes are adopted via written procedure or at the next NMEG meeting. The

[10] Prevention and Management of potential Conflicts of Interest: https://echa.europa.eu/documents/10162/13608/pro_0067_04_coi_management_en.pdf/c4082b12-5830-4647-abf7-47c4a0879c86

[11] See section 7.3

minutes are uploaded on S-CIRCABC for NMEG members and distributed for information to the chairs of MSC, RAC and BPC.

The adopted minutes of NMEG meetings are available on the NMEG webpage: (https://echa.europa.eu/regulations/nanomaterials/nanomaterials-expert-group).

5.2. Reporting and timelines

With the support of the MSCA representatives in the ECHA-NMEG, the ECHA secretariat shall report, when appropriate, on the work of the ECHA-NMEG to the MSC, RAC and BPC.

The table in Annex 1 provides details of the main working procedures, i.e. reporting and timelines.

The NMEG can also be consulted between the meetings via written procedure (open or closed). After the written procedure, a 'response to comments' (RCOM) is prepared and distributed to the NMEG, and/or it is explained directly at the NMEG meeting if/how the comments are taken on board.

6. Assignment of Agenda Items to Open or Closed Sessions of Plenary Meetings of the NMEG

6.1. The work steps

ECHA and the proposing NMEG member(s) must ensure that the discussion items in a meeting or a written procedure are handled correctly in terms of confidentiality and must avoid interference with on-going decision making in a formal regulatory process.

See Annex 2 for a detailed workflow.

6.2. Key considerations on the need for Closed Sessions

As a basic principle, all topics should be discussed in the Open Session in order to allow stakeholder input and transparency.

ECHA will decide on whether a particular topic or substance should be discussed in the Open or Closed Session in consultation with the NMEG member proposing the agenda item. For items proposed for the Closed Session, the NMEG member proposing the item is requested to provide a reason in accordance with the justifications listed below. When it is not possible to discuss an item in Open Session, it is recommended to bring the generic issue raised by the case (without reference to case-specific details) to the Open Session.

The NMEG member is responsible for ensuring that confidential business information is not presented in the Open Session.

6.3. Selection of Closed or Open Sessions

The **Closed Session** should be chosen if one or more of the following conditions apply.

- **Discussions need to involve confidential business information[12] (CBI).**

  It should be carefully considered whether recourse to CBI is indeed needed for discussion.

[12] Instructions are available in the document "Confidentiality aspects related to the use of Registration data for regulatory risk management purposes (version 3), *Checklist of confidentiality aspects in using Registration data_10102013.pdf*", link available in Section 7.4 to this document.

It may however be considered whether a meaningful and effective discussion still would be possible if all aspects, except CBI, would be discussed in Open Session, and only the aspects requiring disclosure of CBI would be discussed in Closed Session.

- **The substance to be discussed is undergoing Substance Evaluation (CoRAP substances of the on-going year or under follow-up evaluation) and the party proposing the agenda item wishes to discuss on the basis of the draft substance evaluation report** *(as background document)***.**

  The draft substance evaluation (SEv) report should not be made available to ASO representatives or the general public.

  However, in the NMEG, substance discussion should preferably take place in Open Session allowing the involvement of ASO representatives. This is possible if:

  - No confidential information is required to address the issue(s) up for discussion *(also see above for further details)*.
  - An extract of the draft SEv report, covering the relevant non-confidential background information is provided by the reporting party[13] and shared with all NMEG members.

  OR

  - An extended presentation covering the relevant non-confidential background information is provided for discussion and shared with all NMEG members from both authorities and stakeholder organisations[14]. (In addition, t*he draft SEv report may be shared but only with Expert Group members representing EU or Member State authorities.)*

- **Other cases where it is necessary to consider the Closed Session.**

  E.g., a party proposing an agenda item has requested inclusion in the Closed Session with justification.

  In such cases, the ECHA chair will scrutinise and decide, in consultation with the proposing party, which session would be appropriate in the specific case.

6.4. Cases which cannot be discussed by the NMEG

NMEG discussion of cases should not interfere with the relevant formal decision making processes. Therefore, the following cases should never be discussed by the NMEG:

- **Draft decisions in the dossier and substance evaluation** decision making processes **after the referral to the MSCAs** for proposals for amendment in accordance with REACH Articles 51 and 52.
- Annex XV dossiers already submitted for identification of substances of very high concern or for imposing a restriction, or Annex VI dossiers submitted for harmonised classification and labelling.
- A biocide assessment already submitted for peer review, unless advice is specifically requested by one of the relevant Working Groups or the BPC.[15]

The NMEG mandate stipulates that the advice provided by the group to the party requesting such advice is of informal nature. Hence, any advice given or conclusion

[13] The evaluating MSCA may however share the draft SEv report with the registrant if this is deemed useful for discussion with the registrant and development of the report

[14] In this latter case the presentation introducing the case and the issues for discussion should be provided at the same deadline that applies for provision of case background documentation, i.e. at the latest two weeks before the meeting.

[15] Or unless justified and agreed with ECHA

drawn by the NMEG does therefore not pre-empt any formal decision to be made under a REACH, CLP or BPR process. Also the party that has requested advice from the NMEG is not bound to consider views expressed or conclusions drawn by the Group for further development or finalisation of their assessment.

7. Distribution of information and documents, including confidentiality

7.1. Distribution of information

ECHA and the NMEG members should pay attention to the correct distribution of the information and documents.

Members are allowed to share the non-confidential meeting documents to which they have been granted access via S-CIRCABC within their organisation. Accredited industry stakeholders are allowed to forward the information/documents, where not restricted, to the member affiliations which are directly involved in the work on a particular item. The documents should not be made public by the members, unless they are already publicly available on ECHA's website or published elsewhere in a lawful manner.

ASO members may report to their hierarchy/members in general terms about the discussions held at the meeting but shall respect the confidential nature of deliberations and views of individual members. Reports to media or to ASO's own media channels shall respect the same conditions.

Documents with the mention « **for NMEG only** » in the filename must not be distributed by ASO participants including in their own organisation.

ECHA has provided a checklist of confidentiality aspects to support an appropriate handling of confidential information when using information from registration dossiers in the NMEG meeting documents (see further details in Section 7.4).

Each NMEG member generating a meeting document is responsible for identifying pieces of confidential information and for handling them appropriately.

The documents generated by MSCAs, ECHA or the European Commission containing confidential information need to be flagged in the file name as "CONF" or "confidential" and the confidential information in the document needs to be clearly pointed out, e.g. by red bold text as confidential.

Confidential information is only distributed by ECHA, MSCAs and the European Commission among these parties. The platform for distributing confidential information is the S-CIRCABC MSCA/COM interest group of the NMEG. In no situation should confidential information be distributed via e-mail.

7.2. Declaration of confidentiality

All ECHA-NMEG members have to make a written declaration of confidentiality before their first meeting. In case a nominated member is replaced by another expert, the latter should also make a declaration of confidentiality (form available here).

7.3. Handling personal data

ECHA will process any personal data received in accordance with ECHA's privacy rules. Please note that for transparency reasons the list of membership of the expert groups, and declarations of interest of the members shall be made public on the Agency's website.

7.4. Confidentiality aspects related to the use of Registration data for regulatory risk management purposes

The following document should be consulted before starting hazard assessment of substances, in particular when registration data will be used:

Checklist of confidentiality aspects

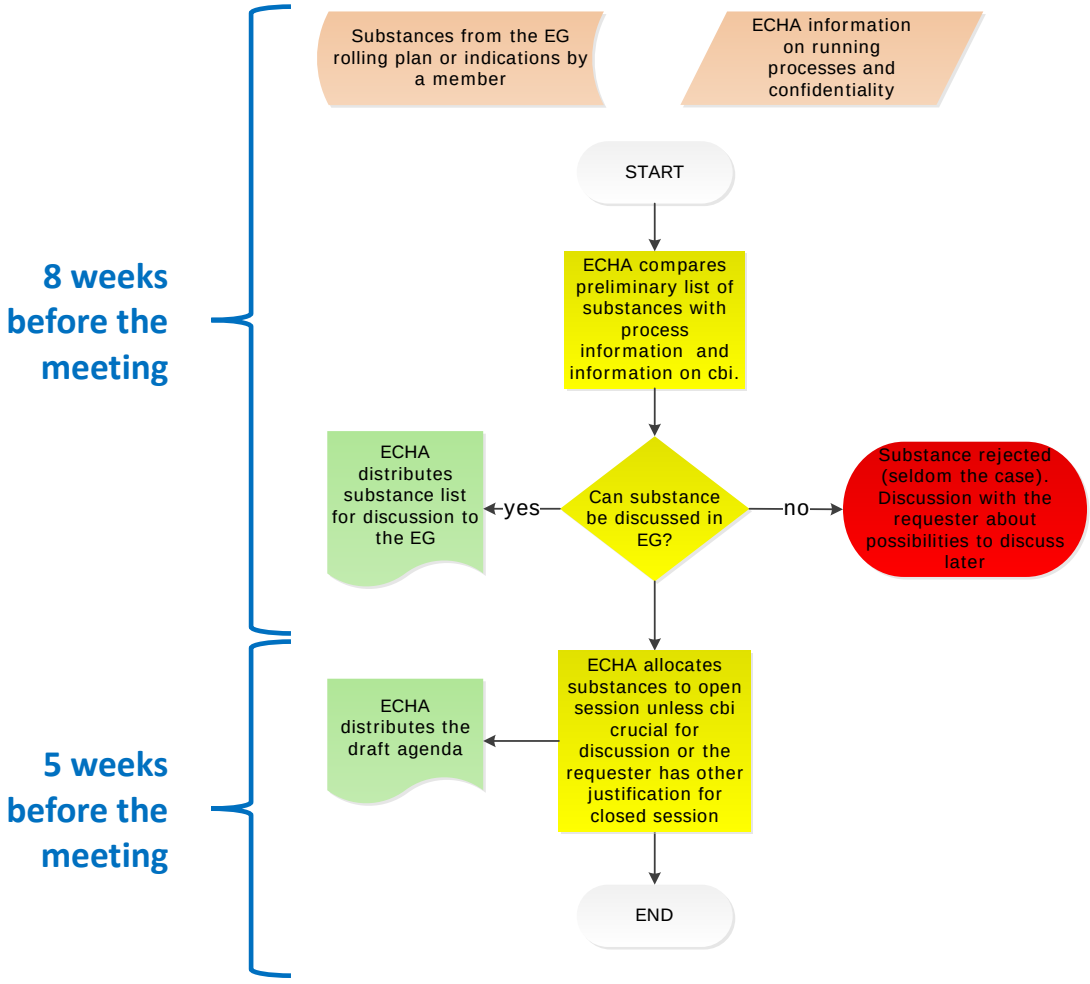
Annex 1: Working procedures for the NMEG

Task	Who	Deadline
MEETING CYCLE TASKS		
Indicate to ECHA any changes to the rolling-plan (including new substances inserted in the NMEG working list, and/or other agenda items which are to be discussed). Indicate if discussion in the closed session is necessary, and if so, provide a justification (see Section 6).	Experts	12 weeks before each meeting
Confirmation of upcoming meeting	ECHA	10 weeks before each meeting
ECHA to scrutinise the discussion items indicated for discussion at the upcoming meeting and allocate to sessions. The rolling plan is updated accordingly and uploaded to S-CIRCABC. An email is sent to inform NMEG members	ECHA	8 weeks before each meeting
Send the invitation of the upcoming meeting with the draft agenda	ECHA	5 weeks before each meeting
If comments are requested before the NMEG meeting, upload on S-CIRCABC the background document(s) to be commented on.	Experts & ECHA	At least 3 weeks before each meeting.
For draft minutes to be adopted in plenary: - Revise the draft minutes of latest meeting based on comments received and upload to S-CIRCABC. These minutes are to be adopted in the subsequent meeting. - Upload meeting documents of current meeting (updated draft agenda, Tour de Table document, rolling agenda, factsheets, background documents, presentations).	ECHA	At least 2 weeks before each meeting.
ECHA to update the agenda before the meeting with the list of documents received for each substance or item. ECHA to change the filenames of the meeting documents in S-CIRCABC to correspond with the agenda item.	ECHA	4 working days before each meeting
If factsheets/other background documents are submitted later than 2 weeks before the meeting, need for written procedure is to be decided at the meeting.	All	At the meeting
In situations where an updated version of any meeting document is brought to a meeting, it is the responsibility of the document owner to upload the latest version to S-CIRCABC.	Expert	At the meeting
If needed, upload new or updated meeting documents to S-CIRCABC	ECHA	1 day after each meeting
Distribute summary report.	ECHA	Max. 3 days after each meeting
Members to provide feedback comments, if necessary, on the summary report from the meeting within 5 working days.	Experts (if necessary)	5 days after receipt of the summary report.
- Distribute adopted minutes of the previous meeting to all members, by upload them on S-CIRCABC. - Request to upload on NMEG webpage several documents of the current meeting:	ECHA	1 to 2 weeks after each meeting

a) agreed summary report b) tour de table and c) final agenda. - Publish a short news item on EUON (with link to relevant documents on NMEG webpage).		
Distribute draft minutes of meeting, by uploading them on S-CIRCABC	ECHA	4 weeks after each meeting
Provide comments to the draft minutes	Experts	4 weeks after receipt of draft minutes.
For draft minutes to be adopted in written procedure: Revise the draft minutes based on comments and distribute them.	ECHA	2 weeks after receiving the comments
For draft minutes to be adopted in written procedure: experts have an opportunity to react on the revised draft minutes -> if no reactions or only editorial changes -> minutes are adopted -> if significant further comments -> a second revision step is initiated by ECHA and the revised draft minutes are distributed to the members within two weeks, after which members have one week time to react to the revisions.	Experts / ECHA	1 week
Experts to check confidential aspects of the draft minutes and flag them to ECHA. Experts to inform ECHA if they have an objection to have their names and organisations disclosed in future Access To Document (ATD) requests. Objection to this should be indicated per e-mail and at the latest by the adoption of the minutes.	Experts	Before the adoption of the minutes (See Section 7.3 – Handling personal data in case of ATD request)
The adopted NMEG minutes (open and closed) will be shared with all members of the NMEG (including stakeholders). The adopted NMEG meeting minutes can be shared with the members of ECHA Committees. The substance specific section of the adopted minutes can be shared with the members of the Biocide Working Groups representing the MSCAs when the particular substance is discussed in the Biocide Working Group. The NMEG Secretariat will specify which part of the substance specific section of the adopted minutes may be shared with a given applicant.	ECHA	
The experts being Rapporteurs of a substance should indicate as a follow-up action to ECHA if they have changed the conclusion in factsheet compared to what was agreed/discussed on the substance. ECHA launches a written procedure for these cases or they go, if deemed necessary by the respective expert, to the agenda of one of the future meetings.	Experts	After revising the assessment
ECHA may arrange Internet platform (audio- or video) meetings between each NMEG meeting in order to tackle any urgent issues and reduce time pressure of meetings.	ECHA	Between NMEG meetings
Members to flag to ECHA during written procedures if there is need of remote or physical meeting (e.g. on controversial issues or issues of general importance).	All	During written procedures
ONE-OFF AND ONCE A YEAR TASKS		
Ask for permission to publish participants name in the NMEG	ECHA to a new	Immediately after the

participants list on ECHA website.	nominee	nomination
All participants sign a declaration of confidentiality.	Experts at request of ECHA	Before the first meeting of the participant (see Section 7.2 - Declaration of confidentiality)
All participants fill in once a year the form for declaration of conflict of interest.	Experts at request of ECHA	Once a year (see Section 3 – Declaration of conflict of interest)
Follow-up monitoring	ECHA and Experts	For the last meeting of each year
Generate the annual rolling-plan.	ECHA and Experts	Start the drafting after the publication of the Draft CoRAP and finalise in January after the comments of the members
ECHA to provide the updated NMEG working list to the MSCA/COM experts	ECHA	Once a year in January
A MS expert may submit a draft final factsheet for non-CoRAP substances after the case has been finalised. The factsheet will be subject to final written procedure. After addressing the comments, the MS expert will distribute the draft final factsheets via S-CIRCABC.		

Annex 2: Work steps of the NMEG for allocating substances[16] to the closed or the open session of plenary meetings



[16] The word 'substance' may be replaced by 'discussion item'.