



**COUNCIL OF
THE EUROPEAN UNION**

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REV 1**

**COMPET 59
IND 22
RECH 24
ECOFIN 65
ECO 12
SOC 59
ENV 70
SAN 29
CONSOM 10
MI 60
CHIMIE 8
ENT 25**

NOTE

from: Presidency

to: COUNCIL

Subject: Preparation of the Council meeting "Competitiveness" (Internal Market, Industry, Research and Space) on 18 and 19 February 2013

REACH

Presidency paper including policy questions on the REACH review

(a) General Report on REACH

(b) Communication from the Commission on "Second Regulatory Review of Nanomaterials"

- Presentation by the Commission and exchange of views

Introduction:

REACH is the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1 June 2007. It streamlines and improves the former legislative framework on chemicals of the European Union (EU). In the context of its revision the Commission has recently adopted two relevant documents: (a) General Report on REACH¹ and (b) Communication on the 2nd regulatory review on Nanomaterials².

The General Report on REACH: (review of REACH) examines the overall operation of REACH and the attainment of its objectives – a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

Nanotechnology: is delivering major advances today and also has the potential to allow “game changing” technological breakthroughs and rekindle economic growth. In recognition of this fact, the European Commission adopted a Communication on the Second Regulatory Review on Nanomaterials, which also includes the Commission’s plans to improve EU law to ensure the safe use of nanomaterials. It assesses the adequacy and implementation of EU legislation for nanomaterials, indicates follow-up actions and responds to issues raised by the European Parliament, the Council and the European Economic and Social Committee. The Communication underlines nanomaterials' diverse nature and types, ranging from everyday materials that have been used safely for decades (e.g., in tyres or as anticoagulants in food) to highly sophisticated industrial materials and tumour therapies. There is an increasing body of information on the hazard properties of nanomaterials, which are difficult to generalise and justify case-by-case risk assessments.

¹ doc. 5864/13

² doc. 14869/12

Commission Conclusions:

The Commission's conclusions from these two documents can be summarised as follows:

- The Commission concludes that the REACH Regulation works well and has achieved the objectives expected after five years of operation. The Commission does not propose changes to the REACH system which would require reopening the legal text, thereby ensuring stability and predictability of the law and responding to calls in this regard. However, the Commission has identified a number of areas requiring improvements in the implementation or changes to annexes and it makes recommendations how to achieve this.
- The Commission recognises the difficulties faced by SMEs and proposes ways to reduce the impact of REACH for these companies while preserving their capacities to fulfil REACH obligations by calling on industry to establish fairer costs-sharing practices and by increasing the reduction of ECHA fees applicable to SMEs.
- The Commission concludes that REACH is the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures. Based on an advice from EU Scientific and Advisory Committees, the Commission concludes that nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. However, the Commission also recognised that within this framework more specific requirements for nanomaterials have proven necessary. Nanomaterials require a risk assessment, which should be performed on a case-by-case basis, using pertinent information. The Commission envisages modifications in some of the REACH Annexes by December 2013 and encourages ECHA to further develop guidance for registrations after 2013. The Commission will carefully follow developments, and report back to the Parliament, the Council and the European Economic and Social Committee within 3 years.

- Further, and beyond REACH, in order to improve the availability of information on nanomaterials, the Commission will create a web platform with references to all relevant information sources, including registries on a national or sector level (where they exist). In parallel, the Commission will launch an impact assessment to identify and develop the best means to increase transparency and ensure regulatory oversight, including an in-depth analysis of consequent data gathering needs. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes.

Questions:

In the light of the overall context described above, the Presidency invites the Council (Competitiveness - Internal Market and Industry part) on 19 February 2013 to address the following questions:

- Review: To what extent do the general conclusions of the Commission with regard to the achievements of REACH objectives align with Member States' perspectives?
- Nanomaterials: Will the consequent implementation of REACH tools such as substance evaluation, along with an adaptation of the REACH Annexes and the development of further guidance, provide a clear basis to improve risk management of nanomaterials?
