MB/66/2013
Helsinki, 18.12.2013

Update of the work plan on nano-materials

Meeting of the Management Board 17-18/12/2013

Item	18
Action	For information
Status	Final - public

Action requested

The Management Board is invited to take note of the attached work plan and provide comments as appropriate.

Background

The updated work plan on nano-materials (NMs) describes the nano-related activities ECHA aims to undertake for the period 2014-2015. In order to ensure the safe use of chemical substances including NM, ECHA will play, within the limits of its mandate, a pro-active and catalyst role in the regulatory debate on NM under REACH and CLP. The document also provides an overview of ECHA's activities on NM for the period 2012-2013.

Activities are being proposed for the coming years in light of ECHA's strategic aims. Specific initiatives will be taken to improve the quality of registration data on NM, support authorities in addressing NM of concern while further addressing scientific and technical challenges and strengthening the capacity of relevant stakeholders in dealing with the safe use of NM.

Matters for consideration

An increase in resource contribution is foreseen in the coming 2 years: in 2014 and 2015, 4.8 and 4 FTE, respectively, will be allocated to address specific nanomaterial related activities. In case the nano-specific provisions will be introduced in the REACH annexes, an additional increase of at least 2 and 2.5 FTE (for 2014 and 2015, respectively) may be needed.

Attachments:

- Updated ECHA Workplan on nano-materials for 2014-2015 (including an report on ECHA activities on nano-materials over 2012-2013)

MB/66/2013
Helsinki, 18.12.2013

Attachment

Updated ECHA Workplan on nano-materials for 2014-2015

1. Introduction

Nanotechnology as key enabling technology is considered as one of the most promising industrial revolutions in chemistry. The rapid increase in the use of nano-materials (NM) in consumer products and industrial manufacturing processes is raising questions about the potential effects on health and the environment and what the risks and benefits are. The overall conclusion so far is that, even though NMs are not dangerous per se (i.e. their hazards and risks are to be addressed case by case), there is still scientific uncertainty with regard to their safety in many aspects. The uncertainty associated to the potential risks of these NM creates new challenges for regulators (Commission and ECHA) as well as all other stakeholders.

REACH and CLP deal with substances, in whatever size, shape or physical state. Under these regulations therefore manufacturers, importers and downstream users have to ensure that their NMs do not adversely affect human health or the environment. [1,2]

Over the last two years (2012-2013), ECHA has increased its activities in this area. For 2014-2015 a further increase in nano-related activities is planned. In order to ensure the safe use of chemical substances including NM, ECHA will play a catalyst and pro-active role in implementing the regulatory actions on NM stemming from REACH and CLP.

ECHA's nano-related activities are being proposed for the next 2 years in line with its four strategic objectives. Section 2 of the current paper provides a more detailed approach on how ECHA will achieve this ambition in the coming years. A brief overview of the major developments and ECHA's contributions in the field of NM covering the period 2012-2013 is provided in section 3 of this document.

The ECHA secretariat wants to draw the attention of the MB to the Commission's on-going impact assessment in relation to REACH annexes for NM[3]. Currently no extra ECHA resources are foreseen to address the potential consequences of such changes in the annexes. Obvious activities that may be affected in case nano-specific requirements would be implemented are:

- Increased activities and discussions at the Nanomaterial Working group
- Updates and changes in the REACH guidance, FAQ, practical guides etc.
- Communication campaigns to Registrants (with specific emphasis on SMEs)
- Support to MSCAs and Commission with scientific and technical advice

In case such changes may materialise ECHA will update its work plan on NM and may need more resources to ensure the implementation of such new legal provisions, which would require a downscaling of other activities.

[1] 'Nanomaterials in REACH'
http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/nanomaterials_en.pdf

[2] 'Classification, labelling and packaging of nanomaterials in REACH and CLP'
http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/nanos_in_reach_and_clp_en.pdf

[3] This impact assessment concerns the relevant regulatory options, in particular for the possible amendments of several Annexes to REACH to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers

2. Overview of ECHA's main nano-related activities for 2014-2015

2.1. Activities in support of Strategic Aim 1 (Maximise the availability of high quality data to enable the safe manufacture and use of chemicals)

2.1.1. Continuation of the ECHA NM working group, informal discussions with registrants and accredited stakeholders

ECHA's Nanomaterial Working Group (NMWG), a group of experts from Member States, the Commission, ECHA and accredited stakeholders (industry and NGOs), was established in 2012 with the mandate to provide informal and non-binding scientific advice on questions related to any aspect concerning NM under REACH and CLP. After one year of activities the usefulness of the working group has been clearly demonstrated (see section 3 of this report) and ECHA intends to further continue the activities of the NMWG. The mandate of the WG will be expanded to support the Biocidal Products Regulation.

Scope of the activity:

The ECHA NMWG foresees the following key activities in 2014-2015:

- Continue to organise NMWG meetings with experts from Member States, the Commission and accredited stakeholders (2 meetings per year)
- Discussion of case-specific challenges emerging from REACH processes (e.g. dossier and substance evaluation cases) as well as scientific and technical discussions on principle issues in relation to NM safety (e.g. Read Across principles).
- Informal discussions with registrants or industry associations on NM dossiers with the involvement of experts from ECHA, Registrants and Member States aiming at understanding the current technical and scientific challenges in these dossiers.
- Informal debates on specific topics related to NM to be discussed with Accredited Stakeholder Organisations, including participating NGOs.

Desired Outcome:

- Within the NMWG mandate: progress on solving key scientific and technical challenges relating to NM under REACH, including substance identification, characterisation, hazard and exposure and risk assessment, and grouping/read across of substances.
- Harmonisation of views among ECHA and experts from Member States on the best scientific approaches towards the evaluation of dossiers/substances containing NM, and resolving case specific challenges in advance of formal processes, such as formal referrals to MSCAs of draft decisions, where possible.

For the informal discussions with industry in the context of the NMWG, the aim is to:

- Improve the quality of data in current NM registration dossiers
- Further improve the existing "best practices" based on knowledge from other substances
- Illustrate ECHA's openness and willingness to engage with Registrants achieving constructive dialogues with the aim to improve overall dossier quality.

2.1.2. Depending on the modification of REACH Annexes for NM: Guidance development, updates and communication on NM

At this moment, it is not possible to anticipate the outcome of the follow-up of the regulatory review of the REACH annexes in relation to NM[4]. Nevertheless, ECHA needs to be prepared to update its guidance documents in response to any such changes. Once the outcome of this review is known, ECHA will assess the current guidance on NM and its adequacy within the new framework provided for in the annexes of the REACH Regulation. Other types of documents such as technical manuals, FAQs or practical guides, might need development or update depending on the extent of the changes in the regulation, experience acquired and the developments (e.g. on applied research or standardization) in the field of nanotechnology. In addition a communication strategy to inform registrants of the implications of the changes to existing and future registrations requirements may become necessary.

In a similar manner, updates of IUCLID manuals specifically for NM may be needed and will be part of the Guidance update following the revision of the REACH annexes for NM envisaged in 2013-2014.

2.1.3. Depending on the modification of REACH Annexes for NM: Targeted Strategic Activities aiming to improve the NM-specific information in REACH registration dossiers

Also in 2014-2015 ECHA will strive to improve the quality of the information on NM characteristics in the current and future registration dossiers submitted to ECHA under the REACH Regulation. The primary focus of attention will be to enhance the clarity, transparency and adequacy of the NM-specific information on substance identity and physico-chemical characteristics for substances that may contain nanoforms. ECHA believes that this is a fundamental element to further improve the hazard and risk assessments of NMs that are registered under REACH.

The timing and exact nature of ECHA's targeted activity on NM will depend on whether and when the REACH Annexes will be modified for NM. In case nano-specific provisions will be introduced in the REACH information requirements, ECHA will use this activity to communicate and disseminate its views on the new obligations for registrants through this targeted campaign. In case no new nano-specific provisions would be introduced, ECHA will need to re-consider the activities described below to most optimally ensure that NM's safe use is addressed under REACH.

In order to use its resources most effectively, ECHA opts to implement a tiered approach: starting with a communication campaign, followed by an update period for registrants and ending with a phase where targeted compliance checks will be initiated on selected substances where the dossiers were not updated. The exact content and timing of the campaign will depend highly on the outcome of the Impact Assessment and REACH Annex revision for NM. Therefore, the periods indicated below are tentative.

A. Communication action

Via a communication campaign after the eventual adoption of new annexes, registrants will be encouraged to update their dossiers with the specific SID and physico-chemical

[4] In particular the outcome of the on-going Impact assessment of the relevant regulatory options for possible amendments of several Annexes to REACH to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers.

(PC) characteristics for NM and or nano-forms. These nano-characteristics will be in line with those indicated in the proposed changes of the REACH Annexes.

This communication action will be specifically targeting the nanomaterial manufacturers and importers using established industry sector organisations that are known to ECHA (i.e. the ECHA NMWG accredited stakeholder observers). The campaign will specify those endpoints to be updated and will encourage the registrants to complement the substance ID with the nano-form specific requirements. The information provided should enable ECHA to verify that nano-forms are within the scope of the registered substance.

ECHA will use the experience generated through the NMWG meetings to guide the development of the request. Via specific communication with such sector associations ECHA will highlight its intention to clarify the physico-chemistry characteristics as a start to create a level-playing field for NM manufacturers and importers in Europe. ECHA will invite companies to pro-actively interact with ECHA experts and update their substance nanoform information. *It needs to be stressed upfront that none of such informal interactions will pre-empt ECHA's right to initiate a compliance check (CCH) on these dossiers.*

The nature of these updates will be mostly reflecting the recommendations that are provided in the IUCLID registration manual of NM (2009) where registrants are asked to report explicitly the (nano)forms as well as the composition they intend to register (IUCLID section 1.1, 1.2 and 1.4). ECHA will recommend and guide registrants through the technicalities of the current IUCLID version for submitting the NM-specific updates.

B. *Update period for registrants*

During the update period, ECHA will provide support to those registrants that wish to update their nanomaterial dossiers and answer incoming questions via ECHA's Helpdesk. A webinar will be organised to specify the technicalities of the updates that ECHA wishes to receive and the ECHA newsletter will be used to further disseminate details of these plans.

In addition, where deemed useful, informal meetings with sector associations may be hosted via Telephone/Video conference, Webex or physical meeting in ECHA premises.

C. *Targeted compliance checks on relevant substances*

The last step in this approach is to initiate targeted compliance checks on dossiers of substances that are known or are suspected to contain nanoform(s) and that have not been updated according to ECHA's advice and the (presumed) new legal information requirements provided for in the annexes of the REACH Regulation. Through this mechanism, ECHA will combine its 'soft measures' with a direct regulatory action where needed. A possible targeted manner to address NM specific characteristics is to develop a customized intelligent IT-based CCH approach for dossiers with nanoforms.

Overall this tiered approach fits well with ECHA's communication on NM challenges in the past where ECHA has actively invited Registrants to contact ECHA in case they would face practical challenges when registering NM and/or nanoforms. The main message has been to avoid the formal process of dealing with CCH-Draft Decisions but to update pro-actively.

In case the Commission will not update the annexes of REACH in 2014, ECHA may nevertheless further 'tighten the net' and gradually address the dossiers of those

substances that matter most to be evaluated via CCH. At first ECHA will focus on substance identity and physico-chemistry. After having these characteristics clarified, ECHA would better judge and select in which cases it can request via CCH decision potential missing hazard, exposure and risk assessments of NM to ensure its safe use in a later stage. When concern is obvious, either CCH or substance evaluation should be undertaken without delay.

Overall ECHA would prefer the phased approach as this would:

- increase the transparency of the scope of the registration dossiers related to nanoforms.
- generate a cascade effect in the sector: either sector-wide or via individual companies these updates may show that it is possible to characterise and document nano-characteristics.
- In line with ECHA's SME ambassador role, communication can be customised to SMEs who are struggling to meet their (nano) information requirements.
- Optimise its resources: dossier improvements are not necessarily obtained via CCH only; a (partial) voluntary response is possible to achieve significant breakthrough. If needed the CCH approach is the 'stick' approach that can be deployed where appropriate.
- Other formal processes (e.g. Art 36 letters) will be deployed via targeted actions.

2.1.4. Provide relevant support in the context of the regulatory impact assessment of changes in the REACH Annexes, and the scheduled review of the EU recommendation on the definition of NM

The Commission has committed to the European Parliament that an impact assessment of the relevant regulatory options for possible amendments of several annexes to the REACH Regulation to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossierswill be performed. In addition, a review of the EU recommendation for the definition of NM by the Commission is required by December 2014. ECHA has provided expert support to Commission services during the on-going impact assessment in order to improve understanding of consequences of possible changes in the annexes of the REACH Regulation. ECHA acts as a supportive partner in these consultation processes based on its experience in the implementation of REACH in its current format. ECHA foresees that once the revisions have been agreed, Guidance will need to be updated/developed and existing (practical) guides and technical manuals updated.

One additional activity in this context is ECHA's involvement in a new contract that DG ENTR wishes to start with DG JRC in relation to QSARs and read-across for NMs. ECHA will be asked to be part of the steering committee of this project.

2.2. Activities in support of Strategic Aim 2 (Mobilise authorities to use data intelligently to identify and address chemicals of concern).

2.2.1. Provide relevant support to MSCAs in the context of the REACH risk management processes and Biocidal products regulation

Although currently no Annex XV dossiers are being submitted, ECHA will be preparing itself to receive potential Annex XV dossiers (for example on request from the Commission) for possible risk management actions. Furthermore ECHA will further

support the nano-specific aspects that are relevant for the implementation of the Biocidal Products Regulation.

2.2.2. Participate and contribute to on-going international regulatory activities

A. On-going OECD Activities

OECD will continue to play an important role as a unique forum where policy makers, in co-operation with stakeholders work together to address potential risks of NMs. ECHA's involvement in the two working parties (WPs), WPMN (Working Party on Manufactured NM) and WPN (Working Party on Nanotechnology, is important from many aspects, such as gaining a political awareness at a global level and the opportunity to share its expertise and knowledge from assessing NMs under REACH. This knowhow is sought after and there is a political pressure on ECHA to increase its involvement. More importantly, there is a need to ensure that any guideline is compatible with REACH. ECHA will be chairing the Steering group for test methods in its new format.

B. On-going CEN activities

The European Committee for Standardisation (CEN) in cooperation with ISO will develop new technical specifications and standards relevant for nanotechnologies according to "*Mandate M/461 - Standardisation Mandate to CEN, CENELEC and ETSI for standardisation activities regarding nanotechnologies and NM*". ECHA will follow the work of the relevant CEN technical committee as the specifications/standards to be developed are very relevant for REACH implementation.

2.3. Activities in support of Strategic Aim 3 (Address scientific challenges by serving as a hub for building the scientific and regulatory capacity of Member States, European institutions and other actors). Establishing ECHA as hub for regulatory scientific support on NM

2.3.1. Strengthening scientific capacity

ECHA will aim to maintain and further develop its internal scientific capacity on NM by providing targeted training towards selected scientific competencies in this field. In order to keep up with recent scientific developments in this area, ECHA will organise lectures and seminars for its scientific staff.

A. Interaction with FP7 projects

Furthermore ECHA will continue to participate in international meetings and conferences to follow the core scientific developments in relation to regulatory safety assessment of NM. It will also participate in international meetings and conferences organised in selected Seventh Framework Programme projects (FP 7) relevant for ECHA's work on NM as these may have an important impact on development of harmonised methods for characterisation of NM within a regulatory context. Currently a number of relevant FP7 projects on NM were selected based on their potential contributions to ECHA's regulatory challenges: NanoREG and Marina, for which ECHA is part of their advisory board, and also NanoSolution, REACHnano and Nanomicex, for which ECHA will follow their developments by participating to their annual meetings and conferences. The objective of ECHA participation in these projects is to promote the regulatory relevance of their outcome and to shorten the time "from scientific innovation to regulatory application".

B. Participation in (the flagship) FP7 project NANOREG

NanoREG is aiming at developing a common European approach to the regulatory testing of NM. The preparation of the project was initiated already three years ago by a number of Member States with the Netherlands in the lead. The ambition of NanoREG was to accelerate the development of answers to the questions posed by policy makers about the applicability of the existing legal framework and risk assessment paradigm, to NM. The project has remained in the hand of Member States but since then, numerous industrial partners have joined. Total funding amounts up to 50 Mio Euro.

ECHA believes that this project will bring considerable added value to the current know-how on NMs both in terms of regulatory as well as scientific output. Therefore it intends to play an active role in this project in order to steer it but also to make sure that adequate results are delivered.

First steps in getting involved in the project have already been undertaken. ECHA will take part in the Regulatory Advisory Committee and contribute as a facilitator in the project to ensure that the outcome has the desired regulatory relevance. Through the participation, ECHA will maintain and further develop its in-house scientific expertise on NM hazards, exposure, and risk assessment whilst sharing its knowhow in the context of implementation of REACH. In addition, ECHA may play a key role in ensuring that regulatory needs are well communicated and this highly funded project delivers adequate results.

2.3.2. Scientific workshop on NM in support of regulatory processes

Through a scientific workshop ECHA will foster a better cross-fertilisation of ideas between the on-going rapid scientific developments in the field of NM and the regulatory day-to-day reality. The main focus of attention will be to support REACH implementation for NM, but it will also involve experiences gained from other regulations (e.g. Biocides, Medical devices, Food Regulation). Such scientific workshop on NM in support of regulatory processes is foreseen in Q4 of 2014.

The aim of the workshop will be to promote common understanding on the major themes related to NM risk assessments: 1) particle characterisation; 2) hazard characterisation; 3) exposure assessments; 4) read across and QSARs. For these themes ECHA will invite scientific experts primarily but not exclusively from on-going Seventh Framework Program projects on NM safety. The main aim of this workshop is to address the key regulatory questions and challenges among REACH and CLP regulatory experts, academia and scientific societies.

The workshop will convene various experts together and offer meeting and discussion opportunities to harmonise scientific understanding and views on how to further drive the boundaries of current risk assessment paradigms in the regulatory context of REACH and CLP. This will result in an overall better understanding and appreciation of the current scientific challenges in this domain. It will help to further develop updated scientific principles for assessing the risks of NM and facilitate the development of improved approaches which ECHA may apply in the implementation of REACH and CLP.

2.4. Overall resource estimation

It is important to note that no resources are yet foreseen to address the consequences of potential changes in the REACH Annexes for NM.

Coordination of overall activities related to NM across the Agency activities requires on average 0.5 FTE on annual basis.

Table 1 below provides an overview of the resource needs to complete the activities presented above. Overall for 2014-2015 a total of 4 FTE per year will at least be needed, which is almost double compared to the resources spent in 2012-2013 nanomaterial workplan (2.5 FTEs on an annual basis). Currently there is uncertainty on the actual need to provide guidance updates. This will largely depend on the revisions of the REACH Annexes, the timing of the legislative adoption of these changes and the extent of the changes. Therefore, these resources are currently flagged as uncertain.

If ECHA wants to become a key-player and leader in this regulatory debate, it will have to dedicate the appropriate resources to achieve these aims under realistic and feasible working conditions for its staff.

Table 1. Resource needs for TFNM activities in 2014-2015

Activity	**FTE (2014)**	**FTE (2015)**
Strategic aim 1		
Continuation of the ECHA NM working group, informal discussions with registrants and accredited stakeholders	1	1
Guidance development and updates for NM	0 (*0.5*)[5]	0 (*1*)[3]
Targeted Strategic Activities aiming to improve the NM-specific information in REACH registration dossiers	0.5 (*1.5*)[3]	0.5 (*1.5*)[3]
Strategic aim 2		
Provide relevant support in context of regulatory impact assessment of changes in REACH Annexes, and scheduled review of EU recommendation on definition of NM	0.5	0.5
Participate and contribute to on-going international regulatory activities (Potential OECD Co-chair tasks ***not*** *included)*	0.5	0.5
Strategic aim 3		
Strengthening scientific capacity	0.2	0.2
Interaction with FP7 projects	0.8	0.8
Scientific workshop on NM in support of regulatory processes	0.8	/
Coordination	0.5	0.5
Total FTE	**4.8** ***(6.3)***[3]	**4** ***(6)***[3]

[5] If REACH annexes are changed with specific information requirements for NM

3. Report on ECHA activities on nano-materials over 2012-2013

The workplan for ECHA Taskforce on NM (TFNM) was structured on four pillars representing a number of key priorities that ECHA intended to pursue over the period of 2 years covered by the plan. The key achievements of these pillars are presented below.

3.1. Pillar 1: Internal and external capacity building

During 2012-2013 ECHA planned and organised extensive training for staff in the field of NM for staff with a scientific background. The training has been focused on two foundation courses on scientific and regulatory aspects on the hazards, exposure and risk assessment of NM (environment and human health). In addition, specialised training sessions focusing on the latest developments in the science and regulatory aspects were organised to provide a deeper understanding of issues related to regulating NM under the current regulatory framework.

ECHA organised a series of meetings with the Finnish Institute of Occupational Health (FIOH) where scientific and regulatory challenges of NM were discussed. Topics were related to immunotoxicty, genotoxicity, occupational and consumer exposure limits for NM and the latest developments in workplace exposure measurements.

The TFNM also interacted with five FP7 research projects, in order to follow on the most recent developments in the research on nanomaterials. Furthermore, ECHA considered more active participation in the NANOREG project ("A common European approach to the regulatory testing of NM"). The aim of this project is to prepare a global health and safety strategy for NM and build upon the lessons learnt from other FP7 nano safety projects.

ECHA launched a webpage dedicated to NM[6] with the aim to provide support for registrants who wish to register their NM (e.g. at the 2013 registration deadline) and to increase external visibility of ECHA's activities on NM. ECHA's NM webpage was launched in October 2012 and since then it has sustained approximately 40-60 views per day.

ECHA initiated a closer interaction with JRC on NMs in the context of capacity building. One member of NMTF received hands-on training on measurement methods for nanomaterials at the JRC premises in Geel in 2012. In 2013, a JRC expert was invited to ECHA to give a lecture on measurement methods for NMs within the scope of the EU definition. Further strengthening of cooperation with JRC on NM is under consideration.

3.2. Pillar 2: Share experience with and generate consensus among MSCA, MSC and RAC members on safety information on NM in REACH registration dossiers

3.2.1. GAARN (Group Assessing Already Registered NM)

The purpose of the Group Assessing Already Registered NM (GAARN) was to build a consensus in an informal setting on best practices in assessing and managing the safety of NM under the REACH Regulation. The GAARN working group was led by ECHA and consisted of representatives from ECHA, Commission (DG ENTR and DG ENV), MSCAs, Cefic, Eurometaux and three lead registrants (LRs).

[6] http://echa.europa.eu/regulations/nanomaterials.

Three meetings were foreseen and took place during 2012-2013. The outcome of these meetings was developing recommendations ("Best practices reports") on how to fill potential information gaps. These reports were published on the NM webpage on ECHA website and may be used as a practical guide by industry stakeholders who struggle in documenting the safe use of their nanoforms.

3.2.2. ECHA – NM Working Group (NMWG)

ECHA-NMWG was founded as an informal advisory group consisting of experts from Member States, Commission, ECHA and eligible accredited stakeholders' organisations (ASOs). Its purpose is to discuss scientific and technical questions relevant to REACH and CLP processes dealing with NM and provide recommendations on strategic issues. It does not interfere with any formal REACH processes.

The kick-off meeting of the NMWG took place in 2012 and two regular meetings were held in 2013 while one more meeting took place via WebEx. Among the topics covered in the meetings were: recent findings and developments on the area of NM characterisation related to the nanomaterial definition, read across and grouping of NM, scientific discussion on organic NM and physico-chemical characterisation of NM. Through breakout groups and case studies further progress was made in understanding these topics. Future meetings will continue the discussions in relation to read across for NM, characterisation of NM and will address other specific challenges e.g. environmental risk assessment for NM.

3.2.3. Nanosupport project

The overall objective of the NANOSUPPORT project was to make an assessment of information on NM available in REACH registration dossiers, to conclude on the adequacy of REACH requirements for NM and to make proposals for amendments to REACH where appropriate. ECHA worked together with JRC in this project. ECHA provided substantial contribution in the overall work for Task 1 especially in identifying the 21 key deficiencies in terms of the adequacy of the information included in 25 of the registration dossiers assessed. Following the project, ECHA provided the Commission with a baseline for reviewing of REACH in relation to NMs. Subsequently, the Commission launched a public consultation in September 2013 for revision of REACH to address the 21 deficiencies noted in the project.

3.2.4. Article 36 decisions

ECHA sent 166 'Article 36' decisions on two NM (carbon black, synthetic amorphous silica) in 2012 in order to request clarification on the scope of the registration, i.e. whether it covers NMs or not and to specify the characteristics of the included nano-forms. In addition, ECHA made preparations for the enforcement for registrants who did not reply to the decisions. The cases were presented to the Forum, and ECHA received a positive response from the Forum on its request to enforce these decisions. Currently the enforcement requests are under drafting.

3.3. Pillar 3: Feedback and advice to registrants updating existing dossiers and new registrants who wish to register NM

During 2012 and 2013 guidance regarding NM has been issued as Appendices to several chapters of ECHA "Guidance on information requirements and chemical safety assessment". In addition, a corrigendum was issued to eight parts and chapters of the

ECHA Guidance on IR & CSA. In addition, IUCLID 5.4, released in 2013, provides new features to help registering nano materials.

Furthermore, 2012-2013 ECHA organized two webinars on REACH and CLP processes related to NM, The first one focused on “Characterisation of nanoforms of substances in registration dossiers”. The topic of the second one was “Human health and environmental hazard assessment for NM”.

3.4. Pillar 4: Participate and contribute to on-going international regulatory activities

ECHA participated in the CASG-Nano meetings during 2012-2013. ECHA contributed to these meetings by sharing overviews with CASG-Nano members on its on-going activities as well as by providing its experiences on NM aspects and REACH registration dossiers.

ECHA also continued to follow the OECD work on NMs. The main focus of ECHA’s contribution has been in the Steering Groups of the WPMN (Working Party on Manufactured NM) where concrete proposals in the context of risk assessment of NMs are being discussed. ECHA also participated in several horizontal expert workshops organised in the frame of WPMN.

The European Food Safety Authority (EFSA) visited ECHA on 29 June 2012. During EFSA’s visit to ECHA, a generic overview on ECHA TFNM activities on NM was presented and first contacts with the EFSA units dealing with NM were established.