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Update of the Workplan on Nanomaterials

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Action	For information
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Key messages

With this updated Workplan for Nanomaterials for years 2016-2018 ECHA continues implementing the legislation to nanomaterials despite the legal uncertainties and lack of progress in the revision of REACH Annexes. The main elements of the plan are

- clarification of ECHA guidance for nanomaterials
- promote improvement of data quality for nanomaterials to ensure their safe use
- identify and address nanomaterials of concern
- ensure synergies via international activities and links with research projects
- contribute to transparency about nanomaterials on the market

ECHA plans to maintain the current level of resource allocation to support the implementation of the workplan, i.e. annually 4-5 FTEs (excluding operational dossier specific work).

Background

Annex 1 contains the ECHA work plan for Nanomaterials for the period 2016-2018. The work plan is a cross-cutting outline for activities addressing various aspects of nanomaterial related work in ECHA Secretariat. In Multi-annual and annual work programmes the specific activities appear under their respective headings (e.g. registration, evaluation, risk management).

The previous ECHA workplan for nanomaterials for years 2014-2015 was introduced to the Management Board in December 2013. A short summary of main deliverables is presented as Annex 3 to this document.

Rationale

Nanomaterials remain a strategically important issue for the successful implementation of REACH. Apart from being of policy and regulatory importance nanomaterials should not only be seen as an isolated issue and different from other categories of substances. In many cases, the impacts of decisions relating to nanomaterials have a direct influence over many other substances; e.g. particulate substances, substances with impurities, forms of substances and UVCBs. This is an important realisation to understand why ECHA keeps the topic high on its agenda.

ECHA continues to implement the opinion shared by the European Commission and MSCA's, that even without explicit provisions on nanomaterials in REACH the Regulation and its provisions also cover substances in nanoform[1]. This implementation is a combination of various elements and activities, as with any other group of substances, consisting especially of

[1] As part of the (bulk) substance registered, or as a separate substance.

- advice and assistance to registrants, with a view to complete any new guidance and tools by June 2016 to assist industry preparations for the 2018 registration deadline
- promoting improvement of data quality for nanomaterials to ensure their safe use; including carrying out compliance checks in line with the principles of ECHA's compliance check strategy, complemented by 'soft measures' (communication, letter campaigns) where appropriate
- identifying and addressing nanomaterials of concern; including continued cooperation with MSCA's under substance evaluation, and preparing for receiving and handling any nanomaterial specific dossiers under risk management processes (in particular harmonised classification and labelling)
- continued and focused contributions to international activities, especially via the OECD and UNGHS, and keeping abreast of main developments in regulatory science
- transparency measures about nanomaterials on the market, their hazards and risks, via ECHA's website and upgraded dissemination portal.

ECHA continues cooperating with Commission, Member States and stakeholders in the implementation of above, and will especially use its informal Nanomaterial Working Group as a sounding board to this end. ECHA plans to maintain the current level of resource allocation to support the implementation of the workplan, i.e. annually 4-5 FTEs (excl. dossier specific operation work, e.g. dossier evaluation).

Overall with the above ECHA aims to contribute to the successful implementation of its strategic objectives, covering in an integrated way improvement of data quality submitted by industry, addressing substances of concern, and regulatory science activities.

Alternative options

This workplan is based on the assumption that the Commission will not be able to come forward with a proposal for changing the REACH annexes in time to enable ECHA to proceed with the guidance update before the guidance moratorium kicks in. Should that happen still this year, this workplan needs to be reviewed, and resources added to enable the guidance update as soon as possible.

Considering the legal uncertainties an option for ECHA could be to not carry out any compliance checks before the final conclusion on changing (or not) the REACH Annexes, and/or before the Board of Appeal has concluded on the nanomaterial related appeals .In this case, it may also be possible to focus the workplan on how to best support registrants by developing future methodology and guidance and thereby reducing the overall resources until the Commission has modified the annexes of the REACH Regulation.

Drawbacks

Clearly the current uncertainty caused by lack of explicit requirements for substances in nanoform is causing additional complications and work for ECHA and the registrants. However, the proposed activity is in line with the MAWP, and may also facilitate clarifying the uncertainties. Furthermore, the proposed work plan will support and reward the efforts of the diligent registrant, with the opposite effect to those who choose not to specifically demonstrate the safety of their substances marketed in nanoform.

Attachments:

- Annex 1: ECHA Workplan for Nanomaterials 2016-2018
- Annex 2: Indicative timeline of actions
- Annex 3: Summary report on the implementation of ECHA Workplan for Nanomaterials 2014-2015

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MB/41/2015 final
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Annex 1

ECHA Workplan for Nanomaterials 2016-2018

Introduction

This document outlines a cross-activity three-year Workplan for ECHA Secretariat relating to Nanomaterials (NM). The Workplan aims to showcase a consistently proactive ECHA in implementing REACH, CLP and BPR for nanomaterials in line with existing expectations from Member States and stakeholders. This is in line with the Commission statement in their communication on the second regulatory review on nanomaterials: "REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures".

Nanomaterials remain a strategically important issue for the successful implementation of REACH. Apart from being a group of policy and regulatory importance nanomaterials should not only be seen as an isolated issue and different from other categories of substances. In many cases, the impacts of decisions relating to nanomaterials have a direct influence over many other substances; e.g. particulate substances, substances with impurities, forms of substances and UVCBs. This is an important realisation to understand why ECHA keeps the topic high on its agenda.

However, there are major uncertainties that need to be taken into account:

1) Over the past three years, the discussions on how to amend the REACH Annexes to ensure a proper applicability for nanomaterials have continued at European Commission level. The delay in coming forward with a proposal has given room for legal uncertainties that in particular has manifested itself in an increase in appeals on both compliance check and substance evaluation decisions. Apart from one, all types of ECHA's evaluation decisions addressing nanomaterials issued so far have been appealed to the Board of Appeal. Beyond the uncertainty this leads to it is also causing further delays and demanding additional resources from both industry as well as ECHA to tackle the process.

2) A fundamental cornerstone in the context of risk assessment of nanomaterials, the EU Recommendation for a Definition of Nanomaterials, is still lacking guidance for industry to promote a consistent determination if a certain material falls within or outside its scope. As an additional complicating factor the definition is subject to a review by the Commission, aiming at assessing if the criteria used in the definition needs to be changed. In the wait for the Commission's conclusion of the review, the issue of the relevance of the current recommended definition has added further uncertainty.

3) The preparation by the Commission on transparency measures regarding nanomaterials on the EU market have not been completed, and it remains open which role ECHA may be expected to play in this regard.

However, even given all uncertainties, several Member States together with the Commission have requested ECHA to "move ahead" with improving its guidance and other measures to help industry to comply.

Taking into account the above this three year Workplan proposes to continue ECHA's specific activities addressing nanomaterials and to strengthen the existing synergies between operational work streams to not only ensure consistency but also a smarter use of resources.

1. Clarify aspects of existing guidance

Using the experience gained through operational work such as compliance checks as well as advancement in science over the past years, an initial assessment and identification has been made of which aspects of the existing guidance may be clarified under the current legal text.

ECHA intends to launch the guidance consultation procedures on several issues related to nanomaterials ahead of the guidance moratorium in mid-2016. Foreseen issues may include e.g. clarification on how to use read-across between nanoforms to fill data gaps, how to distinguish one nanoform from another, how to appropriately address nanomaterials under the existing information requirements, and how to properly cover exposure estimation and worker protection.

Once these guidance updates are finalized, an information outreach through webinar and other necessary channels will ensure that the changes are well communicated and give registrants an opportunity to understand what is expected of them in the preparation of their registration dossiers.

This activity is based on the anticipation that an agreement on the REACH Annexes will not be reached in time to allow ECHA to update the existing guidance ahead of the guidance standstill mid-2016. However, if an agreement is reached and the technical annexes are revised accordingly, this workplan may need to be updated, also taking into account the entry into force date of the provisions in the revised annexes.

2. Improve the quality of the data to enable safe use and manufacture of nanomaterials

In line with the existing Compliance Check Strategy, ECHA will continue to address incompliances in dossiers containing nanoforms when these are found to meet the agreed criteria.

Over the past two years, ECHA has prepared a number of compliance check decisions on nanomaterials. These decisions are in different stages of the evaluation process, and some have already reached the final decision stage. As a result, ECHA has also received a total of five appeals against ECHA evaluation decisions on nanomaterials (one case in Q4 2014, four cases in Q2 2015). These appeals have challenged ECHA's legal grounds for requesting information on nanomaterials, in the absence of any provisions on nanomaterials in the REACH Regulation.

ECHA will analyse the outcome of the appeals, and conclude whether there is any need to alter its approach to assessing nanomaterials. Defending the ECHA decisions in the appeals procedure requires significant resources from both legal and scientific experts.

ECHA believes that the foreseen work in updating specific aspects of the existing guidance will facilitate a common understanding among Member States and Stakeholders on what is expected by registrant to comply with the obligations in REACH.

Upon the completion of this planned work, ECHA will be able to more effectively prioritise dossiers containing nanoforms to assess whether the commonly agreed guidance has been taken on board in the dossiers and in registrants' safety assessments. Compliance checks on nanomaterials included in CoRAP will continue and will be an important aspect also for the guidance developments.

Depending on how the above aspects evolve additional dossiers can be selected in line with ECHA's compliance check strategy, and utilizing existing information sources on what nanomaterials are placed on market in the EU. Evaluation activities may be complemented with the use of the complementary measures, such as letter campaigns targeted to the registrants of nanomaterials.

3. Working together with Member States and Stakeholder to identify and address nanomaterials of concern

A number of Member States have initiated substance evaluation activities on nanomaterials. The first final substance evaluation decision for a nanomaterial, Silicon Dioxide, was completed in Q1 2015, and has been appealed by two groups of Registrants.

The following nanomaterials are included on the current Community Rolling Action Plan (CoRAP);

- Silver 2014 – The Netherlands
- Titanium Dioxide 2015 – France
- Zinc Oxide 2016 – Germany
- Cerium Oxide 2017 – Germany
- MWCNT 2017 – Germany

In addition, there are currently indications by several Member States of additional nanomaterial entries into CoRAP for the year 2018.

The increased interest in nanomaterials at Member States is also evident in relation to preparing dossiers for the harmonised classification and labelling (CLH) of nanomaterials. This indicates a need for an incorporation of risk management approaches into the internal discussion to ensure consistency in the decision making process. Such a holistic approach may also provide a better support mechanism to Member States.

4. Promote synergies via international activities and links with research projects

ECHA's involvement in the work at OECD in relation to nanomaterials is important from many aspects;

- It provides ECHA with awareness of regulatory aspects related to nanomaterials at international level
- It gives an opportunity to share our expertise and knowledge but also to understand better potential differences and learn from other regions
- It provides a platform aiming at ensuring technical convergence of the output with existing legal frameworks in the EU, especially with regard to test guidelines and guidance documents

ECHA is currently focusing its OECD activities in chairing the Steering Group for Testing and Assessment (SG-TA) under the Working Party on Manufactured Nanomaterials. This role has given ECHA recognition as one of the leaders in the work area and an opportunity to influence the work towards a better applicability of the output in the regulatory context of the EU. Within its remit of work, The Steering Group oversees the revision of existing, development of new *in vivo* and *in vitro* test methods for hazard assessment of nanomaterials. The importance of input to these revisions has increased in the absence of revised REACH Annexes.

Another important output from the work at OECD level is the dissemination of the data from the OECD sponsorship/testing Program where 59 endpoints have been addressed for 13 nanomaterials over a period of 6 years. This unprecedented volume of nano-specific information will also form a significant contribution by increasing the publically available hazard data and indirectly enhance the transparency of the potential risk of nanomaterials on the global market. The next step will be at international level assessing this data from a relevance and quality perspective to maximize its use for regulatory purposes.

The UN also started a review in 2014 of the criteria underpinning the Globally Harmonised

System (GHS) to assess their applicability to nanomaterials. Several EU Member States are heavily involved in the collection and analysis of data, mainly from the OECD Sponsorship program. This work is scheduled to be completed by the end of 2016. It is intended that any resulting changes to the GHS which are implemented in the CLP Regulation will lead to its enhanced applicability to the classification, labelling and packaging of nanomaterials. ECHA participates in this work in close cooperation with the Commission.

The launch of the new science strategy triggered the assessment of ECHA's interaction with the nanomaterial-related FP7 projects and the setting of priorities for future involvement. As a result, ECHA has re-structured its work related to the FP7 projects and has generally given lower priority to be able to allocate resources to higher priority areas from regulatory perspective. Although monitoring of ongoing scientific research projects will continue in the field of nanomaterials as for chemicals in general involvement will be limited to NanoREG. This project is closely linked to the regulatory challenges in implementing existing legislation for nanomaterials with a steer on answer a number of questions posed by regulators themselves.

5. Improving the transparency around the risk and safe use of nanomaterials

ECHA's main channel of communication around nanomaterials to external audiences such as the general public, industry, NGOs and policy makers is through the ECHA web pages, including both the general explanations and the substance specific information through the dissemination portal. The increasing expectations for transparency and the new dissemination interface which is to be launched next year have created an opportunity to investigate how ECHA can improve its external communication.

The Commission is currently considering what transparency measures to put in place to improve the EU-wide information on nanomaterials. It is in ECHA's strategic interest as a leader in the dissemination of information around the risk and safe use of chemicals to be part of these discussions at Commission level. ECHA is well placed to build on existing tools and knowledge, and to provide synergies through contributions to the implementation of any new initiatives. This should therefore be further elaborated on, once the outcome of the current preparation by the Commission has been finalized.

6. NMWG as a sounding board

It is expected that the ECHA Nanomaterials Working Group (NMWG) will have an increased importance to support the implementation of this Workplan and in particular to ensure that the preparations for the updates of guidance can consider the views of Member States and stakeholders at an early stage even before the initiation of the Partner Expert Group (PEG) is formed. Therefore, the NMWG will continue its role as a unique sounding board for ECHA in the field of regulatory science and implementation of REACH, CLP and BPR regarding nanomaterials. Two meetings of the NMWG are organized every year, with participation of 35-40 external representatives from MSCAs, Commission DGs (ENV, GROW, JRC), NGOs and Industry associations.

7. Resources

ECHA Secretariat plans to continue to allocate the same amount of resources to the implementation of this workplan as previously. The main variable is if the REACH annexes will be revised in which case additional guidance and resources will be needed. The figures in the table do not include resources for the operational dossier specific work (such as compliance checks).

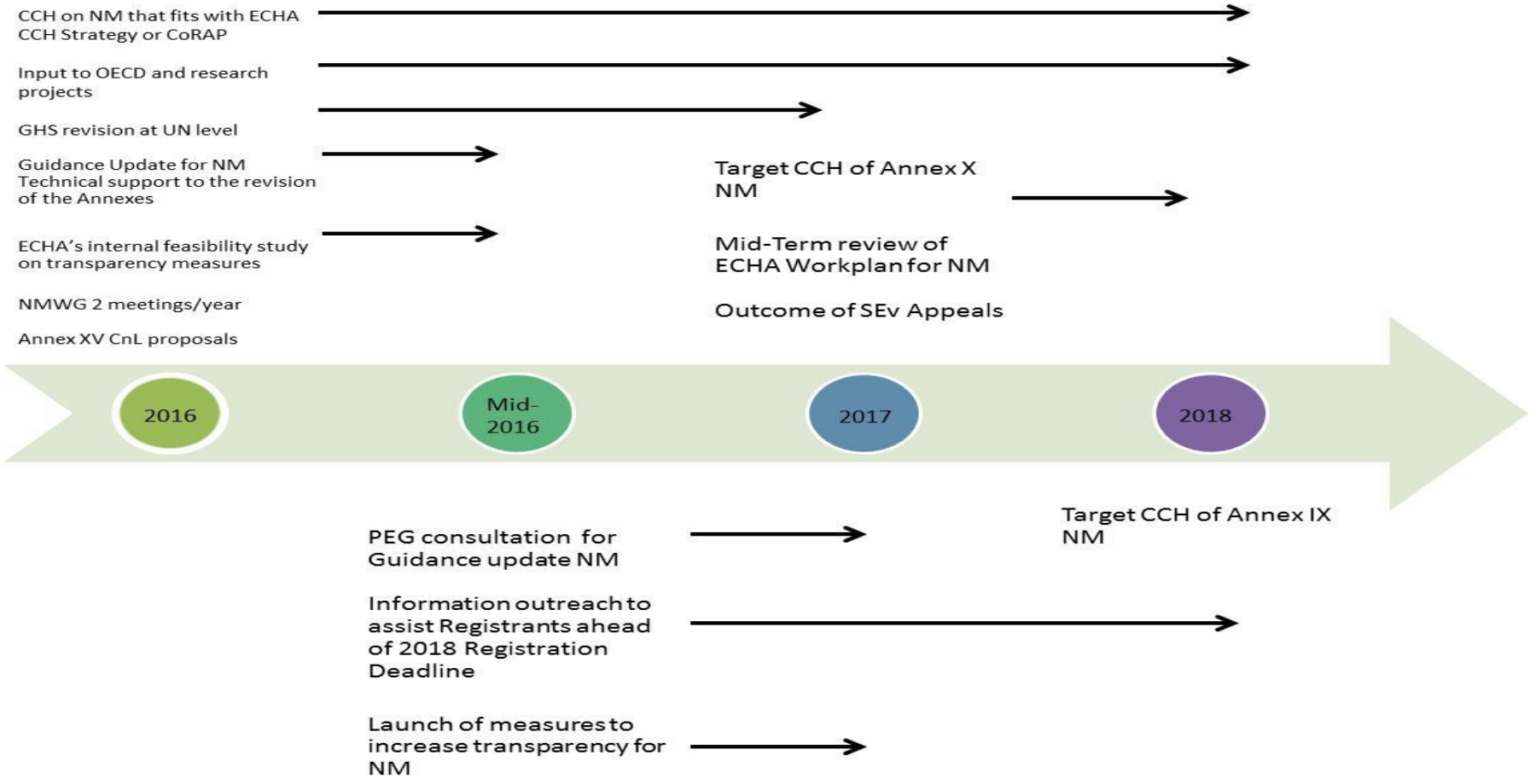
Table 1. Resource needs for2016-2018

Variables	**FTE (2016)**	**FTE (2017)**	**FTE (2018)**
REACH annexes revised in 2016 requiring further guidance updates in accordance with entry into force date	5	4.5	3.5
No change to the legal text	4	4	3.5

MB/41/2015 final
Luxembourg, 25.9.2015

Annex 2

Indicative timeline of actions



MB/41/2015 final
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Annex 3

Report on the implementation of ECHA's Workplan for Nanomaterials 2014-2015

Introduction

This report provides a short overview of the successful implementation of the former ECHA Workplan for the work on nanomaterials for 2014-2015. Throughout the two years, the progress on the issues outline in the Workplan has been regularly reported to the Management Board. It is not the purpose to repeat those updates here but to give a more general view on what has been achieved over the two last years.

Specific deliverables

1. Internal capacity building
    - ✓ Several trainings very organised addressing specific scientific/regulatory aspects
2. External outreach to improve communication to registrants and the general public
    - ✓ Topical Scientific Workshop in Oct 2014 especially addressing interface of nanomaterials research and regulation
    - ✓ Improvements of the external webpages related to nanomaterials, including extension of the pages to cover Biocidal Products Regulation
    - ✓ Bilateral meetings with industry to inform potential registrants of ECHA activities and guidance
    - ✓ Finalising best practices as concrete outcomes from the GAARN discussions
    - ✓ Webinar introducing to the registrants the practical guide based on results of GAARN
3. Activities to improve data quality in industry dossiers
    - ✓ 14 compliance check decisions completed covering 8 different substances in nanoform
    - ✓ Continuation of Nanomaterials Working Group (NMWG) with two annual meetings
    - ✓ Contributions to the JRC led NanoSupport Project
    - ✓ Technical support and input to the Commission on the revision of the REACH Annexes for nanomaterials
    - ✓ Active member of CASG Nano
4. International collaboration
    - ✓ Since the end of 2013 ECHA has hold the chair position for the most prominent Steering Group under OECD Working Party on Manufactured Nanomaterials (WPMN) overseeing the development and revision of the existing test guidelines.
    - ✓ Continue to follow discussions at both ISO/CEN and UN level addressing specificities of risk assessment of nanomaterials

Issues identified

Guidance development was put on hold during 2014 as a response to the ongoing discussions on amending the technical annexes for nanomaterials. It was decided towards the end of 2014 that this delay was no longer a feasible option due to political pressure and time restriction to meet the standstill for guidance developments ahead of 2018 registration deadline. In the early 2015 it was therefore decided to select which guidance may benefit from an update independent of the changes in the annexes. Such changes would instead be based on scientific developments and ECHA's own experience from the operational work.

For this reasons, the proactive strategic communication plan directed to registrants, as outline in the Workplan, was also put on hold until a guidance update has been made. This decision was deemed to ensure a more effective outcome where further clarifications will be available in the guidance on what is expected from the registrants to comply with REACH.

The delay of the agreement on the changes of the technical annexes also had an effect of the resources used which ended up less than expected. This reduction has also to do with the implementation of the Science Board which has centralised the work around regulatory science in ECHA and offered a more effective steer and careful prioritisation of ECHA's involvement in FP7 projects.

In conclusion, ECHA's Workplan for Nanomaterials 2014-2015 was successfully executed within the remit of the areas within the organisation's control.

Resources used

Due to delay in the agreement of the technical changes in the REACH Annexes, the resources used have been lower than forecasted. For 2014, ECHA's nanomaterial activities mounted at 3 FTEs against 4.8 that was estimated and similar situation can be seen for Q1 and Q2 2015 where 1.4 FTE was spent compared to 2.4 FTEs reserved. These resource estimates do not take into account dossier specific operational work e.g. on dossier or substance evaluation.