FINAL REPORT OF NANOKOMMISSION ISSUE GROUP 2

GUIDELINES FOR COLLECTING DATA AND COMPARING BENEFIT AND RISK ASPECTS OF NANOPRODUCTS

Second Dialogue Phase, 2009 – 2010

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CONTENTS

1 Remit

In the NanoKommission's first dialogue phase, a number of nanoproducts were characterised according to their potential risks and benefits. As it was difficult to compare and interpret these descriptions, it was recommended that work in this area should be pursued in the second dialogue phase.

Issue Group 2 was therefore assigned the task of developing a method that would allow the **potential** benefits and risks of nanoproducts to be systematically identified, transparently described and assessed. The assessment tool was to be designed so that a variety of user groups would be able to apply it, and at least two examples of products were to be used as test cases.

As an outcome of this work, Issue Group 2 put forward guidelines for collecting data and comparing benefit and risk **aspects** of nanoproducts throughout their life cycle and tested these on the basis of example products. Owing to constraints on time and resources, as well as difficulties in developing objective, broadly applicable methods of assessing the parameters, the Group was unable to fulfil its remit to produce a "comprehensive assessment methodology" including evaluation indicators. The list of criteria should therefore not be viewed as a (definitive) evaluation tool, but rather as an aid for preliminary appraisal of the benefit and risk aspects of nanoproducts and as a tool for promoting transparent, objective stakeholder discourse.

2 Findings of Issue Group 2

Issue Group 2's Guidelines for identifying and comparing benefit and risk aspects of nanoproducts consist of the following components: a product profile characterising the product to be assessed, a list of criteria enabling systematic identification of benefit and risk aspects selected by the Issue Group as being representative and generally applicable, and guidance relating to procedures for assessing a product and presenting the results.

In some instances compromises had to be struck in order to arrive at a solution that enjoyed the backing of all members of the Issue Group. Section 3 gives details of some of the discussions relating to these.

2.1 Target group

The Guidelines can be used by a variety of groups:

- Companies/product development: for preliminary assessment of benefit and risk aspects of new products
- Companies/marketing: for transparent communication of the benefit and risk aspects of nanoproducts
- Public authorities: for assessing products for compliance checking or licensing purposes, and for the granting of funding for research and development projects
- NGOs: as a basis for making positive or negative recommendations regarding nanoproducts and for communicating with companies, public authorities, the media and the general public.

2.2 Objectives

The Guidelines are intended first and foremost to provide a framework for stakeholder debate on the potential benefits and risks of nanoproducts. In order to do this it is essential that the method should be available to the general public, that the results should be disaggregated, and that it should be possible to query any appraisal published. This applies both to products already on the market and to the setting of development goals for future product development.[1]

As a result, the Guidelines are only able to provide preliminary pointers, as the benefit and risk aspects have not been assessed against indicators or weighed up against each other. More detailed and more comprehensive tools (e.g. life cycle assessment, regulatory risk evaluation) are required in order to conduct a full evaluation of the benefits and risks. One possible outcome of applying the Guidelines may be to prompt the user to obtain additional information or initiate a more detailed evaluation, preferably taking into account the criteria established by NanoKommission Issue Group 4[2].

Use of the criteria does not equate to conducting a risk evaluation, and hence they cannot be used as a basis for making statements concerning risks. The intention is to consider various aspects of benefits and risks. The Guidelines are not intended to establish a link between hazardous properties and exposure; there are already well-established methods of scientific evaluation for doing this.

If scientific risk evaluations are already available, the Guidelines need only be used to consider the risk aspects relating to society and the company, and where the areas of environment, consumers and occupational safety are

[1] The materials have been developed principally for assessing finished products which contain nanomaterials. They may also be applied, however, to nanomaterials, for example, to identify potential applications for these where the risk-benefit ratio is good.

[2] The list of criteria drawn up by Issue Group 4 is available online at www.bmu.de/47547.

concerned, reference should be made to the relevant findings of the scientific risk assessment. If a nanomaterial is known to have no hazardous properties throughout the supply chain, it is nevertheless sensible to examine the risk aspects for society and the company, as well as the benefits.

2.3 Product profile

The product profile is generated by the user to characterise his/her finished product and the nanomaterial used in it by assembling the available information on the product, e.g. from the Safety Data Sheet or other product information sources (own information and information provided by the supplier). In addition, details are given of the reference product[3] used as the basis for comparison of the nanoproduct's benefits, together with the reasons for choosing it. The product profile asks for information on the following parameters:

Parameters concerning the nanoproduct:

- Designation of the product and technical functionality of the finished product
- Specification of the functional unit
- Function of the nanomaterial in the product
- Reference product and rationale for its selection

Parameters concerning the nanomaterial used:

- Name of the nanomaterial and its manufacturer
- Information on the value chain
- Form factor, particle size and particle size distribution
- Surface functionalisation and coating
- Information from the Safety Data Sheet and available scientific research studies (e.g. on toxicity and ecotoxicity)
- Other special features or characteristic properties

2.4 Criteria

The list of criteria is available in the form of an Excel file, and is subdivided into a spreadsheet containing benefit-related criteria and two spreadsheets containing risk-related criteria. Each set of criteria is divided into five categories: "environment", "consumers", "employees", "society", and "company". In each category up to another six different criteria are listed, some of which are further divided into sub-categories. The criteria list is not exhaustive, but rather represents various aspects of the potential risks and benefits of nanoproducts identified by the Issue Group as important.

[3] A product that has the functionality in question, but is manufactured without the use of nanomaterials. This product is used as the basis for comparison of the benefit aspects of the product undergoing assessment.

For each of the criteria in the list the following information is given:

- Designation of the criterion
- Explanation of what is meant by the criterion; examples or specific questions addressed to the user
- Phase(s) in the product's life cycle to which the criterion applies (marked "x")[4]
- Parameter to be determined for testing the criterion, e.g. energy consumption (in qualitative or quantitative terms)
- Means by which the parameter is to be measured, e.g. information sources that may be used.

The spreadsheets containing the criteria are intended solely to help structure information-gathering, and not as a means of presenting findings.

2.4.1 Criteria for benefit-related aspects

Within the five categories in the list of criteria for benefit-related aspects, a number of "core" criteria are listed prominently. Responding to these core criteria is mandatory for all users. Below the core criteria, additional, more specific criteria are also listed. These provide additional, complementary information on important benefit aspects that depend on the particular product type and may not be covered by the core criteria. Assessment of benefit-related aspects is based on a comparison with a reference product. The core criteria are:

Benefits for the environment

- Reduced resource use: energy
- Reduced resource use: water
- Reduced resource use: raw materials
- Prevention of greenhouse gas emissions
- Reduced emissions of pollutants
- Reduced waste volume and hazard

Benefits for consumers

- Products with improved functionality
- Products with improved safety in use (including protection from disease)
- Consumers benefit from improved cost-benefit ratio for products

Benefits for employees

- Advantages resulting from simpler or safer handling
- Health protection in the workplace (risk management)

[4] As a fundamental principle, the entire product life cycle must be assessed. For some criteria and categories (e.g. "consumers"), however, only certain segments of the product life cycle are relevant. In the list of criteria, relevant sections are indicated with a cross ("x") in the columns headed "Production", "Use" and "Disposal".

Benefits for society

- Lower costs for protecting health and the environment
- New skilled job opportunities, job security
- Better product performance; improved export opportunities, improved market position and competitive edge

Benefits for the company

- Creation of new markets, enhanced competitiveness
- Improved product quality and performance
- Reduced costs, e.g. by optimising production processes
- Improved work and process safety

2.4.2 Criteria for risk-related aspects

In the categories concerning the environment, consumers and employees, the criteria on risk-related aspects were centred on gathering information on potential emissions and exposures[5]. It is not necessary to provide quantified data here, but it may be included if available. Basically the intention here is that if the information suggests that emissions and exposures could occur, more detailed assessment should be carried out on the basis of the criteria drawn up by Issue Group 4.

Potential ethical and economic consequences arising from the manufacture and placing on the market of nanoproducts should be shown in the criteria on the relevant risk-related aspects for society and for the company. In the case of many nanoproducts it is likely to be difficult to provide a response on these issues. However, it is considered important to reflect on these aspects as part of the debate on sustainability. The criteria for risk-related aspects are:

Risk aspects for the environment

- Volume used annually in the product
- Probability of emissions
- Measures to reduce emissions
- Probability of exposure affecting environmental media: water, soil, air

Risk aspects for consumers

- Amount used in the product
- Use by the consumer
- Probability of emissions
- Measures to reduce emissions
- Potential exposure routes

Risk aspects for employees

- Amount used in the workplace
- Probability of emissions
- Measures to reduce emissions
- Checks on the effectiveness of measures

[5] For a discussion of the rationale behind this, see also sections headed “Key discussions” on target group, risk-related aspects and on defining the boundaries of this Issue Group’s work in relation to that of Issue Group 4.

- Probability of exposure – presence of employees
- Probability of exposure – measures to minimise exposure
- Probability of exposure – effectiveness of measures

Risk aspects for society

- Potential external costs for society (health/welfare system and/or ecosystem)
- Threat to peace within society
- Incorrect use
- Risks to the national economy
- Social impacts of the product

Risk aspects for the company

- Loss of image
- Financial/economic losses
- Uncertainty of long-term strategies; risks of investment

2.4.3 Using example cases to test the applicability of the criteria

The applicability of the criteria to benefit/risk considerations was tested using five example products while the Guidelines were being developed. These included products already on the market (a glass cleaning product, PET bottles, awning fabric), products in development (a textile cleaning product) and materials in the very early stages of development (wind turbine rotor blades made from materials containing carbon nanotubes (CNT)). All the examples provided valuable insights into the applicability and limitations of the criteria. These were fed back into the subsequent stages of the Issue Group's work.

To illustrate what the results of a test might look like, two of the five example cases were worked through in full for publication based on the most recent version of the criteria list (see Annexes 4 and 5). These were:

- Awning fabric incorporating nanomaterial
- PET bottles with nanoscale titanium nitride

The two examples showed that in principle the product profile and list of criteria are an appropriate means of obtaining a largely qualitative overview of benefit and risk-related aspects of the products assessed. They also showed that it is possible within a reasonable timeframe to obtain a relatively comprehensive, conclusive and clear picture of benefit and risk-related factors.

According to the data provided for both example cases, it is unlikely that the environment, consumers and employees will be exposed to risk. No risk-related aspects were identified for society or for the company. The data on benefit aspects have been kept somewhat short and fairly general. This is largely due to the limited time devoted to the exercise in an effort to minimise the time demand on the participating manufacturers. More detail could be included without much more time input, if so desired, in subsequent stages of the work.

Those working on the example cases reported unanimously that working through the list of criteria had made them more aware of some of the benefit and risk-related aspects of their products. With regard to benefit aspects, comparison with a reference product was viewed as helpful, since it enabled more accurate appraisal than attempting to establish benefit in absolute terms. In this respect confirmation that a product has a benefit allows an initial opinion can be formed and can act as a preliminary decision-making aid for product developers.

In the view of those who worked on the example cases, some of the criteria are formulated in a way that could still give rise to misunderstandings. Likewise it was felt that in some instances, the responses “probably yes” and “probably no” are not very meaningful. Many of the questions cannot be answered quantitatively and gathering the information is perceived to be somewhat laborious.

Work on the other examples revealed that, in terms of enabling sound and comprehensive consideration of benefit and risk-related factors, the list of criteria was only of very limited use in the case of products still in development, where an established supply chain down to the finished product does not yet exist (e.g. in the case of the wind turbine rotor blades made from materials containing CNT). The individual criteria still proved useful, however, as a precautionary evaluation of products for a company’s internal assessment of a product’s state of development, helping to draw attention to potential risks and prompt further testing (e.g. in the case of the textile cleaning product).

It became clear in this course of this work that the criteria are not applicable to products for which a company has already obtained a scientific risk evaluation (e.g. in the case of the glass cleaning product). This is because the risk aspects only partially cover the sections of a risk evaluation. The results obtained in this way are not meaningful and can potentially give rise to false interpretations.

In the end, as a result of these considerations, only two of the five example cases used to develop the criteria have been included in the Report. The environmental and consumer associations are disappointed by this, as they felt that all of the sample cases made an interesting contribution to the development of the criteria set, and that these results should be made public in the interests of transparency. The companies concerned decided against publication in part because it was not possible to carry out a complete assessment, and to prevent misinterpretations resulting from incomplete presentation of the information.

2.5 The Guidelines and presentation of findings

The Guidelines set out the purpose of using the criteria and an overview of potential user groups and cases in which the Guidelines should be applied. A detailed step-by-step guide to applying the criteria is provided, including how to

select a reference product for assessing benefit-related factors. The instructions also contain definitions of key terms used.

3 Key discussions in the Issue Group

Below we present some of the key points from the Issue Group's many discussions on matters of substance.

3.1 Target group and when to apply the Guidelines

On several occasions, discussions in the Issue Group focused on potential user groups and their requirements in terms of assessing benefit and risk factors, as the nature of the target group determines both its level of (scientific) knowledge regarding nanomaterials and nanoproducts and the nature and depth of detail of the information to which the group has access. Both of these affect which criteria are meaningful (information has to be available to the user in principle) and how they are formulated (the user has to understand what information is being gathered and why).

When the Group first began working, no distinction was made between different potential user groups. By the end, our position has shifted somewhat, as the Guidelines are now tailored to the "informed user" in terms of the nature of the information to be gathered and the level of knowledge users were assumed to possess. The target group "manufacturers of nanoproducts" is the only one which in theory has access to all the information; other user groups are generally only able to assess the factors, especially relating to manufacturing and production, for example, if they collaborate with product manufacturers.

In its role as a dialogue tool, the Guidelines can be equally valuable for all user groups: manufacturers of nanoproducts can use the Guidelines for the purpose of providing information. Other stakeholders can scrutinise this information by comparing it with the criteria and explanatory notes, and with the appraisals and procedures of other product manufacturers.

3.2 Purpose of the Guidelines

The Issue Group was unable to fulfil its NanoKommission remit, namely to develop an instrument for ASSESSMENT of the potential benefits and risks of nanoproducts. Attempts were made to do so at the outset, but over the course of many discussions this was repeatedly found to be impossible at the present time. Particularly as regards obtaining a picture of risks, extensive information on hazard and exposure would need to be considered in order to make a conclusive assessment. However, this cannot be done by means of one easy-to-use tool for different user groups. It was agreed that close consultation was needed with Issue Group 4, as they were exploring questions relating to risk factors in more depth.

In the course of the Group's work it became increasingly clear that the sheer number and variety of nanoproducts makes it difficult to develop a method and criteria for assessment that can be applied to all products and applications. As the assessment of benefit and risk factors depends on the nature of the product and how it is used, it is impossible to identify indicators for "high/low benefit" or "high/low risk" in the abstract. It is therefore also impossible to weigh the various benefit and risk aspects against each other in the abstract. For this reason, the Issue Group also rejected the idea of linking benefit and risk aspects to produce an "automatic benefit-risk ratio statement" for a nanoproduct.

Issue Group 2 therefore amended the purpose of the Guidelines to the effect that they should be on the one hand a tool for gathering information and making a preliminary appraisal, not a comprehensive assessment, and on the other can be used in the dialogue process to create transparency, which is the basis for objective debate.

3.3 Risk-related aspects

The Issue Group debated the use and meaning of the terminology used in connection with "risk" in different contexts. These debates were triggered repeatedly both by the title of the Issue Group and the "risk"-related criteria, and by the task of "assessment".

It became clear that the stakeholders in the Group have different ideas and perceptions in relation to the term. Research-oriented institutions tend to define "risk" as a fundamentally quantifiable product of hazard and exposure; for them the concept does not in itself have any negative associations, as it is also possible for risks to be so low as to be negligible.

The Group's members were unanimous with regard to the importance of adopting terminology that makes it clear that the Guidelines are not intended to provide or replace a scientific or regulatory risk evaluation. In addition, it should be evident that the Guidelines are to be seen either as an initial, non-definitive assessment to provide the user with general information regarding his product,

or as a means to create transparency regarding benefit and risk-related factors and thereby facilitate debate.

As regards the criteria relating to risks for society and risks for the company, the Group debated the status these should have in the comparison, as they are not often discussed and it is difficult to collect information on and assess these aspects. In the end they were left in the Guidelines as many Issue Group members felt it was important for users of the catalogue of criteria to debate these issues. Questions relating to use of nanoproducts for military or criminal purposes, and to potential misuse of nanoproducts were also put forward in the course of these discussions. As it is unlikely that answers to these questions will be forthcoming, they were not included in these Guidelines.

In connection with the title of the Guidelines and the criteria relating to “risks”, the terms “concern” and “hazard” were also discussed. These, however, were perceived as conveying a stronger value judgement and as being less clear in terms of reflecting the intention of the criteria. The Issue Group agreed on the use of the terms “risk(-related) aspects” and “benefit(-related) aspects” as a way of distancing the Guidelines from the concept of the “risk evaluation” and of making it clear that only certain aspects of “risk” were being considered.

3.4 Criteria for benefit-related aspects

Establishing criteria on benefit-related aspects was a relatively quick process. Describing and formulating them took rather longer, however. Because the number of possible criteria was so large, it was decided to divide them into “core criteria” and “additional criteria” to make the system more user-friendly. In making this distinction it was seen as important that the core criteria apply in principle to all nanoproducts. The Issue Group members did not support the idea of weighting the different benefit-related criteria in relation to each other. However, the core criteria stand out by virtue of the fact that they are applicable to all products and must be addressed to ensure comparability of different products. By making the core criteria a fixed component of every assessment, the aim is also to prevent users from addressing only those criteria that show the given products or uses in a positive light.

3.5 Criteria for risk-related aspects; defining the boundaries between the work of Issue Group 2 and Issue Group 4

The formulation of the criteria on risk aspects relating to the environment, consumers and employees was guided by a variety of considerations:

- Estimating the hazardousness of nanomaterials requires considerable expertise, which the intended users of the Guidelines cannot be assumed to possess.
  The Issue Group therefore agreed that this information, where it is available or can be provided by the supplier, should be included in the product profile but without being linked to exposure or use of the products.
- Estimating potential exposures requires quantifiable information on exposure levels that is very rarely available to the user. It cannot be assumed that the intended users have the expertise needed to evaluate the information.
  The Issue Group agreed to use the list of criteria to gather data on potential emissions and exposures as a basis for more detailed examination. Where there is an indication that relevant emissions / exposures may arise, the user should then draw on other instruments.

The discussions relating to defining the boundaries between the work of Issue Group 2 and Issue Group 4[6] helped to develop and refine the decisions described above. As a result it was decided that the focus of Issue Group 2 should be to answer the following three questions:

- What information is available on the material used?
- What is the likelihood of release/emissions from the product?
- Could exposure occur, and if so, what sort?

Under the Guidelines, this information is collected and sometimes estimated by the user him/herself, but no benchmarks are provided for doing this. Under the procedure set out in the list of criteria produced by Issue Group 4, on the other hand, an attempt is made to evaluate the information to establish any need for "Further consideration / Need for precautionary measures / Cause for concern", or whether there is "No immediate need for precautionary measures / No cause for concern", and in some cases corresponding assessment indicators are proposed.

[6] Assessment of nanomaterials in terms of their impact on humans and on the environment.

3.6 Products used as example cases

Examples of products were selected on the basis of the following criteria:

- The example cases should be products aimed at consumers and should cover as many different potential exposure routes as possible (dermal, oral, by inhalation)[7]
- Example products should test the applicability of the proposed criteria and their ability to provide meaningful results,
- It should be possible to publish the results of the trial run in order to illustrate the sort of conclusions that can be drawn about a product by applying the list of criteria.

The process of selecting products for this purpose proved more difficult than initially anticipated. Companies declining to participate in the project cited reasons such as stakeholder dialogue being time-consuming, the method not being adequately developed or well enough established, or the fact that it was unclear how the findings would be used. Lack of time or capacity, and the lack of any tangible benefit to the pilot users of the system were also given as reasons for not participating. We did, however, manage to recruit companies to the project.

Selected example products

1) Fabric sunscreen

Nanoproduct: Fabric sunscreen

Product status: product already on the market

Expected benefits: Longer-lasting product; improved appearance (warm light resulting from increased translucency); companies can produce the fabric autonomously, as the finish can be applied in their own production process. Reduced cleaning frequency and cleaning product use.

The fabric sunscreen manufactured by Schmitz-Werke GmbH & Co. KG consists of a woven fabric made from polyester (PES) filament yarn, to which a surface-structuring finish is applied + fluorocarbon (non-nano). This finish, called SNC (Swela Nano Clean), makes the fabric water and dirt-repellent. The base material used for the nano-finish is pyrogenic silica.

2) PET bottles with nanoscale titanium nitride

Nanoproduct: PET bottles with nanoscale titanium nitride

Product status: Product already on the market

Expected benefits: Processing of PET plastic for food packaging is more energy and time-efficient.

[7] Establishing potential consumer exposure to nanomaterials by every possible route was considered especially important by the NGOs in the Issue Group.

PET plastics mixed with nanoscale titanium nitride (TiN) can be heated more quickly and energy-efficiently and hence can be moulded into bottles more easily than conventional PET material without the addition of TiN. In this case nanoscale TiN functions as a highly heat-absorbent compound.

Examination of the PET bottles was carried out by the Fraunhofer Institute for Process Engineering and Packaging (IVV), and does not relate to a specific product from a specific company.

During the Issue Group's work phase there were some changes to the products used as example cases. The "fabric sunscreen (awnings)" was selected as an example product at the outset and its examination completed, while the second example product, "wind turbine rotor blades", was selected by the NanoKommission but not made available for publication. Other example products were added later (PET bottles, nanosilver in protective work clothing, and a glass cleaning product), but with the exception of the PET bottles these were dropped before the end of the project or not selected for publication.

In addition, towards the end of the Group's work phase it became apparent that the products used as example cases were not all equally suitable for a full-scale trial run of the criteria. For example, the criteria set proved to be of limited use for the wind turbine rotor blades, which were still at the development stage.

4 Conclusions and recommendations

4.1 Work process

As a whole, participants felt that the work carried out by Issue Group 2 was fruitful and worthwhile, but pressure of time was immense. Many discussions were started but not concluded, and several steps in the work process had to be handed over to working groups. Examination of the example products did not commence until work on the criteria was completed, and it had not been possible for the Group as a whole to discuss them. Consultation on areas that overlapped with the work of Issue Group 4 could not be carried out in full owing to pressure of time and to the fact that each Group needed to focus primarily on its own priorities and results. The Group was not in favour of integrating Issue Group 4's criteria into the Guidelines in their entirety.

It should also be noted that the tasks which required most discussion, namely identifying and defining criteria and examining example cases, are not necessarily tasks to be carried out in stakeholder dialogue, which should focus instead on evaluating how experts' work in these areas translates into the relevant social context. Moreover, neither companies nor environmental and consumer organisations were able to dedicate enough working time to the task in hand, as inadequate funding had been allocated for this purpose.

4.2 Findings and outlook

The list of criteria and the Guidelines that go with it are complete, stand-alone products of Issue Group 2 and are useful for obtaining a basic assessment of a nanoproduct and for providing a structure for stakeholder dialogue. As far as assessing the potential benefits and risks of nanoproducts is concerned, however, these tools are only a first step and need to be more thoroughly tested and, if possible, quantified. Further measures – such as a detailed risk evaluation – must be taken, particularly for identifying a potential risk (e.g. where exposure cannot be ruled out). Additional steps would also be required to develop a tool allowing an assessment of benefit and risk-related aspects to be obtained that was reliable enough to have legal consequences.

Work on the example products showed that the criteria are basically fit for purpose as a tool for formulating initial statements regarding the benefit and risk aspects of a nanoproduct which can be understood even by the general public. This work also demonstrated that there was a direct benefit to the manufacturer of the product resulting from the intellectual exercise of assessing the information on the product. The discussion surrounding publication of the case studies also revealed that there is considerable interest in transparent communication and focused debate on the benefit and risk aspects of nanoproducts on the part of all the stakeholders. Nevertheless, the Guidelines and criteria need to be improved in several respects to optimise their application and refine what they can tell us.

The Issue Group is very much in favour of continuing work on these areas. Participants felt that more work is needed especially to develop the criteria on risks for society and the company, as the Group was not able to discuss these fully and so the criteria cannot be considered definitive as they stand at present.

Further development of these areas could lead, for example, to establishing a user-friendly, IT-based tool presenting benefit and risk factors and, where appropriate, a basic assessment of them. It was felt, however, that this could best be done in a project-based framework; scientific research institutions, for example, could develop the criteria further, while weighting of the criteria or social contextualisation could be done in a stakeholder dialogue, if so desired.

4.3 Implementing the Group's findings

All participants in the Issue Group affirmed that a tool for identifying and comparing benefit and risk aspects of nanoproducts is helpful and desirable. Whether, how and for what purpose the Guidelines will be actually used in practice will depend, among other things, on how the findings of the NanoKommission and its Issue Groups are publicised. To enhance their implementation the Issue Group recommends:

- Incorporating the use of the Guidelines into the implementation of the "Principles for the responsible use of nanomaterials"[8], for example, to communicate information on nanoproducts and to support stakeholder dialogue
- Publicising the instrument as a basic tool for assessing benefit and risk aspects associated with nanoproducts, and helping users to draw practical conclusions from the results
- Familiarising government departments and sectoral authorities with the use of the Guidelines, and gathering experience with their application; where appropriate, this should feed back into the continuing development process
- Integrating into the Guidelines the findings of the project "Sustainability check for nanoproducts,"[9] or recommending that the Guidelines be used as a "precursor" to the sustainability check
- Developing the Guidelines and criteria further, particularly as regards benefit and risk aspects for society and for the company, based on dialogue and on companies' experience of using them. It would be important to appoint a body or organisation as soon as possible to take charge of developing these areas
- Introducing the Guidelines into the international debate, for example in the context of the Swiss Precautionary Matrix, investigations into the "Environmentally Sustainable Use of Manufactured Nanomaterials" by Steering Group 9 (SG9) of the OECD Working Party on Manufactured Nanomaterials, or in the nano dialogue at EU level
- Reviewing which measures and instruments could be used to create incentives for industry to apply the Guidelines. These could include: providing support for assessing information and using it to decide on options for action; providing opportunities for users of the Guidelines to exchange information (workshops, interactive internet platforms, etc.)
- Expanding and promoting debate on nanotechnologies to include issues concerning society and companies alongside the established issues such as the environment, consumers and employees.

Overall, the Issue Group members welcome the work of the NanoKommission, which is currently the only multidisciplinary and multi-stakeholder body in the Federal Republic that is addressing the key issues of nanotechnology use and formulating policy recommendations. We therefore ask the German Federal Government to assess possibilities for making the work of the NanoKommission more permanent, or for establishing an advisory body with a similarly pluralistic profile (analogous to the German Commission on Radiological Protection, for example).

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[8] This is aimed primarily at industrial users. Concerning the Principles, see the report of the NanoKommission for the first dialogue phase and the present report of Issue Group 1.

[9] The Institute for Applied Ecology (Öko-Institut) is currently working on a project funded by the Federal Environment Agency (UBA) entitled "Analyse und strategisches Management der Nachhaltigkeitspotenziale von Nanoprodukten", (Analysis and strategic management of nanoproduct sustainability), abbreviated to "Nachhaltigkeitscheck von Nanoprodukten" (Sustainability check for nanoproducts).

Annex 1: List of Issue Group members

Name	Institution
Spokesperson of the Issue Group: Michael Jung	Nanogate AG
Ralf Bosse	Schmitz-Werke GmbH & Co. KG
Alexandra Caterbow	Women in Europe for a Common Future – WECF
Dr. Sabine Dippner	Federal/Länder Working Committee on Chemical Safety / Office for urban development and environment, Hamburg – BLAC/BSU
Dr. Wolfgang Dubbert	Federal Environment Agency – UBA
Dr. Alex Föller	TEGEWA (trade association of the German chemical industry serving manufacturers of processing aids for the textile, leather and tanning industries)
Dr. Roland Franz	Fraunhofer Institute for Process Engineering and Packaging – IVV
Dr. Peter Germann	Expert in environmental medicine
Dr. Ralf Greiner	Max Rubner Institute
Dr. Ilka Grötzinger	Federal Ministry of Health – BMG
Sonja Haider	Women in Europe for a Common Future – WECF
Dr. Georg Hofmeister	Hofgeismar Protestant Academy
Prof. Dr. Rüdiger Iden	BASF SE
Dr. Anke Jesse	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Andreas Keil	InnoZent OWL – Innovation Centre for Internet Technology and Multimedia Competence in the Ostwestfalen-Lippe region
Dr. Peter Krüger	Bayer MaterialScience AG
Cornelia Leuschner	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Dr. Wolfgang Luther	Association of German Engineers – VDI, Technologiezentrum GmbH
Christina Meßner	Gesamtverband Textil und Mode – Textile and Fashion Confederation
Dr. Asmus Meyer-Plath	Federal Institute for Materials Research and Testing – BAM
Dr. Karin Michel	Henkel AG & Co. KGaA
Doris Möller	Women in Europe for a Common Future – WECF
Dipl.-Ing. Martin Möller	Öko-Institut e.V. (Institute of Applied Ecology)
Isabelle Mühleisen	Federation of German Consumer Organisations, North-Rhine Westphalia
Stefan Ruholl	Schmitz-Werke GmbH & Co. KG
Rüdiger Stegemann	Friends of the Earth Germany – BUND
Elke Walz	Max Rubner Institute
Dr. Heinz Zeininger	Siemens AG

Annex 2: Guidelines for applying the criteria

GUIDELINES FOR COLLECTING DATA AND COMPARING BENEFIT AND RISK ASPECTS OF NANOPRODUCTS

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Contents

1 Introduction

The Guidelines below were produced by NanoKommission Issue Group 2. The list of criteria contained in the Guidelines, the presentation of the results and the guidance for assessing benefit and risk-related aspects of products containing nanomaterials were developed and agreed in a stakeholder dialogue process.

The "Guidelines for collecting data and comparing benefit and risk aspects of nanoproducts" (hereafter referred to as "the Guidelines") are primarily intended to support transparent dialogue about nanoproducts[10] between different users. The Guidelines can thus be seen as a method and framework for collecting and presenting information, which is the basis for any dialogue of this sort. Information and findings contributed or published by companies, for example, for this purpose are crucial in helping to promote the responsible use of nanomaterials and products which contain nanomaterials.[11]

These Guidelines, and the criteria that go with them, should prove especially valuable in the context of product development if they are used to guide actions and provide ideas early on when the development of new nanomaterials or nanoproducts is being considered, with a view to increasing benefits and reducing potential risks. By using them in this way it will be possible to estimate the new product's impact on sustainable development well before any investment is made in manufacturing or marketing.

1.1 Purpose of the Guidelines

The Guidelines are intended to facilitate identification and comparison of benefit and risk-related aspects of nanoproducts. Using the criteria will help to ensure systematic collection and comparability of the data. Presentation of the results, which provides an initial subjective appraisal of the information, is intended to ensure a high degree of transparency and to support two primary objectives:

- To inform users of the Guidelines about nanoproducts and their potential benefits and risks, and to promote transparent debate on these issues
- To raise awareness among companies and developers of nanoproducts regarding the benefit and risk aspects of their products.

The data produced using the Guidelines is therefore presented in disaggregated rather than aggregated form.

The Guidelines provide companies especially, but also other users, with a useful initial indication of whether sufficient information is available about a

[10] See definitions in section 3.

[11] See the NanoKommission's Principles Paper from the first dialogue phase and the discussion and report of Issue Group 1 on this topic.

nanoproduct or nanomaterials contained in a product. They can also indicate whether the benefit-risk ratio of a product is positive, and where more detailed assessment is needed, e.g. using the criteria to assess the impact of nanomaterials on humans or on the environment in order to identify and manage potential risks.

Presentation of the results should also enable initial conclusions to be drawn regarding recommendations for action, such as “further information should be gathered”, or “more detailed examination of risk aspects is needed”.

The criteria and presentation of the results should be considered a first step for assessing and appraising the benefit-risk ratio of a nanoproduct.

The Guidelines are neither intended nor able to provide a definitive assessment of a nanoproduct in the sense of a risk evaluation. Pronouncements regarding risks cannot be made, as the data are not quantified and the Guidelines do not set out to quantify hazardous properties and exposure, or to establish a link between them.

Appraisal of the information regarding benefit and risk aspects of a nanoproduct cannot be completely objective as it will depend on the perspective of the user, the products selected for comparison, and the applicability of the criteria. This is why appraisal of benefit aspects is done by means of comparison to a reference product (for more details see section 4.1) and risk aspects are assessed against the probability of meeting particular criteria (see section 4.3). In terms of the Guidelines’ role as a tool for dialogue and transparency, a crucial feature here is the presentation of the facts (both quantitative and qualitative) together with additional justifications and explanations.

1.2 Scope of the Guidelines

The Guidelines and the related criteria are geared towards examining finished products which contain nanomaterials. The criteria may also be applied to nanomaterials. Appraisal of benefit and risk aspects can only ever be meaningful in the context of an end use or a finished product.

The benefit and risk aspects of products containing nanomaterials suggested in the Guidelines for assessment represent only a SELECTION of the possible parameters and should by no means be considered exhaustive.

Benefit and risk aspects presented cover the whole of a product’s life cycle, in other words, manufacture of the nanomaterials, any subsequent processing, product use and disposal.[12] It may be that adequate information regarding manufacturing and other upstream processes can be obtained from the Safety

[12] Depending on the group using the Guidelines for collecting data and presenting benefit and risk aspects, different levels of information will be available. In many cases cooperation with upstream participants in the supply chain will be necessary. Consumer associations are more likely to be in a position to scrutinise published assessments than to conduct them themselves.

Data Sheets supplied. In most cases, however, it will be necessary to ask the supplier.

Drugs and medical applications are not covered by the criteria, since there is a special relationship between benefit and risk aspects in these cases, and there are already established rules for assessing it.

Where scientific risk evaluations are already available for a nanomaterial or product containing nanomaterials, there is no need to assess risk aspects using the criteria relating to the environment, consumers and employees. Instead, it is sufficient to cite the results of these evaluations. Consideration of risk aspects affecting society and the company, and benefit-related factors, are not affected.

Even where a nanomaterial is known to have no hazardous properties, it is nevertheless sensible to consider risk factors for society and industry, as well as the benefit-related aspects.

In the case of chemical products that fall within the scope of particular legislation, such as plant protection or biocidal products, there may often be specific potential additional benefits that need to be taken into consideration, (prevention of resistance, contribution to food security, etc.), which are not currently covered by the list of criteria. Permitted products have already undergone assessment regarding their risks, and this information should also be drawn upon.

1.3 Target group for the Guidelines

The Guidelines may be useful for a wide range of different users, for example:

- All users can and should use the Guidelines to facilitate structured, systematic, fact-based discussion on benefit and risk considerations. This may take place in the abstract (discussion of considerations in general in relation to technology development) or on the basis of specific, published product information compiled using these Guidelines.
- Research and development departments of companies which manufacture nanomaterials and are weighing up the advantages and disadvantages of future products
- Representatives of public authorities which have to classify nanoproducts or nanomaterials for the purpose of protecting the environment, human health and consumers, or decide on how to allocate funding
- Company communications departments seeking to present the benefits and risks of their products transparently
- Consumer associations can use the Guidelines to assess nanoproducts
- Consumers can review specific products and, where relevant, contact the manufacturer.

2 Structure of the Guidelines

The Guidelines consist of a product profile and a list of criteria.

2.1 Product profile

The purpose of the product profile is to characterise and describe the nanoproduct, and it is a prerequisite for any analysis of benefit and risk-related aspects. The user of the Guidelines is expected to gather together the available data on his product and on any nanomaterial used in it. Documents to be used for this purpose include the Safety Data Sheet and/or product information on the nanomaterial. Where relevant, information should be obtained from suppliers.

It may be helpful in some cases to define a “functional unit” for the nanoproduct (see section 3.2) in order to describe benefit and risk-related aspects and to be able to use this parameter for comparison with the reference product.

The reference product used as the basis for discussion of a product‘s benefit aspects must also be included in the product profile, giving the reasons for choosing it (see section 4.1). Where a functional unit has been defined, the reference product should also be expressed as a functional unit.

2.2 Criteria

The criteria on benefit and risk-related aspects are subdivided into five categories: environment, consumers, employees, society and company. Within each category, various criteria are listed, in each case stating the stage of the product’s life cycle for which it is useful to collect data and carry out an appraisal.[13]

The criteria represent various benefit and risk-related aspects of nanoproducts that are currently the focus of debate. They are not exhaustive.

For each of the criteria the following information is given:

- Title of the criterion (column headed “Criterion”); this information should be displayed in the results.
- Explanation of what the criterion means; examples or more detailed questions for the user (column headed “Details”; this does not have to be displayed in the results).
- Phase(s) of the product’s life cycle to which the criterion should be applied (columns headed “Production”, “Use”, “Disposal”; the user should place a cross (“x”) in the box indicating the relevant phase(s)); this information should be displayed in the results.

[13] In principle the entire product life cycle should be considered. For certain criteria and categories, however (e.g. consumers), only certain stages in the life cycle are relevant. In the list of criteria, relevant life cycle phases are indicated by a cross in the columns headed “Production”, “Use” and “Disposal”.

- Variable selected to test the criterion, e.g. energy consumption. The variables may be defined in qualitative or quantitative terms and will depend not only on the criterion but also on the product undergoing assessment (column headed “Variable”; this does not have to be displayed in the results)
- Method of collecting data on the selected variable, e.g. information sources that can be used, or nature of qualitative description required (column headed “Measurement method”; this does not have to be displayed in the results)
- Appraisal: here the user gives his appraisal of the nanoproduct[14]; this information should be included in the results
- Justification/explanation: this column is intended for the user to give the rationale for his appraisal or to provide additional, more detailed information; this information should be included in the results.

Particular features of benefit aspects

Criteria concerning benefit-related aspects are divided into:

- **Core criteria**, which are applicable to all products and must be tested and assessed by the user of the Guidelines in all cases
- **Additional, specific criteria**, which either apply only to particular products[15] or are only relevant to particular user groups or applications[16].

Additional criteria can be entered under “other” in the list of criteria. The core criteria are crucial to the appraisal of benefit-related aspects.

3 Definition of terms

3.1 Nanomaterials

The following working definitions were not debated or agreed upon in the Issue Group, but are taken from the final report of the first dialogue phase.

Nanotechnologies: the term nanotechnologies covers a variety of procedures for the study, intentional manufacture and application of processes, structures, systems or molecular materials which have at least one dimension typically less than 100 nanometres (1 nm = 10^{-9}m).

Nanomaterials: The term “nanomaterials” refers to engineered materials in the nano size range which, primarily as a result of their altered surface area-to-volume ratio, develop new properties. There is currently no internationally

[14] Benefit aspects are rated as “better than”, “the same as” or “worse than” the reference product, or the user may indicate that there is “no information”. In the case of risk aspects, the ratings are “probably yes”, “probably no” and “no information”.

[15] e.g. criteria relating to benefits obtained from environmental technologies (benefit = cleaner environment).

[16] These might be benefits relating to production functions which the Issue Group deemed highly specific or which go further than fulfilling one of the core criteria.

agreed definition. According to a draft prepared by Technical Committee of the International Standardisation Organisation (ISO Technical Committee 229), nanomaterials may be subdivided into various groups. These include:

Nano-objects[17]**:** Materials with one, two or three external dimensions at the nanoscale (approximately 1 to 100 nm). Typical examples are nanoparticles, nanofibres and nanoplates. Nanofibres include electrically conducting fibres (nanowires), nanotubes, and nanorods. Nano-objects are often found in groups.

Nanostructured materials have an internal structure in the nanoscale and generally occur in compound systems of nano-objects[18]. Typical examples are aggregates and agglomerates[19]. According to ISO these are not limited in their physical size or form.

Nanoproduct: a product (mixture or article) placed on the market in its own and whose function is primarily determined by the use of nanocomponents (structural elements or constituents which are nanostructured or contain nanomaterials).

[17] For an explanation of the terminology see also ISO Technical Specification ISO/TS27687:2008(E) of 15 August 2008.

[18] Or as a continuous matrix with embedded nano-objects.

[19] Or composite materials.

3.2 Terminology used in the Guidelines and criteria

The sections below give details of key terms used in the context of the Guidelines and criteria, which could give rise to misunderstandings due to the fact that they may be used differently in other contexts.

Employee: In the Guidelines and criteria, an employee refers to a person who handles nanomaterials in the production chain in order to incorporate these into a nanoproduct, or who is involved in processing a nanoproduct already containing nanomaterials (e.g. grinding, moulding, etc.).

Emission: This means the emission or release of nanomaterials from products or facilities containing them (e.g. production facilities) into the environment.

Exposure: This refers to exposure of a person or the environment to nanomaterials emitted from products or facilities which contain them.

Functional unit: A functional unit is a common measure of function used as a reference for comparing a nanoproduct with a reference product. When deciding on a functional unit, consideration must be given to the functional equivalence of the products to be compared. A functional unit must be defined separately for each product and process undergoing comparison. For example, to compare the nanoproduct “wind turbine rotor blades” (made from composite materials containing CNT) with a reference product that does not contain nanomaterials, an appropriate functional unit would be the annual amount of energy generated by a wind turbine.

Reference product: A product which does not contain nanomaterials but has the same functionality as the product undergoing comparison.

Risk: In scientific terms, the product of the extent of the damage or losses and the probability of occurrence. Toxicologists refer to risk when a potential hazard and exposure are present simultaneously. Measures to protect human health are geared to minimising either one variable or both (risk management).
In addition, a risk can also have an economic and social significance, which may, moreover, influence each other. For example, lack of social acceptance (an example of social “damage”) can generate economic losses for a company, in that a particular product does not sell.

Risk(-related) aspect: This term is used in the Guidelines and list of criteria to make it clear that a variety of questions and perspectives are considered with regard to potential risks. Risk aspects may be individual risk factors that are relevant, e.g. a significant probability of exposure or a high level of hazard associated with the materials in question. Risk as defined scientifically (see above) cannot be estimated on the basis of these aspects alone, nor can they provide a complete picture of a potential hazard.

4 Using the criteria

The following steps are recommended for systematic data collection and description of the benefit and risk aspects of a nanoproduct. These are discussed in more detail in the sections that follow:

- **Product profile for the nanoproduct** (product profile table): description of the nanoproduct including general functionality of the finished product, functionality achieved as a result of using the nanomaterial, and functionality of the reference product (see section 4.1). Where relevant, the functional unit is also defined here.
- **Product profile for the nanomaterial** (product profile table): documentation of available information on the nanomaterial from the product information, Safety Data Sheet or from communication with the manufacturer of the nanomaterial.
- **Identification and documentation of benefit aspects** (table of benefit aspects): includes assessing whether/which benefit categories apply and documenting the responses in an Excel spreadsheet[20]
  - Where a criterion does not apply: give reasons why
  - Where a criterion applies:
    - Work through the list of core criteria giving an estimation of how the product compares to the reference product by placing a cross (“x”) in the appropriate box; give a reason for your answer in the space provided
    - Check through the additional, specific benefit aspects and select from the suggested criteria; if none fit, add your own criteria under OTHER.

[20] In particular the reasons for the appraisal should be worded in such a way as to be clear to outsiders. Any information available in quantified form must be included. Commercial confidentiality should be respected.

- **Identifying and documenting risk aspects for the environment, consumers and employees** (table on risk aspects for the environment, consumers, and employees): give an estimation of the probability of an emission or exposure and state the reasons for your answer in the space provided.
- **Identifying and documenting risk aspects for society and the company** (table on risk aspects for society and the company): these criteria are not included in scientific and regulatory risk evaluation. The Issue Group was unable to conclude its discussions on these. Although it is sometimes difficult to gather the relevant information on these aspects, they should nevertheless be assessed and can be useful for looking at the manufacture, use and placing on the market of nanoproducts in a broader context.

4.1 Selecting a reference product

Essentially, the reference product should be a product in which **the functionality[21] under examination is achieved without the use of nanomaterials.[22]** The reason for this is to enable comparison of the nanoproduct with a reference product in order to establish which benefit and risk aspects result specifically from the use of nanomaterials or nanotechnologies.

When selecting a reference product, it is important to ensure that both nanoproduct and reference product have the same basic technical functionality. This principle of **functional equivalence** is very important, as otherwise we cannot be certain that we are comparing like with like. For this reason, the benefit aspects of the product being assessed should be carefully analysed and identified at the start of the process. Using this as a basis, benefit aspects that constitute basic technical functionalities should then be established and distinguished from those representing additional benefits.

If the nanoproduct is an entirely new product or has novel properties that could not have been produced hitherto, it will not be possible in this particular case to identify a reference product that has the same basic technical functionality. In such cases the “next best” reference product must be chosen instead, i.e. with a **functionality most closely resembling that of the nanoproduct[23].** The choice should be guided by the question of which conventional product the nanoproduct might **substitute** when it is placed on the market or if demand

[21] If the reference product has an additional functionality that depends on the use of nanomaterials but this functionality is not relevant to the comparison with the nanoproduct, this does not present a problem. One such example might be nanomaterials that have been used for the same purpose and in the same quantity in both the nanoproduct and the reference product for many years.

[22] In principle it would be possible to use the criteria to carry out comparisons of two or more nanoproducts. It would be interesting, for example, to explore the relative advantages of using a different or new type of nanomaterial compared to the material hitherto used. This line of enquiry, however, is not the focus of debate at present and is therefore not pursued here.

[23] Depending on the product being assessed, there is, however, a “zero option” that may be adopted in extreme cases for the reference product if the functionality in question can only be achieved using the application of nanotechnology.

increases. If there are several potential “candidates” for the role of reference product, it is advisable to consider the products’ current **market share** as well.

Whatever the case may be, it is important to **document clearly the assumptions** on which the choice of reference product is based and include this as supplementary information in the results of the assessment.

Conclusions

The aspects outlined above can be summarised in the form of three key questions, as follows:

1. What constitutes the basic technical functionality of the nanoproduct?
2. What conventional product already available and with a significant share of the market most closely approximates the technical functionality of the nanoproduct and might be substituted by the nanoproduct in the short to medium term?
3. What assumptions and other considerations were used as the basis for selecting and specifying the reference product? Are these realistic and comprehensible to external parties?

4.2 Using the benefit-related criteria

The criteria on benefit-related aspects are subdivided into core criteria, which must be completed and documented in all cases by the person carrying out the assessment (these are always displayed in the Excel spreadsheet), and more detailed secondary criteria (pop-up menus marked with the symbol “+” in the left-hand margin of the table). A product’s benefit aspects must always be assessed in comparison to a reference product and shown by inserting a cross (“x”) in the corresponding cell of the table. This can also reveal where a nanoproduct performs more poorly than the reference product, e.g. higher energy consumption.

In the categories “environment” and “employees”, a distinction can be made for the different phases of the product’s life cycle. This is done using the additional table lines that appear as a pop-up menu opened by clicking on the “+” sign in the left-hand margin under the relevant core criteria.

If one of the core criteria does not apply, for example because a product has no consumer applications or was not developed with the intention of having a particular additional benefit compared to the reference product, this does not mean that it should be given a “negative” rating; this should simply be noted clearly as part of the drive for transparency.

In a second step, the person carrying out the assessment should check whether any of the additional, more detailed criteria apply to the product in question, or whether other criteria might need to be added in order to characterise the benefit aspects of the product fully. The assessor should use his/her own discretion to state additional, more detailed benefit considerations.

4.3 Using the risk-related criteria

Information on risk-related aspects can be collected step by step for all the criteria. As a rule, the information is to be collected in the form of qualitative estimations (this is an INITIAL APPRAISAL!). If available, however, the table may be completed using measurements or modelling data. If scientific risk evaluations have been carried out for the product or a use of the product, the results of this should be given instead of using the table of criteria for assessing the relevant risk aspects for humans and the environment.

Dealing with the risk aspects for society and for the company will present the greatest challenge for the majority of users of the criteria because these do not figure in traditional scientific or regulatory risk evaluation systems. It will generally only be possible to obtain a broad estimation of these aspects. Rating the probability of whether a criterion might apply to a given risk should be viewed as an exercise aimed at placing responsibility for nanoproducts in its broader context and providing a basis for considering the consequences of manufacturing nanoproducts and placing them on the market.

As it was not possible to conclude the discussions and carry out testing on the criteria on risk aspects for society and the company, these should be seen as a work in progress. Where possible, users of the criteria should discuss other aspects, as well as challenges and experiences relating to these risk aspects, in the context of stakeholder dialogue and communicate these to the relevant bodies with a view to contributing to the future development of the Guidelines and criteria.[24]

[24] It is not clear at present whether or how future work on these tools will be organised.

5 Results obtained using the Guidelines

The results obtained using the Guidelines provide a **transparent picture of selected benefit and risk aspects of a nanoproduct** in the form of two tables summarised in the following categories: environment, consumers, employees, society and the company. No attempt is made to provide a risk evaluation by linking information on hazardousness and exposure.

The results can be presented directly using the Excel table, hiding the explanations columns and any additional criteria that are not relevant or were not applied.

This helps to highlight where a nanoproduct's strengths and weaknesses lie with regard to potential benefits and risk aspects.

It should be possible to ascertain:

- whether a product might have benefits and what those benefits are
- where information on emissions suggests that exposures could occur and more detailed investigation, e.g. further assessment using the criteria produced by Issue Group 4, would be beneficial
- where there are information gaps that need to be filled
- where the users of the criteria should set their priorities, e.g. in relation to developing alternative products and applications with a high ratio of benefit aspects, or in relation to identifying products that should be first in line for more detailed assessment.

Furthermore, the results should be published and made available for discussion with other stakeholders. For this reason, care needs to be taken to ensure that the information provided is clear and comprehensible and that precise reasons are given for the ratings chosen. The results obtained using the Guidelines may be useful for product marketing and help to ensure transparency concerning nanoproducts, as called for in the Principles for the responsible use of nanomaterials.

Depending on who is using the Guidelines and criteria, there will be different consequences for subsequent action. For instance, a company with product or product option for which few benefit aspects and multiple risk aspects are identified may decide that the product needs to go back to the drawing board. A consumer association, meanwhile, might advise against purchasing a product, whereas a public authority might use the results to decline an application for funding. Conversely, a company whose product demonstrated many benefit aspects and few risk factors might endeavour to reinforce this positive preliminary assessment if it aims to place the product on the market.

The Guidelines support the collection and presentation of data with a view to providing an initial assessment only. Many of the criteria for benefit and risk

aspects of a product are not quantifiable.[25] By delivering a relatively straightforward assessment, however, this stock-taking exercise can provide useful basic information in the early stages of product development.

6 List of criteria

The criteria have been compiled into an Excel spreadsheet which is available separately at www.bmu.de/47547.

[25] In some cases they may be quantified in principle but the necessary data is lacking.

Annex 3: Extract[26] from the criteria

Product profile		
Parameter	Details	
Designation of the product		
Functional unit		
Technical functionality		
Function of the nanomaterial in the product		
Reference product		
Reason for choosing reference product		

Profile of nanomaterial used		
Parameter	Details	
Material		
Manufacturer		
Information on the value chain		
Description of "consumer" / "user"		
Form factor		
Particle size		
Particle size distribution		
Surface functionalisation		
Coating		
Data from the nanomaterial's Safety Data Sheet		
Information specific to the nanomaterial		
Other special features or characteristic properties		

[26] For the sake of clarity, explanations are not displayed and only the core criteria are listed. The full version can be downloaded from the internet as an Excel spreadsheet at www.bmu.de/47547.

			Life cycle					Rating				Reasons and further information
		Explanations	Production	Use	Disposal	Variable	Measurement method	Better than reference product	Same as reference product	Worse than reference product	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
1	Benefit aspects for the environment							Please mark relevant box with an "x"				
Core criteria, for all products												
UM 1	Reduced resource use: energy		x	x	x							
	- in production		x									
	- in use phase			x								
	- in disposal phase				x							
UM 2	Reduced resource use: water		x	x	x							
	- in production		x									
	- in use phase			x								
	- in disposal phase				x							
UM 3	Reduced resource use: raw materials		x	x	x							
	- in production		x									
	- in use phase			x								
	- in disposal phase				x							
UM 4	Prevention of greenhouse gas emissions		x	x	x							
	- in production		x									
	- in use phase			x								
	- in disposal phase				x							
UM 5	Reduced emissions of pollutants		x	x	x							
	- in production		x									
	- in use phase			x								
	- in disposal phase				x							
UM 6	Reduced waste volume and hazard		x	x	x							
	- in production		x									
	- in use phase			x								
	- in disposal phase				x							
Supplementary, detailed criteria for particular products / specific applications												

			Life cycle					Rating				Reasons and further information
	Criterion	Explanations	Production	Use	Disposal	Variable	Measurement method	Better than reference product	Same as reference product	Worse than reference product	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
2	Benefit aspects for consumers / users / users of finished product											
Core criteria, for all products												Employees who use a nanoproduct in the course of their work activities are considered to be "consumers" for the purpose of this table. Estimation of benefits in the use phase is not envisaged for the category "employees".
V 1	Product offers enhanced consumer utility			x								
V 2	Product offers enhanced user safety (including protection from disease)			x								
V 3	Product offers enhanced price-performance ratio for the consumer			x								
Supplementary, detailed criteria for particular products / specific applications												

3	Benefit aspects for employees in production chain and disposal											Employees who use nanoproducts in the course of their work activities are considered to be "consumers". Estimation of benefits for employees relates to work involving nanomaterials in the nanoproduct's production chain and in the disposal of finished products.
Core criteria, for all products												
AS 1	Advantages resulting from easier or safer handling		x		x							
	Advantages in manufacturing / production chain		x									
	Advantages for disposal				x							
AS 2	Protection of health and safety in the workplace (risk management) (for examples click on the + sign)		x		x							
	Advantages in manufacturing / production chain		x									
	Advantages for disposal				x							
Explanatory sub-criteria												
	Handling and efficiency of protective equipment		x		x							
	Protection from contamination in the workplace (UV radiation, chemicals, etc.) by technical measures		x		x							
Supplementary, detailed criteria for particular products / specific applications												

			Life cycle					Rating				Reasons and further information
	Criterion	Explanations	Production	Use	Disposal	Variable	Measurement method	Better than reference product	Same as reference product	Worse than reference product	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
4	Benefit aspects for society											
Core criteria, for all products												
GES 1	Reduced cost of protecting health and the environment		x	x	x							
GES 2	Creation of new skilled jobs, safeguarding jobs		x	x	x							
GES 3	Enhanced product performance, improved export opportunities, improved market position and competitive edge		x	x	x							
Supplementary, detailed criteria for particular products / specific applications												
5	Benefit aspects for the company											
Core criteria, for all products												
UNT 1	Creation of new markets, enhanced competitiveness		x									
UNT 2	Improved product quality and performance		x	x								
UNT 3	Reduced costs, e.g. by optimising production processes		x	x								
UNT 4	Improved work and process safety		x									
Supplementary, detailed criteria for particular products / specific applications												

			Life cycle					Rating			Reasons and further information
#	Criterion If a scientific risk evaluation of the product has been carried out for the environment or human health, do NOT use the criteria below. Please give the results of this evaluation instead.	Explanations	Production	Use	Disposal	Variable	Measurement method	Probably yes	Probably no	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
	Risk aspects for the environment										
1.1	What is the total volume used in the product?		x								
1.2	Are there likely to be any emissions into the environment?		x	x	x						
	Are there any emissions routes into the environment for nanoparticulate components during production?		x								
	Are there any emissions routes into the environment for nanoparticulate components during use?			x							
	Are there any emissions routes into the environment for nanoparticulate components during disposal?				x						
1.3	Are measures in place to reduce emissions?		x	x	x						
	- in production?		x								
	- in the use phase?			x							
	- in the disposal phase?				x						
1.4	Are exposures likely to arise that will affect environmental media – water, soil, air: – in general?		x	x	x						
	- in the production phase?		x								
	- in the use phase?			x							
	- in the disposal phase?				x						

2	Risk aspects for consumers / users / users of the finished product										
2.1a	What is the total volume / concentration of the nanomaterial in the product?			x							
2.1b	Does the usage pattern potentially entail intensive consumer contact with the product?			x							
2.2	Are there likely to be emissions into the consumer's environment?			x							
2.3	Are measures in place to reduce emissions?			x							
2.4	Is exposure of consumers likely to occur?			x							

			Life cycle					Rating			Reasons and further information
#	Criterion If a scientific risk evaluation of the product has been carried out for the environment or human health, do NOT use the criteria below. Please give the results of this evaluation instead.	Explanations	Production	Use	Disposal	Variable	Measurement method	Probably yes	Probably no	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
	Risk aspects for employees										
3.1	What volume is used in the workplace?		x		x						
	What volume is used in production?		x								
	What volume is disposed of with / in the product?				x						
3.2	Are emissions likely to occur in the workplace?		x		x						
	Are there any emissions during production?		x								
	Are there any emissions during disposal?				x						
3.3. a	Are measures in place to reduce emissions?		x		x						
	Are measures in place to reduce emissions during production?		x								
	Are measures in place to reduce emissions during disposal?				x						
3.3. b	Are measures to reduce emissions tested for effectiveness: – in general?		x		x						
	- in production?		x								
	- in disposal?				x						
3.4. a	Are exposures expected when employees are present: – in general?		x		x						
	- when employees are present during production?		x								
	- when employees are present during disposal?				x						
3.4. b	Are measures in place to reduce exposure: – in general?		x		x						
	- to reduce exposure during production?		x								
	- to reduce exposure during disposal?				x						
3.4.c	Are the measures to reduce exposure effective: – in general?		x		x						
	- in production?		x								
	- in disposal?				x						

			Rating			Reasons and further information
#	These criteria are intended to stimulate reflection, and may not need to be completed in every case or by all users of the criteria. This needs to be taken into account in any overall consideration of the benefit and risk aspects.	Explanation	Probably yes	Probably no	No information	Reasons for rating given / further information Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
4	Risk aspects for society					
4.1	Potential external costs for society					
4.1.1	External costs for the health and welfare system					
4.1.2.	External costs for remediation / conservation of ecosystems					
4.2	Can the use of the product pose a threat to social stability?					
4.3	Is the product likely to be used incorrectly or is it complicated to handle?					
4.4	Risks to the national economy					
4.4.1	Restriction of market mechanisms					
4.4.2	Negative impact of the product on society's acceptance of nanotechnology in general					
4.5	Social impact of the product on society					
4.5.1	Social impact of the product on the value chain					
4.5.2	Social impact of the product's availability					
5.	Risk aspects for the company					
5.1	Loss of image					
5.2	Financial / economic losses due to:					
5.2.1	- rejection by society					
5.2.2	- absence of or negative impact on employees					
5.2.3	- compensation payments					
5.3.	Uncertainty of long-term strategies, risks of investment due to					
5.3.1	- potential that as yet unknown future regulatory measures might prevent or otherwise negatively affect the use of the product					
5.3.2	- dependency on (non-European) competitors if the technology is restricted in Europe					
5.3.3	- too much red tape					

Annex 4: Example product: Fabric sunscreen[27]

Product profile	
Parameter	Details
Designation of the product	swela sunsilk SNC (SWELA Nano Clean) – fabric sunscreen
Functional unit	
Technical functionality	Sunscreen
Function of the nanomaterial in the product	To produce a nano- and micro-structured surface. This creates a "self-cleaning" surface that reduces long-term cleaning requirements, increases the product's lifespan and gives the awning fabric a more luminous appearance. In terms of evaluating resistance to soiling in practice, the number and variety of uses and types of soiling that occur make it difficult to draw any firm conclusions. The general trend, however, is one of significant improvement. Laboratory-based photometric testing of soiling showed a reduction in the delta E value for the difference in brightness from 15 (using the FC finish) to 3 (SNC finish).
Reference product	swela sunsilk SFC (SWELA Fluorocarbon Clean) – fabric sunscreen
Reasons for choosing reference product	The basic woven fabric is the same, but in this case it is treated only with a conventional fluorocarbon resin finish with no self-cleaning surface.
Profile of nanomaterial used	
Parameter	Details
Material	Silica
Manufacturer	Confidential company information.
Information on the value chain	The nanoproduct is supplied to Schmitz-Werke in compound form. It is produced in Germany by a supplier of processing aids. Details of the manufacture of the nanocompound are confidential company information to the supplier of processing aids and as such are not available to us.
Description of "consumer" / "user"	Private individuals, consumers.
Form factor	The basic particle is in powder form, but in the compound it takes the form of an aqueous dispersion rather than individual particles.
Particle size	Primary particle size is 5 to 30 nanometres, but in the compound and on the fabric the particles are no longer separate, but bound in a gel matrix.
Particle size distribution	
Surface functionalisation	Binder for fixing to the surface.
Coating	No
Data from the nanomaterial's Safety Data Sheet	Section 8: Constituents for which occupational exposure limits apply and occupational exposure must be monitored – propanol. Section 10: Does not decompose in normal use. Section 11: LD/LC50 values: product, oral:> 2000 mg/kg rat. Does not cause irritation to eyes or skin; no known sensitisation effects. Section 12: Product ingredients are easily eliminated from waste water. CSB value 325 mg O2/g product. No AOX indication; no heavy metals.
Information specifically relating to the nanomaterial	Manufacturer's declaration of no objection: Dermatological and toxicological tests on silica: oral, rat LD/LC 50 >5000 mg/kg, dermal, rabbit >5000 mg/kg, inhaled, rat 0.139 mg/l/4h. Specific symptoms in animal experiments: no mortality at maximum concentration. Primary irritant effect: no irritation to skin or eyes.
Other special features or characteristic properties	Highly hydrophobic.

[27] Any lines or criteria not completed have been removed from the presentation of the results.

	Criterion	Production	Use	Disposal	Better than reference product	Same as reference product	Worse than reference product	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
1	Benefit aspects for the environment								
Core criteria, for all products									
UM 1	Reduced resource use: energy	x	x	x	X				Due to longer product lifespan. No quantitative data available.
	- in production	x			X				Due to longer product lifespan. No quantitative data available. Production steps are the same.
	- in use phase		x		x				Due to longer product lifespan. No quantitative data available.
	- in disposal phase			x	x				Due to longer product lifespan. No quantitative data available.
UM 2	Reduced resource use: water	x	x	x	x				Due to longer product lifespan. No quantitative data available.
	- in production	x			x				Due to longer product lifespan. No quantitative data available. Production steps are the same.
	- in use phase		x		x				Due to longer product lifespan. No quantitative data available.
	- in disposal phase			x	x				Due to longer product lifespan. No quantitative data available.
UM 3	Reduced resource use: raw materials	x	x	x	x				Due to longer product lifespan. No quantitative data available.
	- in production	x			x				Due to longer product lifespan. No quantitative data available.. Production steps are the same.
	- in use phase		x		x				Due to longer product lifespan. No quantitative data available.
	- in disposal phase			x	x				Due to longer product lifespan. No quantitative data available.
UM 4	Prevention of greenhouse gas emissions	x	x	x	x				Due to longer product lifespan. No quantitative data available.
	- reduction in production	x			x				Due to longer product lifespan. No quantitative data available. Production steps are the same.
	- reduction in use phase		x		x				Due to longer product lifespan. No quantitative data available.
	- reduction in disposal phase			x	x				Due to longer product lifespan. No quantitative data available.
UM 5	Reduced emissions of pollutants	x	x	x		x			Contaminated waste gas is treated using a regenerative thermal oxidation cleaning system. Contaminant levels following treatment are the same for both products, and in both cases are well below the limits stipulated in the German Technical Instructions on Air Quality Control (Technische Anleitung zur Reinhaltung der Luft -TA Luft).
	- in production	x				x			
	- in use phase		x						No emissions
	- in disposal phase			x					No emissions
UM 6	Reduced waste volume and hazard	x	x	x	x				Due to longer product lifespan. No quantitative data available.
	- in production	x			x				Due to longer product lifespan. No quantitative data available.
	- in use phase		x		x				Due to longer product lifespan. No quantitative data available.
	- in disposal phase			x	X				Due to longer product lifespan. No quantitative data available.
Supplementary, detailed criteria for particular products / specific applications									
1.1.	Environmental protection / improved environmental quality								Not applicable

	Criterion	Production	Use	Disposal	Better than reference product	Same as reference product	Worse than reference product	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
1.2.	Environmental remediation / reduced environmental impact								
	Reduced resource use								
1.2.1	Reduced resource use: use of renewable instead of non-renewable resources	x	x		x				Due to the higher calorific value of the waste gas produced during manufacturing (as a result of the additives in the nanocompound), less gas is required for heating purposes in the waste gas incineration process. Precise data is not yet available.
1.2.2	Increased lifespan, – corrosion prevention, reduced wear		x	x	x				Extended product lifespan. Product lifespan depends heavily on how it is used and types of soiling that occur.
1.2.3	More precise dosing / improved emptying of residue		x						Not applicable
1.2.4	Reduced / increased use of limited mineral/fossil resources	x	x	x					Not applicable
	Reduced pollutant emissions								Not applicable

2	Benefit aspects for consumers / users / users of finished product								
Core criteria, for all products									
V 1	Product offers enhanced consumer utility		x		x				Longer product lifespan. Significantly reduced cleaning requirements. Improved appearance and luminosity of fabric.
V 2	Product offers enhanced user safety (including protection from disease)		x						Not applicable
V 3	Product offers enhanced price-performance ratio for the consumer		x		x				The quality and hence also the price-performance ratio of the awning fabric are significantly enhanced. The purchase price has not increased relative to the reference product. Additional manufacturing costs incurred due to the processing aid have been offset by increased sales.
Supplementary, detailed criteria for particular products / specific applications									
2.1.	Practical benefits / fitness for purpose								
	Handling								
2.1.1	Reduced cleaning frequency		x		x				Significantly improved resistance to soiling means that the product requires less cleaning. In terms of evaluating soiling resistance in practice, the number and variety of uses and types of soiling that occur make it difficult to draw any firm conclusions. The general trend, however, is one of significant improvement. Laboratory-based photometric testing of soiling showed a reduction in the delta E value for the difference in brightness from 15 (using the FC finish) to 3 (SNC finish).
2.1.2	Reduced product size, enhanced ease of handling		x						Not applicable
2.1.3	New degrees of freedom for construction		x						Not applicable

	Criterion	Production	Use	Disposal	Better than reference product	Same as reference product	Worse than reference product	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
	Enjoyment value								
2.1.4	Enhanced / increased food shelf life		x	x					Not applicable
2.1.5	Product enhances comfort / quality of life, improved aesthetic value		x		x				Improved appearance and luminosity of fabric.
	Other								
2.2.	Health value								Not applicable
3	Benefit aspects for employees in production chain and disposal								Employees who use nanoproducts in the course of their work activities are considered to be "consumers". Estimation of benefits for employees relates to work involving nanomaterials in the nanoproduct's production chain and in the disposal of finished products..
Core criteria, for all products									
AS 1	Advantages resulting from easier or safer handling	x		x		x			The production steps are the same.
	Advantages in manufacturing / production chain	x							
	Advantages for disposal			x					
AS 2	Protection of health and safety in the workplace (risk management) (for examples click on the + sign)	x		x					Not applicable
	Advantages in manufacturing / production chain	x							
	Advantages for disposal			x					
Supplementary, detailed criteria for particular products / specific applications									
3.1	Improved occupational safety								Not applicable

4	Benefit aspects for society								
Core criteria, for all products									
GES 1	Reduced cost of protecting health and the environment	x	x	x					Not applicable
GES 2	Creation of new skilled jobs, safeguarding jobs	x	x	x	x				The product definitely contributes to safeguarding jobs, although it is not possible to provide precise data on this. Swela sunsilk SNC's market share continues to rise. (In terms of types of awning fabric used by the company, the ratio of polyester (PES) fabrics has now increased from 20% to 60%.)
GES 3	Enhanced product performance, improved export opportunities, improved market position and competitive edge	x	x	x	x				So far none of our competitors has managed to place on the market a product that is comparable in terms of appearance and functions.

	Criterion	Production	Use	Disposal	Better than reference product	Same as reference product	Worse than reference product	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
Supplementary, detailed criteria for particular products / specific applications									
4.2.	Providing technologies & processes / components important for developing / improving other technologies								Not applicable
4.3.	Enabling new product qualities or functionalities								Not applicable
5	Benefit aspects for the company								
Core criteria, for all products									
UNT 1	Creation of new markets, enhanced competitiveness	x							Due to the SNC finish, the product meets the criteria for the Denkendorf quality label for self-cleaning materials, “Self-cleaning-inspired by nature". Compared to a conventional FC finish, soiling resistance of the polyester (PES) fabric is reduced by up to 75% (depending on site-specific soiling type/level). A marketing offensive presenting the product’s new function and effectiveness to consumers is attracting increasing numbers of customers to swela sunsilk SNC. So far none of our competitors has managed to place on the market a product that is comparable in terms of appearance and functions.
UNT 2	Improved product quality and performance	x	x						Longer product lifespan. Significantly reduced cleaning requirement. Fabric appearance and luminosity are enhanced.
UNT 3	Reduced costs, e.g. by optimising production processes	x	x						Production steps are the same.
UNT 4	Increased work and process safety	x							Production steps are the same.
Supplementary, detailed criteria for particular products / specific applications									
5.1.	Benefit aspects for the business environment								
5.1.2	Building new value chains	x	x						Not applicable
5.1.3	Meeting customers’ or suppliers’ requirements	x	x						Whereas swela sunsilk SFC was often criticised by customers in terms of its resistance to soiling, this has been significantly improved in the new product swela sunsilk SNC.
5.1.4	Safeguarding technological advances by means of forgery-proof labelling	x	x						Not applicable
5.2.	Benefit aspects relating to manufacture (company’s own production processes)								Not applicable

#	Criterion	Production	Use	Disposal	Probably yes	Probably no	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
	Risk aspects for the Environment							
1.1	What is the total volume used in the product?	x						Approximately 3 g/m² of the nanoproduct is applied to the swela sunsilk SNC awning fabric in the form of a solid coating. In terms of our annual production volume of around 1.2 million m² this is equivalent to a volume of 3600 kg/year.
1.2	Are there likely to be any emissions into the environment?	x	x	x		x		None. This was demonstrated by measurements carried out in the workplace and by ITV Denkendorf testing of nanoparticle emissions from our awning fabric swela sunsilk SNC. State-of-the-art dosing technology ensures that residual solution is kept to a minimum, and any remaining solution is generally recovered and re-used in the next round of production. Any solution that cannot be re-used is disposed of appropriately.
	Are there any emissions routes into the environment for nanoparticulate components during production?	x				x		The nanoparticles we work with are bound into an aqueous matrix. The finishing solution is produced using dosing equipment. Any residual solution is recovered.
	Are there any emissions routes into the environment for nanoparticulate components during use?		x			x		Due to the additives used in the supplier's compound and the additives used in the formulation of the finish, only nanoparticles in a bound state are involved in the finishing process.
	Are there any emissions routes into the environment for nanoparticulate components during disposal?			x			x	
1.3	Are measures in place to reduce emissions?	x	x	x				Due to the additives used in the supplier's compound and the additives used in the formulation of the finish, only nanoparticles in a bound state are involved in the finishing process.
	- in production?	x				x		Waste gases are treated by post-combustion in a regenerative thermal oxidation system (RTO).
	- in the use phase?		x					No
	- in the disposal phase?			x				No
1.4	Are exposures likely to arise that will affect environmental media – water, soil, air: – in general?	x	x	x		x		This was demonstrated by measurements carried out in the workplace and by ITV Denkendorf testing of
	- in the production phase?	x				x		
	- in the use phase?		x			x		This was demonstrated by ITV Denkendorf testing of nanoparticle emissions from our awning fabric swela sunsilk SNC.
	- in the disposal phase?			x		x		

	Risk aspects for consumers							
2.1a	What is the total volume / concentration of the nanomaterial in the product?		x					3g/m² of woven fabric, bound in a matrix.
2.1b	Does the usage pattern potentially entail intensive consumer contact with the product?		x			x		No contact with the fabric.
2.2	Are there likely to be emissions into the consumer's environment?		x			x		None. This was demonstrated by ITV Denkendorf testing of nanoparticle emissions from our awning fabric swela sunsilk SNC.
2.3	Are measures in place to reduce emissions?		x			x		No emissions
2.4	Is exposure of consumers likely to occur?		x			x		No. This was demonstrated by measurements carried out in the workplace and by ITV Denkendorf testing of

#	Criterion	Production	Use	Disposal	Probably yes	Probably no	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
								nanoparticle emissions from our awning fabric swela sunsilk SNC.
	Risk aspects for employees							
3.1	What volume is used in the workplace?	x		x				No contact due to automated finishing process using dosing equipment.
	What volume is used in production?	x				x		No contact due to automated finishing process using dosing equipment.
	What volume is disposed of in / with the product?			x				
3.2	Are emissions likely to occur in the workplace?	x		x		x		No. This was demonstrated by ITV Denkendorf testing of nanoparticle emissions from our awning fabric swela sunsilk SNC.
	Are there any emissions during production?	x					x	Manufacturing process used by the processing aids supplier is not known.
	Are there any emissions during disposal?			x		x		
3.3.a	Are measures in place to reduce emissions?	x		x				No. This was demonstrated by ITV Denkendorf testing of nanoparticle emissions from our awning fabric swela sunsilk SNC, and by measurements carried out in the workplace.
	Are measures in place to reduce emissions during production?	x				x		
	Are measures in place to reduce emissions during disposal?			x		x		
3.3.b	Are measures to reduce emissions tested for effectiveness: – in general?	x		x				Not applicable
	- in production?	x						
	- in disposal?			x				
3.4.a	Are exposures expected when employees are present: – in general?	x		x		x		No. This was demonstrated by ITV Denkendorf testing of nanoparticle emissions from our awning fabric swela sunsilk SNC, and by measurements carried out in the workplace.
	- when employees are present during production?	x				x		
	- when employees are present during disposal?			x		x		
3.4.b	Are measures in place to reduce exposure: – in general?	x		x		x		
	- to reduce exposure during production?	x				x		
	- to reduce exposure during disposal?			x		x		
3.4.c	Are the measures to reduce exposure effective: – in general?	x		x				No exposure
	- in production?	x						No exposure
	- in disposal?			x				No exposure

#		Probably yes	Probably no	No information	Reasons for rating given / further information Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
4	Risk aspects for society				
4.1	Potential external costs for society		x		
4.1.1	External costs for the health and welfare system		x		We are not aware of any negative impact so far.
4.1.2.	External costs for remediation / conservation of ecosystems		x		Good data availability and no issues giving cause for concern
4.2	Can the use of the product pose a threat to social stability?		x		No
4.3	Is the product likely to be used incorrectly or is it complicated to handle?				Not applicable
4.4	Risks to the national economy		x		Product is well established on the market.
4.4.1	Restriction of market mechanisms		x		No patent
4.4.2	Negative impact of the product on society's acceptance of nanotechnology in general		x		Positive impact
4.5	Social impact of the product on society				Not applicable
4.5.1	Social impact of the product on the value chain		x		Safeguarding jobs in Germany.
5.	Risk aspects for the company				
5.1	Loss of image		x		Placing this product on the market has enhanced the brand's image.
5.2	Financial / economic losses due to:		x		No
5.2.1	- rejection by society		x		Product is well received.
5.2.2	- absence of or negative impact on employees		x		No. This was demonstrated by measurements carried out in the workplace.
5.2.3	- compensation payments				Not applicable
5.3.	Uncertainty of long-term strategies, risks of investment due to				Not applicable
5.3.1	- potential that as yet unknown future regulatory measures might prevent or otherwise negatively affect the use of the product				Not applicable
5.3.2	- dependency on (non-European) competitors if the technology is restricted in Europe				Not applicable
5.3.3	- too much red tape		x		No greater than usual.

Annex 5: Example product: PET bottles

Product profile	
Parameter	Details
Designation of the product	Titanium nitride (TiN) in polyethylene terephthalate plastic (PET)
Functional unit	PET beverage bottles
Technical functionality	Beverage packaging
Function of the nanomaterial in the product	PET bottles are manufactured using preforms and a stretch blow moulding process. This involves re-heating the preforms to the required deformation temperature using an infrared heater. The presence of strongly heat-absorbent substances (called “reheat additives”) in the PET material can greatly speed up the re-heating process and make it more energy efficient. Nanoparticulate TiN – at volumes of up to 20 ppm (mg/kg) in PET – acts as a reheat additive of this sort, while at the same time helping to maintain a high degree of transparency in the finished PET bottle.
Reference product	Conventional PET material without reheat additive.
Reasons for choosing reference product	Reference product is the same product, but without the nano-additive. This enables direct comparison of the two products.

Profile of nanomaterial used	
Parameter	Details
Material	Titanium nitride (TiN)
Manufacturer	No – confidential company information.
Information on the value chain	Raw material produced by a manufacturer in Asia; no information available on environmental criteria relating to manufacture of the raw material.
Description of "consumer“ / “user"	Consumers: private individuals who consume beverages packaged in PET bottles.
Form factor	Form tends to be spherical.
Particle size	Primary particle used: approx. 20 nm
Particle size distribution	Primary particle: no In PET: agglomerates of 100 – 500 nm
Surface functionalisation	No
Coating	No. The particles are suspended in a highly viscous matrix liquid which is incorporated into the plastic.
Data from the nanomaterial’s Safety Data Sheet	The Safety Data Sheet only provides information on the matrix liquid in which the nanomaterial is suspended, because this matrix liquid is the main component of the formulation. Section 8 of the SDS refers to all relevant occupational safety measures. According to section 10, the formulation is stable under normal conditions. Contact with acids and oxidising agents should be avoided. Section 11 indicates potential irritation if inhaled, swallowed or coming into contact with skin. Under section 12, the formulation is described as presenting no hazard for the environment.
Information specific to the nanomaterial	None
Other special features or characteristic properties	See above under function of the nanomaterial.

	Criterion	Production	Use	Disposal	Better than reference product	Same as reference product	Worse than reference product	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
1	Benefits for the environment				Please mark relevant box with an "x"				
Core criteria, for all products									
UM 1	Reduced resource use: energy	x	x	x					
	- in production	x			x				The energy saving in the bottle manufacturing process compared to the reference product is around 10-20%. Given the enormous quantities of PET bottles manufactured around the world (around 16 million tonnes), and the fact that PET containing reheat additives accounts for an estimated 30% share of the market, the amount of energy saved is vast. This could be increased threefold if reheat additives were used in the manufacturing of all PET bottles.
	- in use phase		x			x			
	- in disposal phase			x		x			
UM 2	Reduced resource use: water	x	x	x		x			
UM 3	Reduced resource use: raw materials	x	x	x		x			
UM 4	Prevention of greenhouse gas emissions	x	x	x					
	- reduction in production	x			x				Depends on the energy source (see above under "Resource use: energy").
	- reduction in use phase		x						
	- reduction in disposal phase			x					
UM 5	Reduced emissions of pollutants	x	x	x		x			
UM 6	Reduced waste volume and hazard	x	x	x		x			
Supplementary, detailed criteria for particular products / specific applications									
1.1.	Environmental protection / improved environmental quality								Not applicable
1.2.	Environmental remediation / reduced environmental impact								Not applicable

2	Benefit aspects for consumers / users / users of finished product								
Core criteria, for all products									Employees who use a nanoproduct in the course of their work activities are considered to be "consumers" for the purpose of this table. Estimation of benefits in the use phase is not envisaged for the category "employees".
V 1	Product offers enhanced consumer utility		x			x			In use, the finished bottle is no different from the reference product.
V 2	Product offers enhanced user safety (including protection from disease)		x			x			The nanomaterial cannot migrate out of the PET plastic. Consumer exposure – whether inhaled, oral or dermal – is therefore unlikely.

	Criterion	Production	Use	Disposal	Better than reference product	Same as reference product	Worse than reference product	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
V 3	Product offers enhanced price-performance ratio for the consumer		x			x			There is no impact on the price of the beverage (bottle with beverage).
Supplementary, detailed criteria for particular products / specific applications									
2.1.	Practical benefits / fitness for purpose								Not applicable
2.2.	Health value								Not applicable

3	Benefit aspects for employees in production chain and disposal								Employees who use nanoproducts in the course of their work activities are considered to be “consumers”. Estimation of benefits for employees relates to work involving nanomaterials in the nanoproduct’s production chain and in the disposal of finished products.
Core criteria, for all products									
AS 1	Advantages resulting from easier or safer handling	x		x		x			As far as the employee is concerned, in the preform and bottle manufacturing process there is no difference in terms of work operations. Production is in any case automated.
AS 2	Protection of health and safety in the workplace (risk management) (for examples click on the + sign)	x		x		x			Exposure to employees cannot occur during the preform and bottle manufacturing process.
Supplementary, detailed criteria for particular products / specific applications									
3.1	Improved occupational safety								Not applicable

4	Benefit aspects for society								
Core criteria, for all products									
GES 1	Reduced cost of protecting health and the environment	x	x	x	x				In terms of environmental protection, there is a direct link with the energy-saving potential (see above under “Resource use: energy”).
GES 2	Creation of new skilled jobs, safeguarding jobs	x	x	x		x			No change in work operations (see AS1 above), and hence no jobs are created or eliminated as a result.
GES 3	Enhanced product performance, improved export opportunities, improved market position and competitive edge	x	x	x		x			Practical benefit unchanged.
Supplementary, detailed criteria for particular products / specific applications									
4.2.	Providing technologies & processes / components important for developing / improving other technologies								Not applicable
4.3.	Enabling new product qualities or functionalities								Not applicable

	Criterion	Production	Use	Disposal	Better than reference product	Same as reference product	Worse than reference product	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
5	Benefit aspects for the company								
Core criteria, for all products									
UNT 1	Creation of new markets, enhanced competitiveness	x			x				As a result of reduced costs and higher number of units manufactured.
UNT 2	Improved product quality and performance	x	x			x			Possibly; no data yet available from longer-term production campaigns.
UNT 3	Reduced costs, e.g. by optimising production processes	x	x		x				Due to energy savings in the manufacturing process (see UM1 above).
UNT 4	Increased work and process safety	x				x			
Supplementary, detailed criteria for particular products / specific applications									
5.1.	Benefit aspects for the business environment								Not applicable
5.2.	Benefit aspects relating to manufacture (company's own production processes)								Not applicable

#	Criterion	Production	Use	Disposal	Probably yes	Probably no	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
	Risk aspects for the environment							
1.1	What is the total volume used in the product?	x						PET beverage bottles are manufactured in quantities of several thousands of millions. Demand is still on the increase.
1.2	Are there likely to be any emissions?	x	x	x		x		In the preform and bottle manufacturing process, emissions of nanomaterials into the environment cannot occur. After use, the bottles (in the case of refillable bottles, at the end of their circulation period, or in the case of single-use disposable bottles, when they are empty) are generally returned on account of the deposit system or end up in Germany's yellow sack (or similar) collection system for recycling. Today, PET is collected and the material is reprocessed and recycled into new bottles and in future PET recycling will increase further. The probability of emissions occurring during this process is extremely small. If the waste material collected via Germany's yellow sack system is thermally recovered, the required waste gas purification process will eliminate the agglomerated nanoparticles.
1.3	Are measures in place to reduce emissions?	x	x	x			x	
1.4	Are exposures likely to arise that will affect environmental media – water, soil, air: – in general?	x	x	x		x		It follows logically from the emissions probability outlined above that the probability of environmental exposure arising in the preform / bottle manufacture stage will also be zero or, in the post-use stage, extremely low. It should be noted that only a very tiny amount of nanomaterial is used in the PET material.
	Risk aspects for consumers							
2.1a	What is the total volume / concentration of the nanomaterial in the product?		x					The volume used in the product is extremely small. There is no consumer exposure.
2.1b	Does the usage pattern potentially entail intensive consumer contact with the product?		x			x		
2.2	Are there likely to be emissions into the consumer's environment?		x			x		It is almost impossible in practical terms for the consumer to release the nanomaterial from the PET matrix. This could occur if the consumer were to burn the bottle. In such an event, however, it can be assumed that the primary particles, already in agglomerate form, would agglomerate further.
2.3	Are measures in place to reduce emissions?		x			x		
2.4	Is exposure of consumers likely to occur?		x			x		The likelihood is extremely small or close to zero because the nanomaterial is immobilised in the PET matrix. As a result, consumer exposure cannot occur during use of the product.
	Risk aspects for employees							
3.1	What volume is used in the workplace?	x		x				
3.2	Are emissions likely to occur in the workplace?	x		x		x		In the preform and bottle manufacturing process, emissions of nanomaterials into the work environment cannot occur.
3.3.a	Are measures in place to reduce emissions?	x		x		x		
3.3.b	Are measures to reduce emissions tested for effectiveness: in general?	x		x			x	
3.4.a	Are exposures expected when employees are present: – in general?	x		x		x		It follows logically from the emissions probability outlined above that the probability of exposure to employees will also be zero, and production is automated in any case .

#	Criterion	Production	Use	Disposal	Probably yes	Probably no	No information	Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
3.4.b	Are measures in place to reduce exposure: – in general?	x		x		x		
3.4.c	Are measures to reduce exposure effective: – in general?	x		x			x	

#		Probably yes	Probably no	No information	Reasons for rating given / further information Please use the space below to explain your rating. If no quantified data is available, please provide a qualitative description of the facts. The reasons and descriptions given should be clear and comprehensible to external parties.
4	Risk aspects for society				
4.1	Potential external costs for society		x		
4.1.1	External costs for the health and welfare system		x		
4.1.2.	External costs for remediation / conservation of ecosystems			x	
4.2	Can the use of the product pose a threat to social stability?		x		
4.3	Is the product likely to be used incorrectly or is it complicated to handle?			x	
4.4	Risks to the national economy		x		
4.4.1	Restriction of market mechanisms		x		
4.4.2	Negative impact of the product on society's acceptance of nanotechnology in general		x		
4.5	Social impact of the product on society		x		
4.5.1	Social impact of the product on the value chain		x		

5.	Risk aspects for the company				
5.1	Loss of image		x		
5.2	Financial / economic losses due to:		x		
5.2.1	- rejection by society		x		
5.2.2	- absence of or negative impact on employees		x		
5.2.3	- compensation payments			x	
5.3.	Uncertainty of long-term strategies, risks of investment due to				
5.3.1	- potential that as yet unknown future regulatory measures might prevent or otherwise negatively affect the use of the product		x		This use has been classified by the European Food Safety Authority (EFSA) as being "of no concern" and is permitted under Community food law.
5.3.2	- dependency on (non-European) competitors if the technology is restricted in Europe			x	
5.3.3	- too much red tape		x		