Report

Assessment tools for nanomaterials

Discussion and results of the German NanoCommission's work and the Stakeholder Dialogue „Risk management in the nano world"

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Content

1 Introduction

Since 2006, the German Ministry of the Environment, Nature Protection and Nuclear Safety (BMU) supports a continuous information and experience exchange between stakeholder groups with the German NanoDialogue. In this context the German NanoCommission was appointed in order to consult the German federal government on the responsible use of nanomaterials. Stakeholders from industry, science, authorities and civil society groups were involved in the discussions and have contributed to the final reports and recommendations.

The NanoCommission worked in two consecutive dialogue phases (2006 – 2008 and 2009 – 2011). Selected topics were discussed in-depth in working groups. At the end of the second dialogue phase, the NanoCommission recommended to continue the discussion in form of topic-focused events. The organisational set-up of the third dialogue phase was therefore changed respectively. The current third dialogue phase started in December 2011 and ends in November 2012.

The first two-day FachDialogue[1] was held under the topic “Risk management in the nano world”. Approximately 20 representatives of different interest groups took part and discussed the relationship between preliminary assessment tools for nanomaterials and nanoproducts and the regulatory framework. In addition, options to promote the use of preliminary assessment tools were discussed.

This report summarizes the development process of preliminary assessment tools for nanomaterials and nanoproducts[2] by the NanoCommission and its working groups. It also includes the results of the first FachDialog “Risk management in the nano world”. The German version of the report contains a second part, which is a short guidance document to support the selection of preliminary assessment tools for nanomaterials and nanoproducts. Since this guidance only supports the selection of German tools, it is not translated to English.

[1] Three further events are planned in 2012 on other nanotechnology topics.

[2] The development of the Swiss Vorsorgeraster and the nano sustainability check are not described, because they were not developed in the frame of the stakeholder Dialogue.

2 Development of tools

The development and use of preliminary assessment tools for nanomaterials and nanoproducts[3] was continuously and intensively discussed in the previous two phases of the NanoDialogue: with view to the partial information gaps on possible hazards and exposures to nanomaterials, it was intended to generate an opportunity to implement a preliminary risk management based on the precautionary principle. This required preliminary assessment tools to support decision making. In addition, it was intended to provide orientation to companies at an early stage in the development of nanomaterials and nanoproducts and make a first judgment on the sustainability of their products.

The assessment tools of the NanoCommission do not replace a scientific risk assessment and should be understood as possibility to make a preliminary assessment of potential critical or desired impacts of the materials and products. If scientific risk assessments are available, the instruments are not applicable[4].

2.1 'Concern-criteria' and 'no cause for concern-criteria'

A working group of the NanoCommission had developed 'concern-criteria' and 'no cause for concern-criteria' in the first dialogue phase for a preliminary assessment of potential risks from nanomaterials in order to support risk management decision making in technology development[5]. For the specific areas of application under assessment, the 'concern-criteria'[6] can indicate whether a nanomaterial is problematic. The 'no cause for concern-criteria'[7] can indicate in which application areas risks are likely to be low.

The importance of the criteria for risk management decreases with increasing knowledge about the effects and the expected exposures. In the following the criteria are briefly introduced[8].

[3] Nanoproduct means mixtures and articles which contain nanomaterials.

[4] The preliminary assessments involve conservative assumptions. Therefore, they may indicate critical application areas or risk aspects which are refuted by scientific risk assessments due to the use of more specific information.

[5] The overall goal of a thorough assessment of the use of nanomaterials based on scientific risk assessments is not put into question by this.

[6] High exposures and/or persistence in the environment, indications of problematic effects or difficulties in the analysis and tracing of released nanomaterials are regarded as causing concern.

[7] It is regarded as relief, if nanomaterials in a specific application are permanently embedded in a matrix or quickly lose their possibly problematic nano-specific properties, e.g. by solution or degradation.

[8] The report of working group 2 contains an extended presentation (http://www.bmu.de/files/pdfs/allgemein/application/pdf/nanodialog08_ergebnisse_ag2.pdf).

’No cause for concern-criteria’[9]

A ‘no cause for concern-criterion’ is the loss of the nanomaterial’s nano-specific properties. This can be indicated by different aspects, such as a high solubility, rapid degradability to non-toxic degradation products, firm and enduring incorporation in matrices, the existence of firmly bound aggregates or the formation of large and stable agglomerates.

In addition, nanostructured modifications on surfaces which don’t release particles and are not reactive are regarded as of lower concern.

‘Concern-criteria’

The ‘concern-criteria’ are separated into three areas: exposure, problematic (hazardous) effects and difficulties in risk management.

- Indicators of high exposure are e.g. the production and use volumes for a specific application, a high mobility of the nanoform, targeted release, persistence of nano-specific properties and bioaccumulation.
- Problematic effects are amongst others indications for a high reactivity and for problematic morphologies, interactions, transformations or metabolites.
- Indicators for problems in risk management are e.g. a low detectability and an unclear fate.

The NanoCommission recommended[10] that enterprises use the criteria for orientation but stated that they should be further operationalised and weighted. The NanoCommission proposed in addition to categorise nanomaterials in three groups of risk (risk is probable, possible or not likely). Each risk group should be linked with risk management measures[11].

2.2 Tools for the preliminary assessment of nanomaterials and nanoproducts

In the second dialogue phase of the NanoCommission two assessment tools for nanomaterials and nanoproducts were developed by two different working groups. In this process the ‘concern-criteria’ and the ‘no cause for concern-criteria’ of the first dialogue phase as well as the experience with the Swiss Vorsorgeraster were integrated. A project on the development of an instrument to assess the sustainability of nanoproducts (nano sustainability check) which

[9] The criteria are quoted as they were adopted in the first dialogue phase. Some of the criteria are currently not regarded as relieving, such as the indicator solubility.

[10] Final report of the first dialogue phase, p. 51: „It recommends that businesses estimate the risks […] as accurately as possible. The 'Concern-Criteria' and 'No cause for Concern-Criteria' determined by Working Group 2 should act as a guide for preliminary assessments. They should be rendered operational and weighted during the second phase of the NanoDialogue.

[11] It was not possible to implement this during the first dialogue phase.

was conducted at the time of the 2nd dialogue phase was also considered in the work of the working groups.

The results of the two working groups – a set of criteria for the assessment of impacts of nanomaterials and a catalogue of criteria for the comparison of risk and benefit aspects of nanoproducts – should be understood as orientating support for enterprises.

2.2.1 Criteria for the assessment of impacts of nanomaterials on humans and the environment

In the second dialogue phase the Working Group 4 developed a set of criteria to be applied by "informed users" in an early phase of product research and development in order to assess potential impacts of nanomaterials on humans and the environment in different applications. The set of criteria is based on the 'concern-criteria' and 'no cause for concern-criteria' of the first dialogue phase and can be used even if only few data are available.

Apart from the adaptation to the scientific progress the 'concern-criteria' and the 'no cause for concern-criteria' were simplified and specified by indicators by which to evaluate the need to take precaution. The new set of criteria is structured into the areas "possibility of exposure", "physical-chemical properties", "environmental fate" and "toxicology/ecotoxicology". They cover different subjects of protection and apply to all lifecycle stages. As a result of using the set of criteria, data gaps are presented and a first, qualitative evaluation of the necessity to conduct further assessments or to implement risk management measures is supported.

The work on the criteria could not be finalized in all aspects. Amongst others a concluding discussion about the weighting of the criteria as well as definitions of some unclear terms are missing as of the current day. Furthermore, assistance in the derivation of risk management measures in relation to the results of the application of the criteria is missing.

The Working Group 4 therefore recommended collecting experience with the application of the criteria, offering support to enterprises for the interpretation of the results and promoting an experience exchange on the use of the instrument. In addition, the criteria should be integrated in a larger context, such as the principle for the responsible use of nanomaterials developed in the first dialogue phase.

2.2.2 Catalogue of criteria for the comparison of risk and benefit aspects of nanomaterials and nanoproducts

In the 2nd dialogue phase the Working Group 2 developed an extensive catalogue of criteria to present different risk and benefit aspects of nanomaterials and nanoproducts. The catalogue of criteria can give orientation to enterprises in the development of their products. It is also regarded as instrument to structure a stakeholder dialogue on nanoproducts, according to the working group.

For the areas ‘environment’, ‘workers’, ‘consumers’, ‘society’ and ‘companies’ criteria are proposed, which are relevant with regard to the production, use and disposal of nanomaterials and nanoproducts and which allow an assessment of potential risks and benefits.

The assessment is performed as comparison to a reference product which does not contain any nanomaterials with the categories ‘better as’, ‘equal to’ or ‘worse than’ the reference product. The criteria concern all lifecycle stages. The evaluation is qualitative. The catalogue of criteria was tested using different examples during the development phase.

A specific characteristic of the catalogue of criteria is the coverage of the nanoproducts’ benefits and the integration of the areas ‘society’ and ‘companies’. Thereby it operationalises aspects of sustainability. However a weighting of these areas and a concrete description of the criteria could not be concluded and therefore respective further work was recommended to be implemented by the working group. It was also regarded as important to make the catalogue of criteria known to a wider circle of stakeholders, to integrate it into a wider context and to implement it as an IT-tool[12].

3 FachDialog 1 on “Risk management in the nano world”

In December 2011 a two-day stakeholder workshop (FachDialogue) was organised in the frame of the third dialogue phase in order to discuss the embedding and further use of the tools for a preliminary assessment of nanomaterials and nanoproducts. The 20 representatives of different stakeholder groups participating in the event agreed that the orienting assessment tools are a useful complement of the regulatory frame.

It was confirmed again that the assessment questions are very complex, amongst others due to the large variety of nanomaterials and their uses, the size of the information gaps, the different user groups of instruments and their specific assessment interests.

Two functionalities of preliminary assessment instruments were seen as especially helpful by all stakeholders:

- Use by enterprises as early decision support in the development of products and
- Use as format for communicating with the general public about aspects of possible (benefits and) risks of nanomaterials and products

[12] The tools are published on the website of the German association of nanotechnology (http://www.dv-nano.de/infoportal/instrumente.html).

It was discussed that the thoroughness of an assessment of nanomaterials and nanoproducts before placing on the market does not differ depending on the size of an enterprise. Hence, also the use of the assessment instrument does not depend on the companies' sizes.

The participants of the FachDialogue recommended further promoting the instruments. The establishment of a central contact point, which "takes care" of the tools and collects and evaluates potential questions and feedback from the users was regarded as helpful and necessary[13].

It was furthermore stated that the topic 'sustainability' should be included in the future stakeholder workshops and integrated into the German research strategy.

4 Outlook

The assessment tools of the NanoCommission as well as the nano sustainability check and the Swiss Vorsorgeraster are characterised in a comprehensive format and are made available on the website of the German association of nanotechnology. This should increase the publicity of the instruments. This is supported by active communication within the German chemicals industry association (VCI) and the German Industry Association (BDI) as well as their member associations.

[13] This function is now performed by the German association of nanotechnology (http://www.dv-nano.de).