

ROADMAP

Title of the initiative: **Communication on regulatory aspects of nanomaterials - Progress report**

Type of initiative (CWP/Catalogue/Comitology): CWP

Lead DG/contact person/details: DG Enterprise and Industry; (however, Communication to be presented under co-responsibility with other DGs).

Expected date of adoption of the initiative (month/year): December 2011

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Initial IA screening & planning of further work

A. Context and problem definition

(i) What is the political context of the initiative? (ii) How does this initiative relate to past and possible future initiatives, and to other EU policies?

Nanotechnology is based on the manipulation and control of materials at the nanoscale. The technology opens up for new applications, in areas as diverse as medicine, material innovation, electronics, energy and transport. Nanotechnologies and nanomaterials are therefore believed to provide a strong contribution to various EU policies and to the grand challenges such as energy, conservation of resources, clean production processes and health care. Nanotechnologies are also considered to contribute to the competitiveness of industry and the creation of jobs. Their importance is reflected in funding for research, which at the global level has doubled from around 6.5 billion € in 2004 to around 12.5 billion in 2008. At the same time, precisely because of their novel properties and unknown interactions, nanomaterials can also present new risks to workers, citizens, consumers and the environment.

The policy challenge therefore is to design a policy, bearing in mind the 2020 Strategy and related Commission policies¹, which on the one hand allows the successful introduction on the market of these new innovation-enabling technologies, and which on the other hand maintains the high levels of protection of health, safety and the environment required by EU law and reassures consumers.

The Commission's answer to this challenge was the "Integrated, safe and responsible approach" on nanotechnologies², followed by a 5 years Action Plan³. In accordance with the Action Plan, the Commission presented, in 2008, a Communication on Regulatory Aspects of Nanomaterials⁴, which examined to what extent the EU regulatory framework covers the protection of health, safety and environment.

In this Communication, the Commission concluded that regulatory change may be necessary and states its commitment to introduce regulatory change whenever necessary. However, overall, the Commission expressed the view that the main issue in relation to nanomaterials is to implement existing provisions that already cover risks related to nanomaterials. Implementation is made possible or facilitated by instruments that support implementation (e.g. implementing legislation adopted by Comitology, standards, guidance, risk assessment methodologies). These can only be developed or adapted if sufficiently scientific data are available. As the

¹ e.g. Communication "Towards a Europe COM(2009) 512 final "Preparing for our future: Developing a common strategy for key enabling technologies in the EU" of 30.09.2009.

² Communication "Towards a European Strategy for Nanotechnology; COM(2004) 338 final of 12 5 2004

³ Communication "Nanosciences and nanotechnologies: an action plan for Europe 2005 – 2009"; COM(2005) 243 final of 7 6 2005

⁴ COM(2008) 366 final of 7.6.2008

Communication identified knowledge gaps in relation to risk assessment, it also set a number of priorities for R&D for regulatory purposes. Because of the knowledge gaps and the lack of documents that support implementation, the Commission announced a follow-up report, to be presented in 2011

The 2008 Communication was subject of a critical examination by the European Parliament. In a Resolution adopted in April 2009, the Parliament asked the Commission to present a follow-up report in 2011, to introduce specifically identified regulatory change, to develop a common definition of nanomaterials, to assess the need to review regulation on a number of other specific aspects, and to adopt provisions in regulation or instruments of implementation, specific to nano materials.⁵ In its reaction to the Parliament's Resolution, the Commission reiterated its commitment to present a follow-up report on 2011, paying particular attention to the issues raised by the Parliament.

The 2011 Communication is also much awaited by Member States. Regulatory initiatives are subject of national dialogues with stakeholders and Member States are interested to know the Commission's position in the light of further progress on regulatory issues and related science.

Finally, the follow-up report is much awaited by stakeholders, who all expressed their (diverging) position on regulatory issues (in particular environmental NGOs, consumers, workers, and industry).

The Communication will deliver an assessment of the need to review EU legislation regarding nanomaterials taking into account e.g. work on a common regulatory working definition, the development of guidance under REACH, international cooperation, progress in international and European standardisation, opinions by the EU Scientific Committees and the Commission's position on labelling issues.

It is this promised 2011 follow-up report which is the subject of this roadmap.

What are the main problems identified?

The follow-up Communication is an important element in the public policy debate on regulation of nanomaterials.

A main problem identified in the 2008 Communication was lack of scientific data that allow for the implementation of regulatory requirements, in particular on risk assessment and risk assessment tools, or the adoption of instruments that facilitate implementation, such as implementing legislation, standards, guidance, etc. Consequently, legislation has to be implemented on a case-by case basis. In all cases, however, it remains essential to ensure that legal requirements to provide data and information (e.g. the REACH principle "no data-no market") are fully respected.

Therefore, the Commission will have to report on progress in bridging the knowledge gap in relation to implementation of regulation, in particular on risk assessment, and on any regulatory consequences to be drawn from the knowledge gaps that continue to exist.

The Commission will also report on the need for regulatory change on issues such as the introduction of explicit scope statement for nanomaterials in regulation, labelling of nano ingredients, and an assessment of the need to review legislation in a number of areas identified by the European Parliament.

Who is affected?

The Communication itself will not introduce regulatory change, or instruments of implementation (Comitology, standards, guidance, etc). As such, it will not have a direct effect. However, it will clarify the line the Commission intends to take in relation to regulatory issues concerning potential risks of nanomaterials.

Resulting measures may have impacts on industry, workers, consumers, and / or the public at large.

⁵ European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials;

(i) Is EU action justified on grounds of subsidiarity? (ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)? (iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?

Nanomaterials are covered by a wide range of EU legislation, in particular in relation to chemicals (in particular REACH), worker protection, product legislation (e.g. food, cosmetics, pharmaceuticals) and environmental legislation (e.g. water, waste, production processes). Action in relation to legislation and implementation therefore must take place at EU level. The emphasis of the regulatory debate on nanomaterials resides therefore at the EU level.

The Communication can only be presented by the Commission: it is the Commission who will have to introduce proposals for regulatory change, the Commission is responsible for the coordination of implementation and chairs working groups in charge of coordinating implementation of regulation, it is the Commission who addresses mandates to the Scientific Committees, and it is the Commission who is the link with external organisations, such as the standards organisations and organisations such as the OECD, ICCR and UN.

B. Objectives of EU initiative

What are the main policy objectives?

The main objective of the Communication is to assess progress on the extent to which potential risks of nanomaterials are properly addressed by EU law and its instruments of implementation, to identify areas where regulatory change may be required, to report on progress in developing instruments of implementation, to identify priority areas for R&D in support of regulation, in particular for evolving tools of risk assessment to have a first indication how the Commission proposes to deal with next generation nanomaterials.

On the same occasion, the Communication will fulfil its commitment taken towards the European Parliament to report on progress and on specific requests of the European Parliament in relation to regulation.

The ultimate objective remains to ensure a regulatory framework, which is innovation friendly and enables the introduction of nanotechnologies and nanomaterials, whilst at the same time the high levels of protection imposed by EU law remain fully respected. .]

Do the objectives imply developing EU policy in new areas or in areas of strategic importance?

The objectives can be pursued in the framework of existing EU policies.

C. Options

(i) What are the policy options? (ii) What legislative or 'soft law' instruments could be considered? (iii) Would any legislative initiatives go beyond routine up-date of existing legislation?

This Communication fulfils a commitment made by the Commission, set-out in the 2008 Communication, and a commitment to the European Parliament following its Resolution of April 2009 in response to the Communication.

It is unlikely that a Commission Staff Working Document would satisfy the EP, Member States or stakeholders, who are all interested in a political position and commitment from the Commission on regulatory policy in relation to nanomaterials. This does not exclude that, if deemed necessary, a Commission Staff Working Document may be drafted to accompany this Communication.

In the line of its Communication of 2008 on regulatory aspects of nanomaterials, the regulatory action in its wide sense will cover both regulation and "soft law" instruments, qualified in the Commission's Communication and "supporting documents" and in the EU Resolution as "instruments of implementation".

The option to present a Communication should be distinguished from the debate on policy options for individual measures in relation to the regulatory framework for nanomaterials. As mentioned before, nanotechnology is an enabling technology, covered by a wider range of EU law. Monitoring of this legislation and assessment of the need for regulatory change is an ongoing process, which involves different stakeholders and policy areas. The need for regulatory change in these areas is subject of verification and Impact Assessment in its own right. This Communication will set out the general policy of the Commission and its concern to maintain a consistent and effective approach, e.g. by using a consistent definition of nanomaterials throughout regulation.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Nanotechnology is an enabling technology, and has an impact on regulation concerning the internal market, worker protection, environmental protection, consumer protection, research policy, etc. The 2008 Communication was presented under the joint responsibility of the Commissioners responsible for DG Enterprise and Industry, Sanco, Environment and Employment, in association with the Commissioner responsible for Research and the Joint Research Centre.

Also the follow-up Communication will be made as a joint responsibility involving these DGs and covering these policies.

Explain how the options respect the proportionality principle

The Communication itself will explain and evaluate the Commission's policy line on regulatory issues, taking into consideration the ongoing debate of regulation, based on input from Commission Working Groups, stakeholders, the European Parliament, Member States, international discussions (e.g. OECD, ISO, regulatory dialogues, etc), output from scientific work, agencies (EMEA, ECHA, EFSA) and assessment by the Scientific Committees

Specific measures to be adopted in the framework of this regulatory policy will reflect principles of proportionality, as well as principles of better regulation. The specific assessment of the respect of these principles can only be made each time such specific measures are being proposed.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives?

In the light of commitments taken, a decision not to present a Communication, expressing the Commission's political stance on regulatory issues, would create a significant negative impact from the Parliament and stakeholders.

As described above, the communication will assess whether EU law provides for the use of nanotechnologies and nanomaterials in a way that maintains protection of human health and the environment, and will set out the general policy of the Commission and how it plans to maintain a consistent and effective approach. There may be subsequent initiatives to amend policy and / or legislation, on which Impact Assessments will be performed. These would be likely to impact on businesses and research institutions using nanotechnologies, their workers, consumers, the environment and the general public.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

The Communication in itself will not have an impact on the EU Budget.

Could the options have significant impacts on (i) simplification, (ii) administrative burden or on (iii) relations with third countries?

The Communication in itself will not lead to simplification or administrative burden. Measures that effectively will be implemented in the light of the Commission's position on regulation will have to be assessed specifically and individually on these aspects.

It can be anticipated that the Communication will attract quite some interest from third countries and trading partners, including international organisations.

E. Planning of further impact assessment work

When will the impact assessment work start?

The Communication will report on initiatives undertaken in the various DGs, such as those mentioned already under point A(i) above . These initiatives will be subject, as required, of their own Impact Assessment. .

(i) What information and data are already available? (ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out? (iii) What further information needs to be gathered? (iv) How will this be done (e.g. internally or by an external contractor) and by when?

(v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

As mentioned above, the 2011 Communication itself will explain and evaluate Commission policy on regulatory issues, taking into consideration the ongoing debate of regulation, based on input from Commission Working Groups, stakeholders, the European Parliament, Member States, international discussions (e.g. OECD, ISO, regulatory dialogues, etc), output from scientific work, agencies (EMEA, ECHA, EFSA) and assessment by the Scientific Committees. The communication will assess whether EU law provides for the use of nanotechnologies in a way that maintains protection of human health and the environment, and will set out the general policy of the Commission and how it plans to maintain a consistent and effective approach. A clear distinction must be maintained between the Communication, and the wide variety of measures and degree of progress on which it will report, and which is still being defined. The Communication itself will not be subject of an impact assessment. The subsequent initiatives to amend policy and / or legislation will be likely to impact on businesses and research institutions using nanotechnologies, their workers, consumers, the environment and the general public. These initiatives will be subject of individual and specific Impact Assessments as appropriate.

Which stakeholders & experts have been/will be consulted, how and at what stage?

See above regarding specific regulatory initiatives.

As regards the Communication itself, consumers, workers, environmental NGOs, industry, have adopted position papers on regulatory aspects and on the Commission's 2008 Communication. The 2011 Communication will address the issues identified in these position papers.