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**NOTE**

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from: General Secretariat  
to: Delegations

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Subject: Risks associated with nanomaterials  
- Information from the Netherlands delegation

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Delegations will find annexed an information note from the Netherlands delegation on the above topic, which will be dealt with under "other business" at the meeting of the Council (Environment) on 21 June 2011.

**Risks associated with nanomaterials**  
**- Note from the Netherlands delegation -**

Nanotechnology refers to the production of extremely small particles intended for a large variety of uses. It is a cutting-edge technology with great potential in a wide range of applications, including pharmaceuticals and solar cells. In addition, various EU industries are leaders in the nanotech field.

At the same time, there are clear indications that the nanostructure of some nanomaterials may pose risks to human and/or environmental health. These are different from the risks related to the properties of the base material. Under current EU legislation and the precautionary principle, industry bears primary responsibility for the safety of its products for workers and consumers. However, current legislation is designed to assess the hazards of chemical substances used in products, such as cosmetics, but is not geared to evaluating the specific hazards related to nano-engineered particles. A key problem in this is the lack of a generally accepted definition of what constitutes a nanomaterial.

Legislation on chemicals aims to provide a high level of protection for human health and the environment, and puts the onus on industry to ensure that the substances they manufacture, use or place on the market are safe. Currently, however, many products incorporate nanomaterials without a proper assessment of the safety and risks of their nano-specific features having been carried out. With new nanomaterials coming onto the market every day, it is becoming increasingly urgent that this problem be addressed.

The European Commission has organised a workshop on the coverage of nanomaterials by EU environmental legislation. This is a first step in the right direction. Several assessments, including in the Netherlands, have shown that the coverage is not yet fully sufficient to assess and manage potential risks associated with nanomaterials. Existing EU legislation cannot adequately prevent the prolonged exposure of people and the environment to the potential risks of nanomaterials. This makes it more likely that, sooner or later, a nanomaterial will be linked to environmental or health problems. The resulting public outcry would be detrimental to the reputation and use of all nanomaterials, threatening an innovative, potentially lucrative industry and the employment it generates.

Several studies have been and are being carried out – many at the initiative of the European Commission – into the safety of nanomaterials. Even if science is not always conclusive, it is urgent that action be taken on the assessment and management of risks related specifically to nanomaterials.

The first, essential step will be to reach agreement on a broadly applicable definition of nanomaterials that covers as many materials with nanospecific risks as possible. The second step is to ensure traceability and enable a fast and adequate response should a specific nanomaterial ever be found to be hazardous. Mandatory registration of nanomaterials and products with nanoscale features would serve this purpose, and the data collected in this way would also help identify exposure scenarios, both human and environmental. These could be used in the third step: the development of an adequate risk assessment system for nanomaterials and for products with nanoscale features, and, where necessary, of risk control measures.

All three steps are essential. If, in the absence of Community action, Member States were to take these steps independently, industry could be faced with different, non-harmonised definitions of nanomaterials, different substance databases, additional administrative costs and possible market restrictions for certain materials or products. In the absence of such Community measures, however, Member State initiatives may be necessary to protect health and the environment.

In our opinion, the European Commission is in a position to take the initiative and should propose EU policy as outlined above to ensure a coherent legal framework on the risk assessment and management of nanomaterials that is consistent with both the precautionary principle and EU innovation policy.

The Netherlands calls upon the European Commission to adopt appropriate measures as soon as possible.