ECHA - Nanomaterial Expert Group Manual

Adopted on: 25 March 2019

This document contains all relevant administrative forms (declaration of conflict interest and declaration of confidentiality) that should be filled in by ECHA-NMEG members or supporting experts before the meetings. The manual provides relevant information to consider before a plenary meeting (travel instructions, supporting experts and WebEx requests). General provisions such as mandate of the group and working procedures are also documented.

This ECHA-NMEG manual replaces the ECHA-NMEG mandate signed on 27.2.2017.

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1. Mandate of the ECHA - Nanomaterials Expert Group

The mandate of the ECHA Nanomaterials Expert Group (ECHA-NMEG) is to provide informal advice on scientific and technical issues regarding implementation of REACH, CLP and Biocidal Products Regulations (BPR) in relation to nanomaterials[1], such as:

- Substance identity
- Data sharing and supply chain communication
- Dossier evaluation (Compliance Checks and Testing Proposals)
- Substance evaluation
- Risk management dossiers for substances with nanoform
- Development of tests and assessment methods for nanomaterials
- Guidance for registrants
- Any other scientific and technical issues on nanomaterials related to REACH, CLP and BPR.

ECHA-NMEG aims also at facilitating discussions with industry regarding 1) its experience gained in documenting intrinsic properties of nanoforms of substances using the most appropriate methodologies and 2) its obligations towards fulfilling REACH, CLP or BPR requirements.

ECHA-NMEG is an informal ECHA expert group independent from any of ECHA Committees or any other existing group. ECHA-NMEG will provide non-binding scientific advice on questions related to nanomaterials under REACH, CLP or BPR, and this activity will not interfere with these formal regulatory processes. Where scientific solutions are not adequate or feasible and where further policy developments may provide a way forward, ECHA secretariat will report this issue as defined under section 5.2 of this manual.

The discussions taking place in the ECHA-NMEG may improve understanding or expertise on specific issues concerning nanomaterials, leading to more efficient discussions at Member State Committee (MSC), Risk Assessment Committee (RAC) or Biocidal Products Committee (BPC) level. This may hence improve MSCAs' capacity to evaluate nanomaterials and accelerate the decision-making process relating to dossiers concerning nanomaterials.

2. Membership

The ECHA Nanomaterials Expert Group (ECHA-NMEG) is consisting of experts from EU Member State Competent Authorities (MSCAs), the EU Commission and relevant Agencies, ECHA and eligible Accredited Stakeholder Organisations (ASOs).

To benefit from the expertise that is available at Member State level and to ensure that those national experts are supported by their Competent Authorities, nominations for participation will be requested through the members of CARACAL.

The size of the expert group is limited to one permanent expert nominated per MSCA, Commission service and relevant EU Agencies. These permanent expert members shall guarantee the continuity and consistency of the technical and scientific discussions facilitating REACH, CLP and BPR implementation.

MSCAs, the Commission services and relevant EU Agencies may appoint auxiliary expert(s) to the permanent nominated expert member. However, any costs related to

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

the participation of these further experts in the meeting shall not be reimbursed by ECHA. EU Commission and EU Agencies experts are not reimbursed by ECHA.

Experts from Industry and Non Governmental Organisations (NGOs) can also participate in the ECHA-NMEG as Observers. The selection of ECHA-NMEG Observers will be made between ECHA's ASOs that expressed their interest to participate at ECHA-NMEG and fulfil the eligibility criteria as defined by ECHA Nanomaterials Expert Group Procedure for admission of Observers. ECHA foresees a renewal of the expression of interest and appointment of ECHA-NMEG Observers every 2 years. Each of the ECHA-NMEG Observers should identify a nominated expert at the ECHA-NMEG and may also appoint an auxiliary expert. The list of experts nominated at the ECHA-NMEG will be published on ECHA website.

To ensure consistency of the Expert Group discussions, ECHA-NMEG Observers are appointed for a minimum period of one year. In case of need, ECHA may appoint permanent representatives at the meetings among the representatives of the ECHA-NMEG ASOs who may then act as a contact point for the wider Industry or NGO group.

For specific scientific or technical questions additional experts may be invited to the meetings on a case-by-case basis, when such a need is identified, and following suggestions by MSCAs, Commission, relevant EU agencies, ECHA, or ECHA-NMEG Observers from Industry or NGOs.

A maximum of three nominated permanent experts representing Industry and three nominated permanent experts representing NGOs may participate in the ECHA-NMWG. Each of the ECHA-NMWG Observers attending the ECHA-NMWG may appoint an auxiliary expert. ECHA will reimburse the travel expenses of one (permanent) expert per Member State Competent Authority and of the experts representing the NGOs.

3. Declaration of conflict of interest

ECHA has a policy on managing conflicts of interest in place. This is provided on ECHA website at the following link: https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/conflicts-of-interest.

The policy is implemented also in the Expert Groups. For this purpose, the participants are asked, at the beginning of each meeting, to declare any potential conflicts of interest to any of the agenda items of the meeting. The authority experts and representatives of non-governmental environmental or human health organisations are assumed by definition to have a conflict of interest due to the representation of their affiliation and this does not need to be declared. The authority experts need to declare any interest raising from the private activities. The industry stakeholder members are requested to declare interests related to both to the interests of their employer, the organisation they present and their private activities.

All ECHA-NMEG members have to make a declaration of conflict of interest before their first meeting and at least once a year by submitting the form to the secretariat:

Declaration of interest and commitment [DOCX]

4. Communication between the experts and ECHA

The following tools are used for communicating with the ECHA-NMEG:

4.1. S-CIRCABC

S-CIRCABC is used as an interface where confidential and/or non-confidential information can be exchanged with the members of the expert Group. Two interfaces have been created, one specific to Member States/COM members (S-CIRCABC/ECHA - Nanomaterials Expert Group (MSCA/COM)) and another one specific to the Stakeholder

members (S-CIRCABC/ECHA – Nanomaterials Expert Group (ASO/IND)). The documentation related to the ECHA-NMEG meetings is stored by default on S-CIRCABC. As a rule, confidential information is never disclosed to the stakeholders.

S-CIRCABC is mainly used to communicate to the ECHA-NMEG:

- General documentation (Work procedures, instructions, templates).
- Documents related to meetings:
    - o Rolling plan
    - o Follow-up monitoring
- Meeting specific documents:
    - o Invitation to the meeting
    - o Meeting agenda (draft and final versions),
    - o Meeting documents (presentations, background documents),
    - o Follow-up documents of the meeting
        - ▪ Minutes of the meeting (draft and adopted versions)
        - ▪ Other document, where needed
- Guidance and scientific development related documents.

4.2. ECHA-NMEG functional e-mail box

Functional e-mail box is mainly used for non-confidential communication between ECHA and the NMEG members. For confidential or restricted information, an e-mail may be sent via the functional e-mail boxes (FMB) in order to inform the experts that relevant information has been uploaded to S-CIRCABC such as meeting documentation (presentations…).

Major part of this communication via the functional e-mail boxes **is saved only in the e-mail box.**

The functional e-mail boxes can be used, e.g., to send the following information:

- Preannouncement of the meetings,
- Invitation to the upcoming meeting with the draft agenda,
- E-mails reminding on actions agreed,
- E-mails triggering actions based on the work procedures,
- E-mails clarifying work procedures and schedules,
- Information on upcoming events such as workshops or other activities where the members are recommended to participate,
- Informal e-mails linked to the meetings (confirmation of agenda point…), and/or to the latest scientific developments.

5. Working Procedures

5.1. Organization of the meetings

The ECHA secretariat will provide the chair for the meeting and will also take care of preparing and distributing the draft minutes for commenting. Final minutes will be adopted via written procedure or at the next NMEG meeting. These minutes will be uploaded on S-CIRCABC for ECHA-NMEG members and distributed for information to the chairs of MSC, RAC and BPC. The minutes of ECHA-NMEG meetings will be available on the ECHA-NMEG webpage. All ECHA-NMEG ASOs Observers will have access to a non-confidential version of meeting documentation.

ECHA will develop the agenda for the meetings in consultation with the members of the ECHA-NMEG. Proposals for agenda items may be submitted by the participating experts, the MSCAs, MSC, RAC and BPC members, ECHA secretariat, EU Commission, EU Agencies and representatives from Industry or NGOs.

The meetings will usually be held in open session. However, based on the confidentiality of the discussed issues, ECHA may decide to have closed sessions restricted to MSCAs, EU Commission and EU Agencies only (see section 6 for details).

The mandate and functioning of the Expert Group shall be assessed by NMEG and thereafter reviewed by ECHA at the end of a mandate period.

The following Table provides the ECHA-NMEG main working procedures and timelines.

Regarding the timelines, we wish to stress the importance of respecting the deadlines provided in the following Table to allow participants to get appropriately acquainted with the topics and justified opinion making by the experts.

Table 1: Working procedures for ECHA-NMEG

Task	Who	Deadline
MEETING CYCLE TASKS		
Send the invitation of the upcoming meeting with the draft agenda	ECHA	9 weeks before each meeting
If comments are requested before the NMEG meeting, upload on S-CIRCABC the background documents to be commented at least three weeks before the meeting.	Experts & ECHA	At least 3 weeks before each meeting.
- Revise the draft minutes of the previous meeting based on comments received and upload to S-CIRCABC. The minutes are to be adopted in the subsequent meeting. - Upload meeting documents of current meeting (updated draft agenda, Tour de Table, rolling agenda, background documents, presentations).	ECHA	At least 2 weeks before each meeting.
Upload new or updated meeting documents to S-CIRCABC	ECHA	1 day after each meeting
- Upload adopted minutes of the previous meeting on S-CIRCABC. - Request upload on NMEG webpage of: a) adopted minutes of previous meeting and b) tour de table and final agenda of current meeting.	ECHA	1 week after each meeting
Upload draft minutes of current meeting on S-CIRCABC	ECHA	4 weeks after each meeting
ECHA to arrange teleconferences or WebEx meetings between each NMEG meeting in order to tackle any urgent issues.	ECHA	Between each NMEG meeting
Comments on the minutes	All	4-6 weeks after upload on S-CIRCABC
ONE-OFF AND ONCE A YEAR TASKS		
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)

5.2. Reporting

With the support of the MSCAs 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.

6. Assignment of Agenda Items to Open or Closed Sessions of Plenary Meetings of the ECHA - Nanomaterials Expert Group

6.1. The work steps

Both ECHA and the NMEG member involved in the topic to be discussed should assure that the topic suggested to be discussed in a meeting is handled correctly in terms of confidentiality issues, avoiding interference with on-going decision making in formal processes.

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 of the process. There should be good justification for discussion of agenda items in the Closed Session. When it is not possible to discuss an item in Open Session, it may be possible to bring the generic issue raised by the case (without reference to case-specific details) to the Open Session.

ECHA will decide on whether a particular topic or substance should be discussed in the Open or Closed Session of the NMEG in consultation with those proposing agenda items. In particular, those proposing discussion of a specific topic should indicate which Session they recommend for discussion and provide the reason in accordance with the justifications listed below.

The expert presenting a substance or a discussion item at the NMEG is responsible for ensuring that confidential business information is not presented in the Open Session.

ECHA will ensure that there is no interference between formal REACH processes and the NMEG discussions. ECHA holds information on on-going REACH decision-making processes and therefore is in the best position to decide whether there could be possible interference between an on-going process for a particular substance and its discussion by the NMEG.

6.3. Selection of Closed or Open Sessions

The **Closed Session** should be chosen if one or more of the following conditions apply. ECHA will scrutinize whether a substance or generic topic suggested to the agenda does fulfil one of the conditions below and will case by case, if necessary in consultation with the suggesting party, decide on the appropriate Session.

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

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

  CBI cannot be discussed in Open Session. In case CBI is required for discussion of a substance or another topic this discussion needs to take place in Closed Session. It may however be considered whether meaningful and effective discussion still would be possible if only the aspects requiring

disclosure of CBI would be discussed in Closed Session and all other aspects in Open Session.

- **The substance to be discussed is undergoing Substance Evaluation (CoRAP substances of the on-going year or under follow-up evaluation) <u>and</u> 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 report should not be made available to representatives of Accredited Stakeholder Organisations (ASOs) or the general public.

  However, in the NMEG, substance discussion should preferably take place in Open Session allowing the involvement of representatives of Accredited Stakeholder Organisations. 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 and shared with all NMEG members (from both authorities and stakeholder organisations).

  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. (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, ECHA will scrutinize 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

To avoid interference with the relevant decision-making process 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 Articles 51 and 52 REACH
- 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.

It further should be noted that the mandate of the NMEG stipulates that the advice provided by the group to the party requesting such advice is of informal nature. Hence, any advice given or conclusion drawn by the Expert Groups does therefore not pre-empt any formal decision to be made under a REACH process. Also the party that has requested advice from the NMEG is not bound to consider views raised 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 members should pay attention to the correct distribution of the information and documents of the expert group.

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 website or elsewhere.

ASO members may in general terms report to their hierarchy/members 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.

For documents having « **for ECHA-NMEG only** » in the filename means that ASO participants should not distribute the document in their organisation.

The MS generating a meeting document is responsible for identifying pieces of confidential information and for handling them appropriately.

The documents generated by the MS, ECHA or COM containing confidential information need to be flagged in the file name as "CONF" and the confidential information in the document needs to be pointed out by red bold text separately as confidential.

Confidential information is only distributed by ECHA, MS and COM among these parties. The platform for distributing confidential information is S-CIRCABC MSCA/COM interest group of the ECHA-NMEG expert group. In no situation confidential information should 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, as follows:

Declaration of confidentiality [DOCX]

7.3. Handling personal data

As a general rule, personal information of nominated members will not be blanked out from expert group documents unless a participant specifically requests to delete their information in a specific document. Personal information of supporting experts is according to standard procedure deleted out from documents which are distributed to third parties, e.g., in an Access To Document (ATD) request.

8. Practicalities

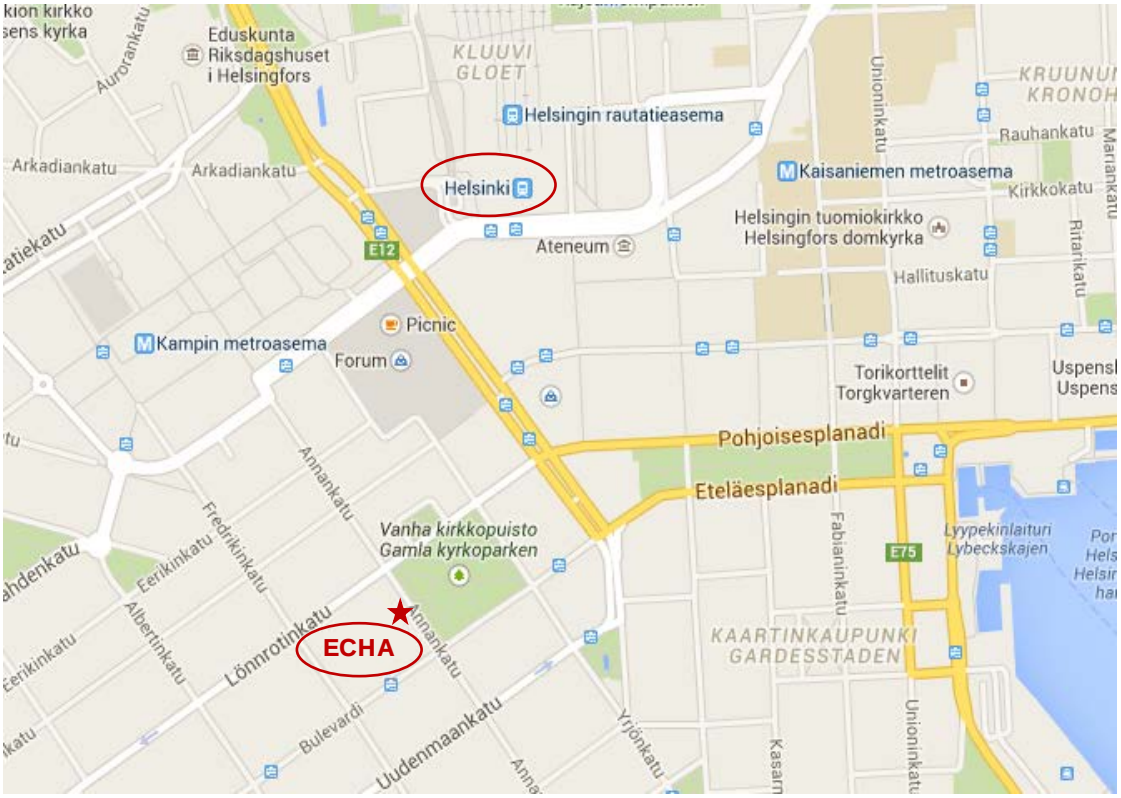
8.1. Travel instructions

From the airport, you can get to the city center:

- **By taxi**: The drive from the airport takes about 25–30 minutes. Taxi companies apply various fares so it is advisable to check the pricing system before the ride. Taxies are available in front of Terminal 1 and 2.
- **By airport taxi**: There is also an airport taxi service in Helsinki. They offer a collective taxi service from and to the airport for a fixed price. They usually have their booth inside the arrivals' hall. You might have to wait for about 10 minutes before the taxi leaves.
- **By Finnair Citybus**: The trip takes about 35 minutes from the airport directly to the Central Railway Station. The bus leaves every 20 min from 5 am to 12 pm in front of both Terminals 1 and 2. For route and timetable please consult the Finnair site.
- **By bus**: The bus No 615 takes about 40 minutes and it leaves from both Terminals 1 and 2 to the city railway station 1-2 times per hour. You can buy HSL single tickets from HSL ticket machines at bus stops of the airport shuttle bus.
- **By train**: The direct walking route between Helsinki-Vantaa Airport and the Airport train station is open for passengers. Both terminals are located close to escalators. Train leaves every 10-15 min and will take you directly to the Central Railway Station. Ticket vending machines can be found on the platform.

From the Railway Station to ECHA

From the Central Railway Station it is a 10–15 minute walk to ECHA.



8.2. Security information

In ECHA premises, please consider the following housekeeping rules:

Emergency

- The emergency exits are indicated with **green signs**.
- In case of emergency, follow the instructions of the security personnel or ECHA staff members.
- Do not use the lifts, please take the stairs and go outside.
- Assembly point is in the park opposite the ECHA building main entrance.

Registration

- All participants will receive a visitor badge at the Reception of main entrance.
- The badge must be worn visibly whilst on ECHA premises.
- Visitor badges must be returned at the end of each meeting day and obtained again in the morning upon arrival.

Venue

- In general, the Conference Center is located in floor K3.
- The area for coats and luggage is located in floor K3 and main entrance of ECHA. The cloak room is unattended; please do not leave any valuables.
- A luggage room is available at the registration desk in the main ECHA lobby.

Administrative issues

- Please register by signing the attendance list in the lobby next to the Conference Center.
- In case you need to book a taxi please call +358 1000600 (pre- bookings) and +358 1000700 (immediate booking).

Coffee breaks

- During the breaks, coffee and other refreshments will be served in the lobby next to the Conference Center.
- A smoking area is located next to the self-service restaurant *Fazer* on the first floor terrace.
- ECHA will offer lunch to the participants entitled to reimbursement. If you have a badge with **red dot** on it, you are entitled to lunch that includes: a main dish, side salad **or** soup, bread and spreads, drinks and a choice of one dessert **or** fruit and in addition coffee **or** tea.

Technical equipment

- There is the possibility to connect to a wireless network (**SSID: ECHA_Guests**; **password: GuestW1F1**).
- Public computers with Internet access are installed in the lobby of meeting rooms, in floor K3.
- Printing documents (e.g. boarding pass) is possible.
- Public computers are intended for accessing non-confidential information only.

Data protection

- The meeting will be transmitted via WebEx to allow members or supporting experts to follow/participate in discussions. It will also be recorded in order to facilitate the drafting of the meeting minutes.
- The European Chemicals Agency will ensure on its part that your personal data is processed as required by Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community Institutions and bodies and on the free movement of such data. You have the right to access and rectify that data. To exercise these rights, please contact the data controller at scientificevents@echa.europa.eu.

8.3. Webex request

Technically the participation to ECHA-NMEG meetings via Webex is possible, and can be agreed upon if travelling to Helsinki is not possible. However, we do not want to encourage this, as the use of Webex will inevitably affect the conversational atmosphere that a face-to-face meeting has. Also, as with any on-line tool, there can be security issues when confidential issues are discussed in the meeting.

However, if you are compelled to use Webex it will be your responsibility to inform us in advance if anybody else will join you. This person also will have to sign the declaration of confidentiality before the meeting.

We will not be able to dedicate one of our staff to monitor the Webex connection during the entire meeting, and thus we cannot guarantee that we will be able to facilitate potential requests for the floor that you may have.