COUNCIL OF THE EUROPEAN UNION

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NOTE

from:	Presidency
to:	COREPER/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" (c) Roadmap on substances of very high concern - 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 3 relevant documents: (a) General Report on REACH[1], (b) Communication on the 2nd regulatory review on Nanomaterials[2] and (c) Roadmap for the identification of all relevant Substances of Very High Concern[3].

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.

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1 doc. 5864/13
2 doc. 14869/12
3 doc. 5867/13

The **Roadmap** for the identification of all relevant Substances of Very High Concern was developed in discussion with Member States Competent Authorities for REACH. It addresses this part of the regulatory work within the Restrictions and Authorisations processes which has been left to the discretion of the Commission and Member States. The plan recognises a need for increased collaboration and effectiveness in processing candidates for Substances of Very High Concern – paving a way for these subjects to be covered by the authorisation scheme within REACH.

Commission Conclusions:

The Commission's conclusions from these 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.
- The Commission met its own objective with regard to the number of substances included in the Candidate List for Substances of Very High Concern by end of 2012. The Commission recognises the challenges in meeting its commitment to have all relevant, known substances of very high concern on the candidate list by 2020. It proposes to use the concept of Risk Management Option (RMO) for further work in this area. This approach will result in a decision on the most appropriate action for each substance. Available information will be analysed to determine whether a regulatory action is required under REACH (authorization, restriction or evaluation) or other specific legislation. To implement this Roadmap the cooperation of Member States is necessary. The Commission and ECHA have committed to continuing their provision of assistance and coordination and to share their experiences with Member States.

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?
- Roadmap: Do delegations agree with the Commission plan of assessing potential candidates for Substances of Very High Concern? What is the scope for enhanced co-operation between Member States, Commission and ECHA in the framework of this roadmap?