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Comments from Henkel KGaA to the Consultation on the SCENIHR report “The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials”

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Question 1: *Assess the appropriateness of risk assessment methodologies (effects and exposure assessment) described in the current Technical Guidance Documents of the chemicals legislation, for the risk assessment of Nanomaterials.*

Answer: We mostly agree.

We agree with the general conclusion of the SCENHIR report that the current Technical Guidance Document (TGD) is likely to be able to identify the hazards associated with the use of nanomaterials while considering additional physico-chemical characteristics.

In our point of view the document does not provide very clear guidance for the assessment of nanomaterials and many uncertainties remain.

Existing OECD test guidelines can be used for assessing different toxicological endpoints, with some modifications or improvements possibly being necessary concerning analytical and exposure measurements. The existing test methods are robust and provide useful information. We do not agree that, in general, there is an established need for new standardized ecotoxicity tests (maybe including new taxa) for nano-sized material.

Question 2: *Where current risk assessment methodology may be improved for assessment of nanomaterials, and taking into account the practical limitations of the information available for risk assessments, provide concrete suggestions for improvement of the methodology. Distinctions should be made between improvements that can be made based on current knowledge, improvements that would require specific information on the nanomaterials, and improvements that will require scientific research before they can be implemented.*

Answer: We mostly disagree.

In general, we consider that risk assessment methodology is the same for nanomaterials as for bulk materials. However, we would like to make specific comments:

For the risk assessment of nanomaterials an additional consideration of physico-chemical parameters will be necessary besides regarding the chemical composition. A very important step is to define which characteristics are necessary for the assessment of a nanomaterial, e.g. particle dimensions and size, morphology, agglomeration and aggregation, or reactivity. In this context improvements will be needed in the future concerning analytical techniques in order to describe the specific properties and to measure exposure.

We agree that highly characterized and standardized reference material will be needed. In the scientific area already some types of nanomaterials have been commonly used and there is also knowledge about naturally occurring nanomaterials, but up to now there is a lack of standardized material.

We consider validated *in vitro* assays as very important for the testing strategy. It should be distinguished between test systems of regulatory relevance and those of scientific relevance (mode of action investigations). No further *in vivo* testing should be needed, if sufficient information is gained through *in vitro* or *in silico* methods and/or sufficient data is in place for the bulk material.

For the testing itself guidance should be given on how the material can be prepared e.g. as dispersion.

We assume that improvements of existing test protocols with appropriate analytical and exposure measurements are needed. But we do not agree (as mentioned under Question 1) that, in general, there is an established need for new standardized ecotoxicity tests for nano-sized material.

For Environmental Risk Assessment, and especially the “PBT” consideration, it is important to clarify the definitions. Classically, persistence can only be determined for organic compounds. Does “persistence” in this case mean that the “nano”-dimensions are pertained?

Question 3: *Where possible, provide practical examples of how risk assessment of nanomaterials can be performed and of nanomaterials, forms of nanoparticles etc that may cause significantly different adverse effects or different exposure behaviour.*

Answer: Uncertain.

A staged approach as it is lined out in the SCENIHR opinion is generally supported for hazard and risk assessment.

Due to the current knowledge, and with regard to the broad variety of different nanostructured materials and related applications, we strongly support that emphasis should be put on a case-by-case evaluation of potential risks. There is currently no appropriate justification to consider nanomaterials per se as hazardous only due to the particle size.

The process should start with characterizing existing nanomaterials and developing relevant risk assessment parameters. Differences in characteristics and parameters that influence the behaviour and toxicity need to be worked out. New engineered nanomaterials can then be compared with existing materials already on the market (benchmarking). This makes it easier to decide if and which additional considerations might be needed for new nanomaterials.

Concerning the strategy we agree that a staged approach for the identification of possible adverse effects should have a major focus on exposure assessment which then triggers potential hazard evaluations.

We want to point out that concerning hazard identification and characterization the statement "…only limited in vivo tests may be needed" should be applied in all cases (Stage 3 in the tiered approach for Risk assessment page 55, upper part). The opportunity of no further *in vivo* testing should also be provided if no effects are observed with valid *in vitro* or *in silico* methods and sufficient data is in place for the bulk material.

The fact that certain subpopulations may be more susceptible to adverse effects is a general truth and does not specifically apply to nanomaterials (mentioned on page 51, lower part). Also the topic of tissue distribution is an important aspect for both non-nanoscale and nanoscale substances. Therefore, these issues should not be stressed especially with regard to nanomaterials. The same applies for the statement that effects on risk can be caused by adsorption of other chemicals onto the surface of nanomaterials. This is not exclusively the case with nanomaterials but can also happen with bulk material.

It has to be kept in mind that there are several scientific projects ongoing that should be considered before finalizing such a decision framework, because new experience will be gained within the next years and data will be useful for risk assessment purposes.