



**COUNCIL OF
THE EUROPEAN UNION**

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NOTE

from: Presidency
to: Permanent Representatives Committee / Council

Subject: REACH
(a) Report on the Review of the REACH Regulation
(b) Communication from the Commission on "Second Regulatory Review on Nanomaterials"
- Presentation by the Commission
- Exchange of views

Delegations will find in Annex a Note by the Presidency on the above-mentioned subject, which includes a question for the exchange of views at the Council (Environment) meeting on 21 March 2013.

REACH

- Note by the Presidency -

Introduction

1. REACH is the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1 June 2007. REACH was adopted with the aim of ensuring 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. REACH can be regarded as a key element of the EU's commitment towards the implementation plan adopted at the 2002 World Summit on sustainable development which aims to ensure that, by 2020, chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment.
2. The REACH Regulation 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 Second Regulatory Review on Nanomaterials².
3. **The General Report on REACH** (review of REACH) examines the overall operation of REACH in its first 5 years and assesses its success in achieving its objectives of protecting human health and the environment, as well as ensuring competitiveness and innovation in the European chemicals industry.

¹ 5864/13.

² 14869/12.

4. **Nanotechnology** is recognised as having the potential to allow “game changing” technological breakthroughs and rekindle economic growth, while providing resource efficiency benefits. 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 tumor therapies. There is an increasing body of information on the hazardous properties of nanomaterials, which are difficult to generalise and, therefore, justify risk assessment performed on a case-by-case basis.
5. 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 either improvement in implementation or changes to annexes and it makes recommendations on how to achieve these.
 - The Commission finds that, as expected, it is still too early at this stage to quantify the health and environmental benefits arising from implementation of the REACH Regulation. Nevertheless, the Commission notes that progress towards these objectives is materialising as key elements of the Regulation are implemented, namely registration, information in the supply chain, and authorisations and restrictions. Progress towards meeting the human health and environmental objectives of REACH is expected to accelerate as the Regulation is fully implemented. The Commission notes shortcomings in some areas in relation to quality of registration and assessments, which could impact on the achievement of health and environmental benefits, and calls on Member States, the European Chemicals Agency (ECHA) and industry to address these issues.

- The Commission recognises the difficulties faced by SMEs and proposes ways to reduce the administrative and financial burden of REACH for these companies while preserving their capacities to fulfil REACH obligations.
- 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 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 recognises 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.
- In addition, 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.

6. The Council (COMPET) held an exchange of views on 19 February 2013 on the basis of the abovementioned Commission documents and questions put forward by the Presidency.

Question for the exchange of views

In light of the overall context described above, the Presidency invites the Council (Environment) on 21 March 2013 to address the following question:

To what extent do the conclusions of the Second Regulatory Review of nanomaterials and the general conclusions of the Commission with regard to the achievement of the objectives of REACH, in particular for the environment, align with Member States' perspectives?
