



Council of the
European Union

Brussels, 3 October 2018
(OR. en)

12487/1/18
REV 1

ENV 615
RECH 394
SAN 288
CONSOM 263
IND 253
CHIMIE 62

NOTE

From: General Secretariat of the Council
To: Delegations

Subject: 'Berlin Declaration' on nanomaterials
- Information from the German delegation, supported by the French and Luxembourg delegations

Delegations will find in the Annex an information note from the German delegation, supported by the French and Luxembourg delegations on the above subject, to be dealt with under "Any other business" at the Council (Environment) meeting on 9 October 2018.

'Berlin Declaration' on nanomaterials
- Information from the German delegation, supported by the French and Luxembourg delegations -

The 'Berlin Declaration' summarises the conclusions and recommendations of the 12th International Nano-Authorities Dialogue of Germany, Liechtenstein, Luxembourg, Austria and Switzerland and was acknowledged by the environment ministers of those countries at their annual meeting in June 2018.

The declaration acknowledges the progress that has been made in the regulatory framework for nanomaterials in the last few years, and especially the European Commission's Decision to adapt the annexes of the REACH Regulation to the requirements of nanomaterials. It also sets out the needs identified for further activities in this field, most of which will have to be addressed at EU level. These needs include:

- the adaptation of test methods within the context of the OECD;
- a transversal definition of nanomaterials in all relevant regulatory contexts in the EU;
- the approach to be taken to the emerging topic of 'advanced materials';
- the continued support of research activities and SMEs in the field of nanomaterials;
- provisions to give the European Chemicals Agency (ECHA) a permanent mandate for the EU Nano-Observatory.

Germany asks the Environmental Council to take note of the Declaration:

BERLIN DECLARATION

Conclusions and recommendations from the 12th International Nano-Authorities Dialogue (7 and 8 June 2018, Berlin)

The authorities in Germany, Liechtenstein, Luxembourg, Austria and Switzerland have been cooperating successfully for many years in the field of nanotechnology. The 12th International Nano-Authorities Dialogue took place in Berlin on 7 and 8 June 2018. At this meeting, conclusions on the current situation were drawn up and recommendations were made for dealing with this key technology up to the year 2025 (Roadmap 2025). This roadmap covers chemicals law, occupational health and safety, environmental protection and consumer protection.

The 2018 dialogue meeting focused on analysing existing regulations on nanotechnology in selected areas and extending the topics covered to include advanced materials.

In April 2018, another milestone was reached with the European Commission's unanimous decision to adapt the annexes of the REACH Regulation to the requirements of nanomaterials. The implementing regulation will enter into force in January 2020. It will then be possible to carry out systematic risk assessments using information from the registration dossiers.

However, it is clear that further action is required, in particular regarding the adaptation of OECD test methods to the requirements of nanomaterials. The OECD test methods form the basis for tests under the REACH Test Methods Regulation.

The Malta Initiative, which was launched by Germany at European level, aims to adapt the necessary test methods as quickly as possible. The European Union provided EUR 5 million to that end. Thirteen Member States are now working in this initiative with industry, the European Chemicals Agency (ECHA) and the European Commission's Joint Research Centre (JRC).

Gaps to be closed were also identified in other regulatory fields. In particular, a uniform and unambiguous definition of nanomaterials in all relevant regulatory areas has not yet been achieved.

Nanomaterials are defined independently in legislation on medicinal products for human and veterinary use. A risk-benefit assessment is carried out. Against this background, legislation on medicinal products should retain the specific definition, in contrast to the Medical Device Regulation.

Cooperation between authorities and coordination on concepts are required in order to tackle the above-mentioned challenges. The following measures are a precondition for this (the European Commission will play a key role in implementing these measures):

- using a uniform and unambiguous definition of nanomaterials – with the exception of legislation on medicinal products for human and veterinary use;
- determining which definition forms the basis for advanced materials;
- drawing up and adopting a regulating strategy for advanced materials. This strategy must include studying patterns of dust generation and assessing the threat posed by the release of nanoscale and microscale inhalable and biopersistent particles and fibres;
- securing the permanent operation of the nano-observatory to ensure in particular that data from the registration dossiers can be incorporated from 2020;
- ensuring the development of all relevant test and detection methods to provide the basis for implementing existing and future regulations for nanomaterials;
- providing sufficient resources for regulation research;
- supporting SMEs in characterising nanomaterials pursuant to regulatory requirements.

Compliance with these recommendations would contribute to setting standards for safely dealing with advanced materials and safely using nanotechnology innovations.