INCEPTION IMPACT ASSESSMENT			
TITLE OF THE INITIATIVE	Possible amendments of Annexes to REACH for registration of nanomaterials		
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	DG ENV UNIT A.3 CHEMICALS (W. DG GROW UNIT D.1 REACH IN CO-LEAD) AP 2014/ENV+/013	**DATE OF ROADMAP**	01/2016
LIKELY TYPE OF INITIATIVE	Measures that can be proposed by the Commission via the Committee procedures under the legal basis provided by REACH		
INDICATIVE PLANNING	*N/A*		
ADDITIONAL INFORMATION	*http://ec.europa.eu/research/industrial_technologies/policy_en.html*		

This Inception Impact Assessment is provided for information purposes only and can be subject to change. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.

A. Context, Subsidiarity Check and Objectives

Context

Political context of the initiative

This initiative was announced by the Commission in its Communication on the 'Second Regulatory Review on Nanomaterials' (COM(2012) 572)[1]. The Communication reports on studies undertaken by the Commission with a view to determine the adequacy of existing legislation to ensure protection of the environment, health and safety in relation to nanomaterials. Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (hereinafter called "REACH") was identified as one of the key pieces of EU legislation for the risk management of nanomaterials. In the 'Second Regulatory Review on Nanomaterials', the Commission concludes that "*REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures, but more specific requirements for nanomaterials within the framework have proven necessary. The Commission envisages modifications in some of the REACH Annexes and encourages ECHA to further develop guidance for registrations after 2013*." The announcement concerning the impact assessment of a modification of the REACH Annexes was re-affirmed in the General Report on the operation of REACH (COM (2013) 49)[2].

Under REACH, the different forms (solids, powders, nanomaterials, etc.) of the same substance can be considered within a single registration of a substance. However, the registrant must ensure the safety of all included forms and provide adequate information to address the different forms in the registration, including the chemical safety assessment and its conclusions (e.g. through different classifications where appropriate).

ECHA has updated their guidance to take account of some specific aspects related to nanomaterials and the Commission has adopted a Commission Recommendation (2011/696/EU) on the definition of nanomaterials[3].

Relation to other initiatives and to other EU policies

Since its 2005 Communication "Nanosciences and nanotechnologies: An Action Plan for Europe 2005-2009"[4], the Commission has promoted a "safe, integrated and responsible approach" to nanotechnologies. As part of the Action Plan, the Commission committed to review how EU legislation is able to deliver in accordance with the policy approach.

The first Communication on regulatory aspects of nanomaterials was adopted in 2008. The Communication was extensively discussed in the European Parliament (EP) and led to a resolution in 2009 in which a number of detailed questions were raised in regard to how EU legislation including REACH would ensure safety in practice given the many uncertainties surrounding the risk assessment of nanomaterials and the volume-based approach to registration.

Nanotechnology (which is a significantly broader concept than 'nanomaterials') has been identified as a key enabling technology (KET) providing the basis for further innovation and new products. In its Communication "A

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0572:FIN:en:PDF
[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0049:FIN:EN:PDF
[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:en:PDF
[4] http://eur-lex.europa.eu/legal-content/IT/TXT/?uri=uriserv:i23024

European strategy for Key Enabling Technologies – A bridge to growth and jobs" (COM (2012) 341) the Commission has outlined a single strategy for KETs, including nanotechnology, built upon three pillars: technological research, product demonstration and competitive manufacturing activities.

In parallel to this initiative, the Commission is preparing a separate impact assessment (*'Potential transparency measures for nanomaterials on the market'*) evaluating the most adequate means to increase transparency and ensure the regulatory oversight for nanomaterials on the EU market.

Evaluation of the existing policy

REACH is subject to periodic general reviews in accordance with its Article 117(4), and to the specific review of certain of its elements in line with its Articles 75(2), 138(2), 138(3) and 138(6). The first REACH Review was published in February 2013 in the form of a report from the Commission (COM (2013) 49) and its accompanying Staff Working Document (SWD (2013) 25); the second review is due by June 2017.

Related specifically to nanomaterials, the evidence base used by the Commission in its preparations for the 'Second Regulatory Review on Nanomaterials' included the REACH Implementation Project on Nanomaterials (RIPoN) reports[5] on the adequacy of the ECHA guidance (and the subsequent update of certain guidance provisions in April 2012) and a project report prepared by the Commission Joint Research Centre (JRC) in collaboration with ECHA, on the scientific and technical assessment of registrations that had been submitted by the first REACH registration deadline (30 November 2010) (the Task I report)[6].

The results showed that there were registrations for substances known to have nanomaterial forms that do not mention clearly which forms are covered or how the information provided relates to a nanoform. Only little information is specifically addressing safe use of the specific nanomaterials supposed to be covered by the registration dossiers. These findings can partly be explained by the absence of detailed guidance to registrants on how to compile registrations for nanomaterials and the absence of specific wording in the REACH Regulation Annexes.

The Commission is committed to revisit its assessment of the adequacy and implementation of EU legislation on nanomaterials by 2015 and is thus at the moment compiling information to prepare the 3rd regulatory review.

Issue

Reasons behind the initiative

The information requirements for a REACH registration apply to the total tonnage of a substance, including all forms. There is no prescription to undertake specific tests for each different form, or to spell out the way in which the different forms have been addressed in the registrations, although the REACH dossier structure allows this and the technical advice from ECHA encourages it. The Commission Recommendation on a definition of nanomaterials clarifies terminology, but in itself does not provide the necessary clarity to the registrants on how to address nanomaterials in REACH registrations. In close collaboration with ECHA, the Commission has assessed how nanomaterials have been addressed in REACH registrations.

The Commission has identified a necessity for more specific requirements for nanomaterials to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers in order to attain the aims of REACH as defined in its Article 1. In case of inaction the potential results can be:

i) Inadequate demonstration of safe use for nanomaterials in the REACH registration dossiers; and

ii) Registration uncertainties for companies and impaired innovation motivation.

This could lead to increased risks for:

1) Health and the environment, if inadequate demonstration of safe use in the REACH registration dossiers leads to harmful use;

2) Industry, affecting innovation, investment decisions and impaired competitiveness due to lack of clarity over what needs to be included in the REACH registration dossiers.

The problem and its main drivers

Accordingly, the main problem this initiative aims at solving is how nanomaterials should be addressed and safety demonstrated in REACH registration dossiers.

[5] REACH Implementation Project Substance Identification of Nanomaterials (RIPoN1), March 2011 http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon1.pdf
Specific Advice on Fulfilling Information Requirements for Nanomaterials under REACH (RIPoN2), 1 July 2011 http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon2.pdf
Specific Advice on Exposure Assessment and Hazard/Risk Characterisation for Nanomaterials under REACH (RIPoN3), 7 July 2011 http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon3.pdf

[6] Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf

The following key underlying drivers have contributed to the problem and may explain why the current system has not delivered for nanomaterials:

- the lack of a definition of a nanomaterial at the time when registrations were submitted;
- the physico-chemical properties which are to be described in the registration dossier were not extensively listed;
- uncertainty about the application of test methods to nanomaterials;
- insufficient guidance over the substance identification for nanomaterials and the scope of the registration dossiers; and
- uncertainty on how to deal with the multiplicity of forms in the chemical safety assessment.

Subsequently, a number of initiatives, such as the nano-specific ECHA guidance and ECHA compliance decisions, have already addressed some aspects of the identified problems. However, of the thousands of dossiers submitted by the second registration deadline in 2013, only four indicated to cover nanomaterials.

Who is affected and how

Immediately affected is the industry dealing with nanomaterials with an obligation to register these (both EU manufacturers and importers). The effects will be a possible change of the administrative burden and a clearer legislative environment for fulfilling the obligations. A study performed for the European Commission in the context of the first REACH Review[7] estimated the total number of European nanomaterial manufacturers in the range of 200 to 400. In addition, downstream companies using nanomaterials may be affected. The direct employment in the nanotechnology sector was estimated at around 300,000 to 400,000 jobs in the EU in 2011[8].

ECHA, competent authorities and enforcement authorities will also be affected when performing their dedicated tasks in accordance with REACH.

There will also be impacts on the protection of the health of workers in industry handling nanomaterials, the environment (e.g. aquatic environment, wildlife), and to a lesser extent on the health of the public at large.

Subsidiarity check

REACH provides rules and registration obligations for the circulation of chemicals in the internal market, including the manufacture or use of nanomaterials. Article 114 TFEU is the legal basis of REACH. The current initiative concerns clarification of the existing provisions established in the REACH Annexes. Consequently, legislative initiatives at Member State level pertaining to substances and mixtures including their nanoforms would be in breach of REACH. As REACH is an EU Regulation, any modifications to REACH and its Annexes can only be adopted at EU level. Based on these considerations, there is a clear added value of action to be taken at the EU level.

Main policy objectives

REACH aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances (mainly to reduce animal testing), as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. As identified above, there is a lack of clarity of REACH registration requirements for nanomaterials. In line with the aim of the legislation, the general objective of this initiative is to ensure clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers, thus allowing REACH to be fit for the purpose of dealing with nanomaterials. This objective does not imply developing EU policy in new areas as they are already established *acquis* in the EU.

In order to achieve the general objective and to address the main consequences of the problem, the following specific objectives have been established:

i. clarify the REACH information requirements for registrants on how nanomaterials must be registered pursuant to REACH;

ii. ensure adequate demonstration of safe use of nanomaterials in registration dossiers.

B. Option Mapping

Baseline scenario – no EU policy change

The baseline scenario corresponds to '**option 1: No change**' in the impact assessment. Option 1 is a continuation of the current situation under REACH assuming that there are no new policy actions and that the

[7] http://ec.europa.eu/DocsRoom/documents/11897/attachments/1/translations/en/renditions/native

[8] Final report of the High-level Expert Group on Key Enabling Technologies, European Commission, June 2011, p.13 http://ec.europa.eu/enterprise/sectors/ict/files/kets/hlg_report_final_en.pdf

implementation is based on what currently is known i.e. including the guidance updates from April and May 2012, the full use of the Commission Recommendation on the definition of Nanomaterial and the updates of OECD Test Guidelines.

Options of improving implementation and enforcement of existing legislation or doing less/simplifying existing legislation

Option 2: Clarifying the existing information requirements

Option 2 would introduce changes to the description of certain information requirements in the legal provisions of the REACH Annexes, clarifying what companies are expected to do when registering nanoforms. The information requirements are in accordance with the registration obligations of REACH and the specific ECHA guidance. Based on advice given by ECHA, the measures contained in this option are targeting more precise description of the nanoforms of a substance covered by the dossier, clarification of standard information requirements for nanoform specific information in a number of endpoint sections of the REACH Annexes, and clarification of how data is to be reported. While ECHA's guidance still needs to be provided in some cases, these measures outline necessities for an accurate information base to allow for a reasonable hazard assessment.

This option would therefore, according to ECHA, not change any existing obligations as they are understood to exist and these measures are/will be pursued as such in formal ECHA evaluation, but it would provide companies with a clearer understanding on what information they must provide in the registration dossier. ECHA indicated that it considers option 2 as derived from the general REACH requirements and thus can be considered as part of the baseline.

Option 3: Soft law measures

This option would introduce measures of a non-legally binding nature with a view to providing more clarity on the registration obligations for nanomaterials without changing any legal provisions in REACH. Within the operation of REACH, numerous soft law measures are already applied. The following could also be applied to improve the clarity of obligations for registrants of nanomaterials:

i. development of further specific ECHA Guidance; presently only rather generic guidance on nanomaterials is available to registrants, integrated in the general guidance on registration;

ii. enhanced use of the Directors Contact Group to further identify possible solutions for problems related to nanomaterials in the registration process;

iii. initiatives to enhance information and dissemination at EU and Member State level.

Option 4: Scientific-technical recommendations tailoring information requirements

This option would introduce additional measures that are recommended from a technical/scientific perspective to demonstrate safe use in cases where the existing information requirements in REACH are not tailored for nanomaterials or where specific considerations are required for nanomaterials, such as application of waivers, consideration of the most appropriate route of exposure or applicability of methods. The option implies the full implementation of option 2 and complements it by further measures.

Option 5: Reduced information requirements

This option would include two types of measures:

i. measures, in addition to option 1 but less demanding than option 2, providing clarity on how nanomaterials should be addressed and safety demonstrated under REACH by clarifying relevant provisions and specifying information requirements for nanoforms with the aim to provide for specific solutions that increase predictability for registrants in the current regulatory framework;

ii. measures reducing certain information requirements for nanoforms for the purpose of the registration in lower tonnage bands, allowing companies to reduce compliance cost and allocate more resources to support competitiveness and innovation.

Option 6: Exhaustive information requirements

This option assumes full implementation of options 2 and 4, and would put additional emphasis on the generation and documentation of further targeted information with the objective of reducing uncertainty, considering that knowledge is still under development regarding the influence of particle and nanomaterial specific properties on risk. The option would contain three types of measures:

i. more prescriptive rules as regards the organisation of the chemical safety assessment and its documentation for individual nanoforms and the influence of particle and nanomaterial specific properties;

ii. request specific information (e.g. toxicokinetics, repeated dose toxicity testing) in a targeted fashion and

at lower tonnages;

iii. address some remaining open questions regarding the scope of current REACH provisions, drafted without specific consideration to nanomaterials.

Alternative policy approaches/instruments

Different policy instruments are listed above; they include soft law approach (option 3), and regulatory measures (options 2, 4, 5 and 6).

Another approach would be to develop a proposal for a stand-alone Regulation on nanomaterials outside of REACH. However, this would contradict the conclusions of the Regulatory Review on nanomaterials and of the earlier REACH Review.

Alternative/differentiated scope

The options considered (from 2 to 6) have different scopes. As a general limitation, changes to REACH, if any, are to be introduced on the basis of the empowerment given to the Commission under REACH Article 131 (Amendments to the Annexes) in accordance with REACH Article 133 (Committee procedure).

REACH is already balanced between its requirements for new and existing substances, and between high production volume and other chemicals, with its transitional provisions for existing substances based on production volume, reduced requirements for low volume substances, exemptions for PPORD and a fee structure benefiting SMEs. As the options do not change any of these parameters and only aim to implement what is already considered within the objectives of the REACH Regulation, no particular extra measures will be needed.

Options that take account of new technological developments

All options take specific account of technological developments.

Preliminary proportionality check

The different policy options presented range from no EU action to EU legislative measures of different magnitude; the proportionality of each option will be assessed in detail in the impact assessment.

C. Data Collection and Better Regulation Instruments

Data collection

Information and data already available

How nanomaterials have been addressed in registrations submitted by the 2010 deadlines was extensively analysed by JRC and ECHA in the so-called 'Nanosupport report'[9]. It has been thoroughly discussed with Member States competent authorities and stakeholders. The report includes not only an assessment of what has been done, but also a set of options on what could be proposed to improve the situation. These recommendations have been taken into account for the development of the different options set out above and for the assessment of their impacts.

A public consultation on this initiative was carried out for 12 weeks (from 21 June to 13 September 2013), which resulted in inputs from 142 respondents (see below).

In addition, three meetings with the Competent Authorities for the implementation of REACH as well as stakeholders were held in 2013-14 with a view to discussing progress of the work and to gather data and information to improve the evidence base.

Additional information

Additional information necessary to assess the policy options such as information on cost of testing and assessment of impacts of individual measures considered under different options was gathered through two external studies concluded in 2013[10] and 2014[11].

Contact with stakeholders and Member States

The Communication on Second Regulatory Review on Nanomaterials and its Staff Working Paper waere presented and discussed at a stakeholder meeting in February 2013 and have generally been promoted by the Commission at external events on nanomaterials. The development process has been followed by Member States and stakeholders through regular updates in the subgroup of the group of Competent Authorities for REACH and CLP (CARACAL). Following the eventual adoption, no specific activities have been envisaged beyond the useful awareness to be done by ECHA.

[9] Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information, JRC, 12 March 2012 http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf

Consultation approach

A Public Consultation took place from 21/06/2013 to 13/09/2013. The consultation exercise was a targeted process that sought to gather stakeholder views relating to the Problem Definition, the Baseline scenario and the five additional substantive options under consideration. All documents related to the consultation can be found at http://ec.europa.eu/environment/consultations/nanomaterials_2013_en.htm. The results highlighted the unclarity of the REACH obligations with regard to how nanomaterials shall be addressed and safety demonstrated in the registration dossiers. The majority of industry and private companies preferred reduced information requirements for nanoforms of a substance and thus lower associated cost, while governments, academic/research institutions, NGOs and consumer organisations favoured more extended requirements.

Will an Implementation plan be established?

☐ **Yes** ☒ **No**

The chosen option, if different to the baseline scenario, will take the form of a Draft Commission Implementing Regulation amending certain REACH Annexes and will be submitted to the REACH Committee for opinion in accordance with Article 133(4) to REACH before its adoption by the Commission.

D. Information on the Impact Assessment Process

Work on the Impact Assessment is expected to conclude by the end of 2015. An IA Steering Group met for the first time in November 2012 and is envisaged to meet three times in total. Written consultations have also been used. The DGs which were invited are the following: Secretariat General, Legal Service, TRADE, EMPL, TAXUD, CNECT, ENER, MOVE, CLIMA, SANTE, RTD and JRC.

E. Preliminary Assessment of Expected Impacts

Likely economic impacts

Companies manufacturing and placing nanomaterials on the market (both EU producers and importers) would be directly affected by the measures under this initiative. Most of the economic impacts will depend on how much additional testing and analytical work is required by the changes that would be introduced by each option. The main costs of the initiative are expected to be the additional compliance costs for companies registering substances with nanoforms. These costs will depend on the additional requirements imposed by the different options; option 5 is expected to be the least burdensome and option 6 the most burdensome. However, the legal clarity and certainty which this initiative would generate may positively affect companies' investment decisions. The potential impacts on downstream users, competitiveness and innovation, as well as the impacts on SMEs will also be assessed.

Likely social impacts

None of the options is expected to have a significant impact on employment and labour markets. While there are indications that potential health benefits in terms of more appropriate risk management measures (for workers and consumers) are to be expected as a result of better information availability for nanomaterials, it will not be possible to quantify these. On the other hand, this initiative may improve consumers' trust in the safe use of substances with nanoforms.

Likely environmental impacts

It is considered for the assessment that extrapolation from the scarce information on the few specific nanomaterials available at present is more appropriate than drawing conclusions from the environmental impacts of chemicals in general. The analysis will be, however, limited to a qualitative discussion. Likewise social impacts, this initiative may lead to better knowledge about the potential effects of nanoforms on environment, and hence to more appropriate risk management measures.

Likely impacts on simplification and/or administrative burden

The initiative would not have any major simplification impact; however, it is expected that the clarity of the obligations for operators flowing from the legislation will be improved. As for the administrative burden, the ongoing work indicates likely resource implications.

Likely impacts on SMEs

SMEs would likely be affected differently by each of the options, depending on the magnitude of the changes that each of them would introduce; option 5 is expected to be the least burdensome one for SMEs and option 6

[10] Examination and assessment of consequences for industry, consumers, human health and the environment of possible options for changing the REACH requirements for nanomaterials, BiPRO, 14 January 2013 http://ec.europa.eu/environment/chemicals/nanotech/pdf/Final_Report.pdf

[11] A study to support the Impact Assessment of relevant regulatory options for nanomaterials in the framework of REACH, Matrix, 31 March 2014 http://ec.europa.eu/DocsRoom/documents/5826/attachments/1/translations/en/renditions/native

the most burdensome one. The way SMEs will be affected will also depend on whether they are producers or downstream users of nanomaterials. As is the case for REACH in general, SMEs would be faced with relatively higher burden.
Likely impacts on competitiveness and innovation
The effects on the competitiveness of EU firms operating with nanomaterials is expected to be twofold: on one hand, increments in costs could potentially harm the ability to compete in international markets; on the other, regulatory certainty, improvements in the knowledge and exchange of information could bolster competitiveness. Regarding innovation, extra requirements could add compliance cost to companies that otherwise could have been spent on research and development; however research and innovation can be fuelled by legislative requirements and the acquired knowledge.
Likely impacts on public administrations
The initiative will not have any significant impact on public administrations. It is anticipated on the contrary that the overall compliance and enforcement costs for public authorities may decrease, since the initiative aims to create more clarity on what it is expected from registrants.
Likely impacts on third countries, international trade or investment
None of the options are likely to have significant impacts on relation with third countries, international trade or investment. However firms in third countries placing nanomaterials on the EU market will need to comply with any changes. The investment environment may be adversely affected due to increased compliance costs, but may also improve due to regulatory certainty, increased knowledge and exchange of information.