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*Projectleider Risico's  
Nanomaterialen*

Datum: **06 JULI 2012**  
Betreft: Note on the safety of nanomaterials

**Ons kenmerk**  
IENM/BSK-2012/126104

**Bijlage**  
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Dear Mr. Potočník,

On behalf of my colleagues from Austria, Belgium, Czech Republic, Denmark, France, Italy, Luxembourg, Spain, Sweden and Croatia I would like to bring the attached note to your attention.

By means of this note the Commission is urged to take action to guarantee the health of European citizens and the protection of the environment by ensuring that EU legislation takes possible risks associated with the production and use of nanomaterials into account.

Despite the valuable work the Commission has completed regarding a definition of nanomaterials, additional steps are required. The note outlines the discussions that have taken place within the European institutions on this subject, explains what action is needed and calls on the Commission to take the steps mentioned as soon as possible.

I have also send this letter to your colleagues the Commissioner for Industry and Entrepreneurship and the Commissioner for Research and innovation.

Yours sincerely,

THE STATE SECRETARY OF INFRASTRUCTURE AND THE ENVIRONMENT,

Joop Atsma

## **Note addressing the safety of nanomaterials**

*By means of this note, the Netherlands, Austria, Belgium, Czech Republic, Denmark, France, Italy, Luxembourg, Spain, Sweden and Croatia wish to urge the Commission to take action to guarantee the health of European citizens and the protection of the environment by ensuring that EU legislation takes possible risks associated with the production and use of nanomaterials into account. Despite the valuable work the Commission has completed regarding a definition of nanomaterials, additional steps are required. Below, we outline the discussions that have taken place within the European institutions on this subject, explain what action is needed and call on the Commission to take the steps mentioned as soon as possible.*

Nanomaterials are extremely small particles intended for a wide variety of uses. They are a driver of innovation and have great potential for a wide range of applications. However, there are clear indications that some nanomaterials may pose risks to human health or the environment. There is an urgent need for a harmonised approach to manage these potential risks.

On 20 December 2010, the Council adopted conclusions regarding environmental policy instruments that invite the Commission to evaluate the need to develop specific measures for nanomaterials relating to risk assessment and management, information and monitoring, including the further development of a harmonised database for nanomaterials, while considering potential impacts.

A Dutch note on this topic, ref. 11626/11, was tabled during the Environment Council of June 2011. The note identified three steps necessary to ensure the safety of nanomaterials:

- establish a broadly applicable definition of nanomaterials;
- ensure the traceability of nanomaterials and enable a rapid and adequate response if needed;
- develop an adequate risk assessment system and, where necessary, risk control measures for nanomaterials.

The note called on the Commission to adopt appropriate measures in this respect.

Today, one year on, we welcome the definition adopted in October 2011, and hope to see similar progress on the other two steps mentioned.

In March 2012, the Netherlands hosted a conference addressing nanomaterial safety issues with participants from 14 Member States, industry and NGOs. None of the participants considered the current situation adequate to limit and manage the risks of nanomaterials and all the participants were of the opinion that additional guidance or legislation at European level is necessary.

This is in line with the European Parliament's resolution of 24 April 2009 on regulatory aspects of nanomaterials, which called for numerous measures to reduce health and environmental risks.

Current legislation, including REACH, applies to nanomaterials but does not take adequate account of their specific characteristics. It is indisputable that there are knowledge gaps regarding both the prevalence of nanomaterials on the EU market and the risks associated with their production and use. This inhibits effective risk management, and may compromise the safety of consumers and

workers and the protection of the environment. On the other hand, improvements in legislation on nanomaterials could stimulate innovation and public acceptance.

Time is an important factor. It may take as long as eight years before an amendment to REACH takes effect. This timeline encourages Member States to develop national initiatives, even though the best option for the internal market is for legislation on chemicals to be harmonised at EU level.

One of the objectives set out in the 6th Environmental Action Programme is that by 2020 chemicals should only be produced and used in ways that do not lead to significant negative impacts on health and the environment. Despite the opportunities to take further steps within the scope of the 7th EAP, the pressing timeline necessitates early action with the aim of achieving:

- a. Better knowledge of what is on the market (e.g. which nanomaterials, products and uses). This can raise awareness among consumers and workers and will help to ensure the traceability of nanomaterials, thereby enabling a fast and adequate response if needed.
- b. An adequate risk assessment system for nanomaterials allowing risk management where needed.

We therefore call on the European Commission to take the following measures without delay:

1. Provide for adaptations to *existing legislation* (e.g. on chemicals, biocides, cosmetics, additives and labelling) to improve its application to nanomaterials, including amending relevant REACH annexes and guidance documents and, where appropriate, aligning the definition of nanomaterials with the one adopted in Commission Recommendation 2011/696/EU of 18 October 2011.
2. Propose *legislation* on registration or market surveillance of nanomaterials or products containing nanomaterials.
3. Either through *an amendment of REACH* or through *supplementary legislation*, whatever is most appropriate given the urgency, publish a proposal or an appropriate mix of effective measures that should include:
  - a solution to the current lack of a definition within REACH;
  - a review of the current tonnage levels (which determine which information is required) for nanomaterials within REACH;
  - shortening the period within which information must be obtained;
  - introducing specific requirements for nanomaterials such as characterisation and testing.

The measures to be taken should balance risks and societal, environmental and economic benefits and be proportionate, taking into account innovation and competitiveness on the one hand and environmental and human health aspects on the other.