

Nanomaterials: Special report by the German Advisory Council on the Environment confirms BfR assessment

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Nanomaterials are increasingly used in the manufacturing industry and in products intended for consumers. However, so far little is known about their effects on human health. This opinion held by the Federal Institute for Risk Assessment (BfR) has recently been confirmed by the special report "Precautionary Strategies for Nanomaterials" of the German Advisory Council on the Environment (SRU). Nanomaterials are a great challenge. The challenge partly arises from the multiplicity of structures that are created through coating and other modifications. Since hardly any toxicological studies nor data on the effects of exposure are currently available, it is not possible at this point in time to conduct a comprehensive risk assessment of such materials, according to BfR. The BfR and the Advisory Council concur that all precautionary measures taken by the government must be based on a scientific risk assessment. The BfR therefore welcomes the precedent-setting demand of the SRU that within public nanotechnology funding, the proportion allocated to risk assessment be significantly increased.

For a risk assessment of specific nanomaterials within the framework of the regulations governing chemicals (REACH), basis data sets on the particular materials are required. In the opinion of both the BfR and the SRU, significant gaps currently exist in the basic assessment of nanomaterials. One important reason for these gaps are methodological problems in connection with test procedures for the detection of health risks and their recognition at the national and international level. In consequence, more funding should go to the development and standardisation of toxicological testing methods. International validation is a requirement for recognition by the OECD.

Apart from basic toxicological data, additional data on the potential exposure of consumers are needed. At the moment, the BfR and the Advisory Council are communicating a lack information on exposure of consumers to nanomaterials from various sources. Both institutions state that the estimation models for exposure to nanomaterials are inadequate and that they are in need of further development.

Against the background of this knowledge gap, the use of nanoscale materials in sprays intended for consumers as well as the processing of nanomaterials that may be harmful to human health in products for use by consumers in particular cause concern. Thus there are indications for various forms of carbon nanotubes (CNTs) and nanoscale titanium dioxide particles (nano TiO₂) to suggest that inhalation of these materials can cause cancer in sensitive animal models.

The BfR and the Advisory Council therefore deem it necessary to introduce a partially public product register with compulsory registration for components containing nanomaterials in order to improve risk evaluation. In the opinion of the BfR, this could be set up in the BfR following the example of the already existing product register for chemical preparations intended for use by consumers.

Akin to the Advisory Council on the Environment, the BfR sees a danger of the gap between technological development and risk awareness becoming wider. Apart from the focal points for future risk research such as long-term studies or structure-effect relationships, the BfR is of the opinion that it is necessary to develop methods and procedures that allow better

control in future of the structural variety in risk assessments while at the same time making allowance for animal rights concerns. One instrument to achieve this is the proposed “Decision Tree for Risk Categorisation”. In the estimation of the BfR, the necessity of international coordination at EU and OECD level which is necessary for the desired regulatory acceptance can be supplemented in this area.

The debate within society on nanotechnology must also be promoted and developed. In line with the participatory risk communication policy of the BfR, the SRU too emphasises the necessary transparency of both communication and assessment processes, maximum inclusion of various interested groups in the discussion on development and regulation as well as equal emphasis on the opportunities and risks associated with nanomaterials.