European Commission

ROADMAP

Roadmaps aim to inform citizens and stakeholders about the Commission's work to allow them to provide feedback and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to share any relevant information that they may have.

TITLE OF THE INITIATIVE	REVIEW AND POTENTIAL REVISION OF THE EU RECOMMENDATION ON THE DEFINITION OF NANOMATERIAL (NO 2011/696)
LEAD DG – RESPONSIBLE UNIT	ENV- UNIT B2
LIKELY TYPE OF INITIATIVE	Revision of Commission recommendation
INDICATIVE PLANNING	Q1 2018
ADDITIONAL INFORMATION	http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm

This Roadmap is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Roadmap, including its timing, are subject to change.

A. Context, problem definition and subsidiarity check

Context [max 10 lines]

Context and basic terms: nanotechnology, nanomaterial and nanomaterial definition

Nanotechnology is a key enabling technology (KET), providing the basis for further innovation and new products (https://ec.europa.eu/programmes/horizon2020/en/area/key-enabling-technologies). Nanotechnology employs nanomaterials – materials manipulated at very small scale that have new or enhanced properties compared to the same material at bigger scale. Some nanomaterials, compared to any other material or product even when made of the same chemical, may have different (positive or negative) environmental impacts or interact with the biosphere in a specific way, e.g., reaching different cells and organs. The area of nanomaterials is developing very dynamically with rapid progress in technology, new materials and information generated in need to be assessed under different regulatory schemes. Specific regulatory provisions targeting nanomaterials therefore appear inevitable.

The Commission Recommendation on the definition of nanomaterial 2011/696/EU provides a common reference to which different regulations are expected to refer to, providing consistency and coherent implementation across different regulatory domains. The Recommendation foresees a review[1] of the definition three years after its adoption. In particular, the review has to look at issues where there was incomplete information at the time of adoption.

The Commission is expected to make use of the revised EU nanomaterial definition when preparing amendments to REACH Annexes on the registration of nanomaterials (2014/ENV+/013) and when updating the definitions used in other EU law referring to nanomaterials.

Problem the initiative aims to tackle [max 25 lines]

The on-going review (see C below) has taken as its starting point the question of the effectiveness of the current Recommendation. It has generated the following interim findings:

a) The uptake of the Recommendation in EU regulation to date has taken place (e.g. Biocides Regulation[2]) but has not been as comprehensive as anticipated. The reasons for this are however not due to the definition itself, but

[1] Recital from the Recommendation 2011/696/EU: Technological development and scientific progress continue with great speed. The definition including descriptors should therefore be subject to a review by December 2014 to ensure that it corresponds to the needs. In particular, the review should assess whether the number size distribution threshold of 50 % should be increased or decreased and whether to include materials with internal structure or surface structure in the nanoscale such as complex nano-component nanomaterials including nano-porous and nano-composite materials that are used in some sectors.

[2] OJ L 167, 27.6.2012, p.1

due to delays in the processes planned to include the definition e.g. the possible amendment of REACH Annexes for nanomaterials and the delay in the adoption of the Novel Food Regulation[3], by which time the review was launched.

b) There is general consensus[4] between the stakeholders on the adequacy of the main elements of the definition. These are notably the neutral scope in terms of origin of the materials and its focus on particles. It is generally accepted that the definition uses the size of particles as the only defining parameter, applying to a 1-100nm particle size range and bases the threshold for being a nanomaterial on a number concentration instead of mass;

c) There are currently difficulties in directly applying the Recommendation in legislation. For example, it includes a threshold that has a default value but is not fully defined in advance and might require an additional process to determine its value: "*In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %....".* Also, application of the additional criteria based on the specific surface area by volume is considered ambiguous by some stakeholders. These prevent the Recommendation from being referred to in full by different regulations (e.g. the Biocides Regulation) and force individual selection of its elements during each regulatory uptake, which could eventually lead to inconsistencies;

d) There is a need to clarify some terms in use and how the criteria are applied: e.g. the definition of 'particle', the precise meaning of particle's 'external dimension' and the use of the concept of the "constituent particle" in respect to agglomerates and aggregates;

e) There are issues of scope: e.g. the present Recommendation in addition to the general criteria explicitly identifies also three carbon-based materials (graphene flakes, single wall carbon nanotubes and fullerenes) as nanomaterials while very similar non-carbon materials are not included;

f) Implementation remains challenging; there is no single universally applicable measurement method, and refinement of existing measurement methods is still in progress. In particular, to quantify "constituent particles" in all cases still poses a challenge. No easy implementation routes are presently provided to quickly determine for certain when a material is or is not a nanomaterial.

Basis for EU intervention (legal basis and subsidiarity check) [max 10 lines]

The Commission Recommendation as such is not legally binding and falls under shared competence.

The purpose of the definition is to achieve consistent application of the term “nanomaterial”, avoiding confusion and easing implementation, across all legislation. Harmonisation at EU level achieves this, whereas it would not if each Member State would do so nationally. Moreover, the EU nanomaterial definition is primarily addressing EU regulation, where the EU action has already been justified. For these reasons, the EU level is considered the most appropriate level of harmonisation.

B. What does the initiative aim to achieve and how [max 25 lines]

In 2013 the Commission launched a review of EU Recommendation 2011/696/EU on the definition of nanomaterial, with the objectives:

- of presenting the experience with the regulatory uptake and implementation of the EU nanomaterial definition since 2011
- of addressing identified issues of regulatory uptake, clarity and implementation.

An extensive scientific-technical assessment and stakeholder survey have already been performed and are published in the JRC reports :

a) Compilation of information concerning experience with the definition (EUR 26567 EN)

b) Assessment of collected information concerning the experience with the definition (EUR 26744 EN)

c) Scientific-technical considerations to clarify the definition and to facilitate its implementation (EUR 27240 EN)

Work to date is pointing to the need for a revision of the Recommendation and provide additional technical guidance to the users.

[3] OJ L 327, 11.12.2015, p.1

[4] Opinions vary; details are provided in the JRC reports that included stakeholder consultation. Links to the reports provided in the text under point B.

The intention is now to prepare a revised Recommendation to be adopted by the Commission, accompanied by a Staff Working Document that will report on the review undertaken and the rationale for the modifications.

It is envisaged that the Commission will then :

- Promote the revised Recommendation within the EU and, as appropriate, in the international community
- Develop guidance (including technical requirements), sector-specific guidance and implementation tools.
- Support the uptake of the Recommendation in the relevant policy areas (chemicals, cosmetics, food; etc.)
- Setup a system of continuous monitoring of implementation across sectors, facilitate quick dissemination and uptake of any relevant scientific/technical developments, and if considered appropriate trigger actions to support quality assurance and control of the measurements and their application in the nanomaterial definition

C. Better regulation

Consultation of citizens and stakeholders [max 10 lines]

The review has already compiled very comprehensive information under the three JRC reports including a stakeholder survey and a report from a dedicated Workshop, attended by all major stakeholders.

The draft changes to the Recommendation, considered on the basis of the information compiled in the review, will be subject of a 12 week online public consultation. During that period, major relevant stakeholder groups (e.g. CASG Nano, subgroup under Competent Authorities group CARACAL supporting REACH implementation) will be explicitly notified and are expected to address the public consultation questions as well.

The launch of stakeholder consultation related to this initiative will be announced in the consultation planning that can be found at http://ec.europa.eu/yourvoice/consultations/docs/planned-consultations_en.pdf.

Evidence base and data collection [max 10 lines]

It is not envisaged to carry out an impact assessment for the review /revision of the Commission Recommendation. As mentioned above, based on the findings of the review, the changes are likely to be small and will have limited and largely positive impacts as they will facilitate more effective application of the definition by industry and the regulator.

Impact of nano-specific provisions under individual EU regulations cannot be attributed to the Recommendation but is assessed separately before the adoption of the regulation that uses the Recommendation. For the existing regulation, impact is considered when its own definition gets updated using the Recommendation.

At the same time, a substantial body of evidence was compiled during the review in the JRC reports (see links under B), including information on cost. This information will be summarised and used in the Review report.

Information on the review process can be found at http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm.

Information on NanoDefine, a major research project supporting the implementation of the Recommendation and contributing to the review, can be found here: http://nanodefine.eu/