

ECHA - Nanomaterial Working Group

(ECHA-NMWG)

Mandate

1. Purpose

Without prejudice to any future decision or recommendation relevant to nanomaterials or chemicals substances in general, the purpose of the ECHA NanoMaterial Working Group (ECHA-NMWG) is to discuss scientific and technical questions relevant to REACH, CLP and the Biocidal Products Regulation (BPR) processes dealing with nanomaterials and provide recommendations on strategic issues. Although there are no explicit requirements for nanomaterials under REACH, or CLP, they meet the REACH substance definition and are thus covered by REACH, and CLP. Furthermore, the BPR provides some specific provisions on how to address nanomaterials in the context of this legislation. The publication of the European Commission recommendation¹ on the definition of nanomaterials has highlighted the need for a focused expert group to address scientific and technical issues relating to their registration under REACH and their further evaluation.

ECHA-NMWG is an informal advisory group consisting of experts from Member States, the Commission, ECHA and eligible accredited stakeholders organisations, with the following mandate:

Provide informal advice on any scientific and technical issues regarding implementation of REACH, CLP and BPR legislation in relation to nanomaterials, such as:

- **Substance identity**
- **Data sharing and supply chain communication**
- **Dossier evaluation (Compliance Checks and Testing Proposals)**
- **Substance evaluation**
- **Guidance for registrants**
- **Any other scientific and technical issues on nanomaterials related to REACH, CLP and BPR.**

ECHA-NMWG aims also at facilitating discussions with industry regarding 1) its experience gained in documenting intrinsic properties of nano-forms of substances using recent methodologies (e.g. similar to Group Assessing Already Registered Nanomaterials (GAARN)) and 2) its obligations towards fulfilling REACH requirements.

There is a clear distinction between the mandates of the Commission Advisory Group CASG Nano and the ECHA-NMWG. While the former would deal with any need for further policy development in this area, the latter is focused on scientific and technical issues regarding REACH, CLP and BPR implementation. Potential overlap between the activities of both groups CASG Nano and ECHA-NMWG needs to be avoided.

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF>

ECHA-NMWG shall support but not interfere with decision making under REACH, CLP or BPR. It will mainly serve as an expert forum providing scientific and technical recommendations on dealing with specific questions related to nanomaterials under REACH, CLP and BPR. 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 point 4 of this mandate.

ECHA-NMWG is coordinated by ECHA and supervised by MSCAs in their respective areas of competence via direct reporting to CARACAL and through MSCAs representatives in the ECHA-NMWG.

It is envisaged that the discussions taking place in the ECHA-NMWG may facilitate MSCAs gaining understanding or expertise on specific issues involving nanomaterials, leading to more efficient discussions and more limited concerns at Member State Committee (MSC) or Risk Assessment Committee (RAC) level. This may hence improve MSCAs capacity to evaluate Nanomaterials and accelerate the decision-making process relating to dossiers involving nanomaterials.

2. Membership & confidentiality

ECHA-NMWG is an informal ECHA expert group independent from any of ECHA Committees or any other existing group.

To benefit from the expertise that is available at Member State level and to ensure that these 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 Member State and Commission service. These permanent expert members would guarantee the continuity and consistency of the technical and scientific recommendations facilitating REACH, CLP and BPR implementation.

Member States and Commission services may appoint auxiliary expert(s) to the permanent nominated expert member. However, any costs related to the participation of these further experts in the meeting shall not be reimbursed by ECHA. Commission services experts are not reimbursed by ECHA.

Experts from Industry and Non Governmental Organisations (NGOs) can also participate in the ECHA-NMWG. The selection of ECHA-NMWG Observers will be made between ECHA's Accredited Stakeholders Organisations that expressed their interest to participate at ECHA-NMWG and fulfil the eligibility criteria as defined by ECHA Nanomaterials Working Group Procedure for admission of observers. ECHA foresees a renewal of the expression of interest and appointment of ECHA-NMWG Observers every 2 years. A maximum number of three nominated experts representing Industry and three nominated experts representing NGOs may participate in the ECHA-NMWG. Each of the ECHA-NMWG Observers with a nominated expert at the NMWG may appoint an auxiliary expert.

To ensure consistency of the working Group discussions ECHA-NMWG Observers are appointed for a minimum period of one year. If more than three experts representing Industry and three experts representing NGOs express their interest and fulfill the eligibility criteria, the participation at the ECHA-NMWG meetings will be done on a rotation basis as agreed by the selected ECHA-NMWG Observers. In case of need, ECHA may appoint permanent representatives at the meetings among the representatives of the ECHA-NMWG ASOs who may then act as a contact points 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 Member States, Commission, ECHA, or ECHA-NMWG observers from industry and NGOs.

ECHA will reimburse the travel expenses of one (permanent) expert per Member State Competent Authority and of the three nominated experts from the Non Governmental Organisations.

All meeting participants and members of the group will be bound by a relevant confidentiality declaration to be endorsed prior to their participation in any meeting. ECHA's policy for managing potential conflicts of interest applies to the working group.

3. Organization of the meetings

The ECHA secretariat will provide the chair for the meeting and will also take care of developing and distributing the minutes. Minutes will be distributed to all members of the ECHA-NMWG as well as for information to CARACAL and CASG Nano members and observers and to the MSC and RAC. All ECHA-NMWG Accredited Stakeholder Observers will receive non-confidential versions of meeting documentation.

ECHA-NMWG meetings will be held 2-3 times per year with duration of 1,5 to 2 days per meeting.

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

Based on the confidentiality of the discussed issues, ECHA may decide to have closed sessions restricted to MSCAs and Commission services only.

The mandate and functioning of the expert group shall be reviewed after one year (or after three meetings have been held).

4. Reporting

With the support of the Member State Competent Authorities representatives in the ECHA-NMWG, the ECHA secretariat shall report when appropriate on the work of the ECHA-NMWG to the Member State Committee, Committee for Risk Assessment and directly to the CARACAL meeting.

ECHA-NMWG non-confidential reports and recommendations will also be disseminated on ECHA's website.

This updated ECHA-NMWG mandate replaces the original ECHA-NMWG mandate signed on 12.10.2012.

Done at Helsinki,



Jukka Malm
Deputy Executive Director