FINAL REPORT OF NANOKOMMISSION ISSUE GROUP 4

CRITERIA FOR PRELIMINARY ASSESSMENT OF NANOMATERIALS WITH REGARD TO THEIR IMPACT ON HUMAN HEALTH AND THE ENVIRONMENT

Ökopol
Institut für Ökologie und Politik GmbH

29 SEPTEMBER 2010

CONTENT -

1 REMIT OF THE ISSUE GROUP ..... 4 -
2 RESULTS OF THE ISSUE GROUP'S WORK ..... 6 -
2.1 GUIDELINES FOR USING THE CRITERIA 6
2.1.1 Purpose 6
2.1.2 Scope 7
2.1.3 Target group / users of the criteria 7
2.1.4 Features of the criteria 7
3 CRITERIA FOR PRELIMINARY ASSESSMENT ..... 8 -
3.1 BACKGROUND TO THE CRITERIA 8
3.2 HOW THE CRITERIA ARE ORGANISED 10
3.3 THE CRITERIA 11
3.4 EVALUATING THE ASSESSMENT 13
4 KEY DISCUSSIONS ..... 14 -
4.1 PUTTING THE CRITERIA IN CONTEXT 14
4.2 SCOPE 15
4.3 CRITERIA HIERARCHIES, WEIGHTING AND EVALUATION 16
4.4 THE CONCEPTS "CAUSE FOR CONCERN" AND "NO CAUSE FOR CONCERN" 16
4.5 DISCUSSIONS ON EVALUATION PROCEDURE 17
4.6 UNRESOLVED ISSUES AND FUTURE WORK 17
5 CONCLUDING REMARKS AND RECOMMENDATIONS ..... 18 -
ANNEX 1: LIST OF ISSUE GROUP MEMBERS ..... 21 -
ANNEX 2: HOW THE CRITERIA WERE DEVELOPED (DIALOGUE PHASE 1 → DIALOGUE PHASE 2) ..... 22 -
ANNEX 3: GUIDELINES AND CRITERIA ..... 24 -
1 INTRODUCTION ..... 26 -
2 DEFINITION OF TERMS ..... 26 -
3 APPLYING THE CRITERIA ..... 29 -
3.1 PURPOSE AND CONTEXT OF THE CRITERIA 29
3.2 WHAT CAN BE ASSESSED USING THE CRITERIA? 30
3.3 WHO CAN USE THE CRITERIA? 30
3.4 WHAT ARE THE KEY FEATURES OF THE CRITERIA? 31
3.5 BASIS OF THE CRITERIA 32
3.6 BACKGROUND: HOW THE CRITERIA WERE DEVELOPED 32
4 CONCEPT OF PRELIMINARY ASSESSMENT ..... 34 -
5 THE CRITERIA ..... 36 -
6 EVALUATING THE ASSESSMENT ..... 42 -
6.1 POTENTIAL RISK MANAGEMENT CONTACTS 44
6.2 POTENTIAL TOOLS FOR TARGETED RISK ASSESSMENT 45
7 ABBREVIATIONS ..... 47 -
ANNEX 4: MINUTES OF THE EXPERT WORKSHOP ..... 48 -
1 INTRODUCTION AND OBJECTIVES ..... 49 -
2 PRESENTATION OF THE CRITERIA DEVELOPED BY ISSUE GROUP 4 ..... 49 -
2.1 PRESENTATION CONTENT 49

2.2 SUMMARY OF QUESTIONS, RESPONSES AND COMMENTS ON THE ISSUE GROUP 4 CRITERIA 50
3 PRESENTATION OF THE SWISS PRECAUTIONARY MATRIX ..... 51 -
3.1 PRESENTATION CONTENT 51
3.2 SUMMARY OF QUESTIONS, RESPONSES AND COMMENTS ON THE SWISS PRECAUTIONARY MATRIX 52
4 HOW SWISS RETAILERS USE THE PRECAUTIONARY MATRIX ..... 54 -
4.1 PRESENTATION CONTENT 54
4.2 SUMMARY OF QUESTIONS, RESPONSES AND COMMENTS 54
5 CONCLUSIONS / POINTERS FOR THE WORK OF ISSUE GROUP 4 ..... 55 -

1 Remit of the Issue Group

In the NanoKommission's first dialogue phase, criteria indicating "no cause for concern" or "concern" were developed for carrying out a preliminary risk assessment of nanomaterial applications. As an outcome of this assessment, nanomaterials were classified into three groups according to the degree of concern identified[1].

In its 2009/2010 dialogue phase, the NanoKommission set up Issue Group 4 to refine the criteria for "concern" and "no cause for concern" developed in the first dialogue phase by bringing them up to date, making them more specific and operationalising them. This was to include:

- reviewing whether the criteria are still appropriate and accurate in the light of advances in knowledge in recent years
- specifying and formulating clearly the terms and parameters used in the individual criteria
- specifying appropriate measurement methods for collecting information under each of the criteria
- identifying indicators for each of the criteria to establish "concern" or "no cause for concern" with regard to a particular application of a nanomaterial
- giving a weighting to the criteria
- if possible, the following additional steps were also to be undertaken:
    - connecting the preliminary risk assessment approach based on criteria indicating "concern" or no "cause for concern" with the NanoKommission's "Principles for the responsible use of nanomaterials"
    - developing rules for applying appropriate precautionary risk management measures as dictated by whether or not the various weighted criteria apply
    - coordinating the Group's findings with those of Issue Group 2.

Issue Group 4 was tasked with building on the findings of the first dialogue phase, taking into account any similar initiatives currently under way, such as the Swiss Precautionary Matrix. In addition the Group was to develop a criteria set with a guide setting out the context of the criteria[2] as well as explaining how to conduct the assessment process and present the findings.

As a result of its work, Issue Group 4 has produced a set of criteria complete with guidelines for conducting a preliminary assessment of nanomaterials in terms of their impact on human health and the environment.

---

[1] See NanoKommission Report (2008) and the Final Report of Working Group 2 on "Risk and safety research".

[2] The aim here was to show how the criteria relate to risk assessments conducted in the regulatory context, and to set out possible consequences of the assessment outcome, e.g. as a catalyst for further investigation or, where relevant, risk management measures and/or steps to obtain more information.

In order to create a practicable, user-friendly criteria set, and given that significant knowledge gaps remain, the criteria were simplified while at the same time taking advances in knowledge into account. The criteria were grouped into content-related blocks (see section 3.2). It was not possible to give a clear description and explanation of concepts that have not yet been defined (e.g. “containment”, or “easily released”).

Because the criteria were simplified, specifying a measurement method was only necessary in a few cases. Simplification of the criteria also led the Group to decide not to weight the criteria relative to each other. Indicators were devised for all criteria to show whether there is “No immediate need for precautionary measures / No cause for concern”, or “Further consideration / Need for precautionary measures / Cause for concern”. The Group debated long and hard about the terminology used in this context (see also section 4.4).

In summary, we can state that the Issue Group fulfilled its remit to “develop the criteria further with an eye to their applicability”. In the course of the work, however, the Group realised that it would have to deviate somewhat from the terms of reference set out by the NanoKommission in order to produce criteria that were relevant in practice for the chosen target group (“informed users”; see section 2.1.3) while at the same time taking into account current knowledge. Challenges for the Issue Group included:

- Describing scientifically accurate, and yet simple and practicable parameters for identifying the need for precautionary measures / grounds for concern and no cause for concern for nanomaterial applications. This task took up nearly all the Group’s attention, organisational resources and time.
- Identifying appropriate measurement methods for each of the criteria was often not necessary (data not quantifiable, data collection not standardised) or not possible, because relevant standards are not (yet) in place. This task was carried out as and when necessary, although, like the first task, it was more scientific than socio-political in focus.
- The Group did not favour weighting the criteria produced or ranking them in any sort of hierarchical order; this was deemed neither necessary nor useful. In the Group’s view, it is in any case not possible to give the criteria a weighting in the abstract, because the importance of particular criteria might increase or decrease depending on the application in question. On the other hand, however, simply grouping the criteria together would mean losing information and could result in errors.

Overall, it should be pointed out that the number of meetings scheduled in order to achieve the desired result was too small and the allotted timeframe too narrow.

The group does not dispute that it would be desirable to have a differentiated set of criteria with simple, specific measurement procedures stipulated in each case, and a broadly accepted weighting of the criteria. Work on developing testing procedures is currently being carried out by ISO Technical Committee 229, the OECD’s Working Party on Manufactured Nanomaterials (WPMN) and the

European Chemicals Agency (ECHA). Additional scientific input is needed to establish and monitor appropriate testing procedures and for a definitive debate on weighting the criteria.

To arrive at an outcome supported by all the Issue Group participants, compromise was necessary in some instances. Section 4**Fehler! Verweisquelle konnte nicht gefunden werden.** sets out details of some of the discussions relating to these. In addition, footnotes have been included in some cases giving details of differing opinions held by some Issue Group members.

2 Results of the Issue Group's work

This section describes the actual output of the Issue Group – a document setting out guidelines for carrying out a preliminary assessment (see below) of nanomaterial applications in terms of their impact on human health and the environment. The guidelines are available online as a stand-alone file.

2.1 Guidelines for using the criteria

2.1.1 Purpose

The criteria are intended to help carry out a preliminary assessment of nanomaterials in terms of their impact on human health and on the environment. They are useful tool for highlighting information gaps, further testing requirements and, where relevant, risk management measures that need to be taken to ensure the responsible use of nanomaterials[3].

Preliminary assessment is intended to cover the nanomaterial's entire life cycle and the result should be reviewed on a regular basis to take into account advances in knowledge regarding nanomaterials.

Responses to questions on the criteria indicate "Further consideration / Need for precautionary measures / Cause for concern", "No immediate need for precautionary measures / No cause for concern", or "Data gap" in four separate thematic "blocks". In terms of its scope, level of detail and ability to provide meaningful results, this preliminary assessment is very different from a scientific risk evaluation, which can provide detailed evidence of the risks associated with the use of a nanomaterial based on scientific knowledge (testing of the material's physico-chemical, toxicological and ecological properties and potential exposure scenarios). Practical examples were used to test how well the criteria set performs as a tool for assessing the impact of new materials.

[3] Friends of the Earth Germany (BUND) point out that the first NanoKommission Report (2008) called for a guide to be produced for making preliminary assessments, and that this guide "should be rendered operational and weighted during the second phase of the NanoDialogue". If too little information is available to demonstrate "No cause for concern", the nanomaterial should be ranked in the "concern" category on precautionary grounds. In this regard, BUND's view is that the consequences to be drawn from applying the criteria are not sufficiently binding.

If a statutory or comprehensive voluntary risk evaluation has already been carried out, this takes precedence over any assessment carried out on the basis of these criteria.

2.1.2 Scope

The criteria can be used for all intentionally manufactured nanomaterials, in other words both for nanomaterials at the research and development stage and those already available or in use. In addition they can also be use for free nanomaterials and their aggregates and agglomerates[4], as well as for products which contain nanomaterials bound in a matrix[5].

When carrying out the assessment, it should be borne in mind that a nanomaterial may have undergone a variety of modifications (such as surface functionalisations, imperfections in the crystal lattice, etc.), or may be used in different products and matrices. Each different modification or application needs to be separately assessed in its own right.

2.1.3 Target group / users of the criteria

The user of the criteria needs to possess background knowledge about the specific nanomaterials and the product containing them which is the subject of the assessment. The criteria set is therefore intended primarily for the informed user. Informed users may include:

- manufacturers of nanomaterials: for testing during research and product development, and testing of products already on the market
- users of nanomaterials: for improving consumer information or enhancing risk management
- those involved in disposal of nanoproducts: for assessing impact on waste management
- distributors of nanoproducts: for improving product classification, and enhancing consumer advice and information
- occupational health and safety officers: for making assessments for the purpose of risk management and communication in the workplace
- compliance evaluators: as an aid to assessment of and decision-making about products containing nanomaterials
- NGOs: for improving consumer information.

2.1.4 Features of the criteria

The particular features of the criteria are listed below:

---

[4] This includes nanomaterials that may foreseeably be generated during use, for example by special spray heads in an aerosol spray. Definitions of terms used are provided in the guidelines.

[5] It is recommend that nanomaterials which fall outside the size range stipulated in the working definition should also be assessed, as the definition is a temporary one and in other contexts different (e.g. larger) sizes may be relevant.

- Applying the criteria can help provide an initial assessment of nanomaterials early on, even where very little data is available.
- The criteria can be used by a variety of actors and cover a variety of protection targets and all life cycle stages.
- The criteria are not a rigid matrix and can be applied irrespective of the amount of information available.
- The criteria can act as a decision-making aid for undertaking further steps towards risk evaluation as part of a weight-of-evidence approach.
- To facilitate use by a broad range of users with varying degrees of knowledge, and to incorporate information available at an early stage, the criteria are relatively straightforward by comparison with those used for scientific risk assessment.
- To ensure that it is relatively straightforward to obtain information, the assessment of impact is restricted primarily to qualitative statements.
- Using the criteria to assess the impact of new materials has not yet been validated or established in practice. In contrast to a comprehensive scientific risk evaluation, which is based on tried and tested procedures, initial experience with the use of the criteria has yet to be gathered.
- Assessment is voluntary. It cannot be used either to justify (fully), or to revoke or query any official decision.

3 Criteria for preliminary assessment

3.1 Background to the criteria

The present criteria were developed on the basis of the criteria for “concern” and “no cause for concern” produced in the first nanodialogue phase. The criteria set was intended to be a user-friendly tool which, in contrast to the criteria produced in the first dialogue phase, would be more scientific in approach and geared towards informed, but non-expert users. Due to the choice of target group, it was necessary to focus the criteria appropriately. To do this, the criteria were couched in the form of questions requiring a “yes” or “no” response.

Criteria for which questions could be formulated without difficulty were adopted without alteration.

Criteria that could not be couched as a simple question, or for which measurement methods were not yet available, were modified so as to obtain relevant information. The coupling of the criteria to methods of measurement should be questioned given the choice of target group (users of the criteria). Measurement methods are useful particularly for an expert audience which, however, represents only a small minority of the target group or already has the relevant knowledge without the matrix.

If any of the criteria could not be reformulated into questions that could not be answered without a significant increase in research effort, then these were classified as belonging to scientific risk evaluation or research and consequently removed from the latest list.

Additional criteria were also included to close gaps resulting from modifications made to the list of criteria from the first dialogue phase and in view of the objective that the criteria would be "easy to use, target group: informed users". The list below summarises how the criteria from the first dialogue phase were incorporated into the criteria set produced in the second dialogue phase. (See Annex 2 for a detailed table setting out the rationale for changes).

The following criteria from the first dialogue phase were adopted unchanged:

Production volume, intentional release, high level of reactivity, problematic morphology, solubility in water.

The following criteria were modified:

- High level of mobility in nanoform[6] → stable bonding in a matrix[7]
- Rapid degradability in non-toxic degradation products → complete degradability
- Stable and permanent bonding in a matrix → stable bonding, minimal release during use and disposal, tendency to dust formation
- Presence of firmly bound agglomerates, or formation of stable agglomerates → surface[8]
- Biological reactivity → toxicological / ecotoxicological effects.

Parameters not considered in the context of preliminary assessment because of poor measurement methods and the need for significant research effort:

Mobilisation potential, persistence[9] of nano-properties[10], bioaccumulation, indications of problematic interactions or transformations, poor verifiability and unclear fate, solubility in body fluids.

---

[6] Mobility in the environment is an indication of a substance's distribution in the environment and therefore needs to be distinguished from "Release from matrices" in the thematic block "Probability of exposure". Because methods for ascertaining the behaviour of nanomaterials in the environment are lacking, this criterion has been limited to bonding within a matrix. This should be amended in accordance with technological progress.

[7] Friends of the Earth Germany (BUND) point out that from their perspective a high degree of mobility of a material in nanoform constitutes grounds for concern as a matter of principle. Hence, in their view the questions about bonding in matrices do not go far enough.

[8] The concept of "aggregate" was subsumed under the criterion "surface" because size is the decisive parameter; the criterion "agglomerates", on the other hand, is excluded as agglomerates depend to a significant extent on the surrounding conditions and hence cannot be used as a basis for assessment.

[9] BUND points out that this criterion is very important for assessment and hence should not have been removed from the list. The persistence of nano-properties, in their view, is generally a cause for concern and has considerable regulatory relevance in terms of exposure.

[10] It is not yet possible to define the term "nano-properties", so they cannot yet be subjected to experimental research.

Another parameter not considered was the criterion “nanostructured surfaces”, because the objective of the criteria list is to assess nano-objects (including their agglomerates/aggregates).

A new inclusion is:

Use in a consumer product; processing carried out in a closed facility.

3.2 How the criteria are organised

The criteria should not be applied to nanomaterials for which the bulk form is known to be classified or to meet the criteria for classification as a hazardous substance in accordance with the EU Dangerous Substances Directive (No 67/548/EEC) or Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. In such cases a scientific risk evaluation must be carried out.

If a comprehensive scientific risk evaluation covering the application in question is available, the criteria should not be applied. Instead, the conclusions of the risk evaluation should be used.

The criteria are grouped into four thematic blocks: “Probability of exposure”, “Physico-chemical properties”, “Behaviour in the environment”, and “Toxicology and ecotoxicology”. Within each block the criteria are arranged according to the amount of effort needed to obtain the required information.

Each of the criteria is in the form of a guiding question requiring a “yes” or “no” answer; each individual answer is assigned to one of the following categories: “No immediate need for precautionary measures / No cause for concern”, or “Further consideration / Need for precautionary measures / Cause for concern”. In the absence of information to answer the question, the response “Data gap” can be given.

If there are data gaps for many criteria in the assessment, this is indicative of a significant lack of knowledge concerning the nanomaterial in question and its uses. More detailed examination of the relevant criteria is therefore needed. The fewer data gaps are identified, and hence the greater the number of criteria to which a response is given, the more comprehensive and meaningful the assessment. It is envisaged that the user will check and respond to all criteria.

Each criterion is assigned a letter denoting the protection target(s) for which it is relevant (**U** = environment and people (***U**mwelt und Mensch*), A = Employees (***A**rbeitnehmer*), V = Consumers (***V**erbraucher*[11])). In some cases the criteria are accompanied by additional notes, e.g. concerning testing procedures.

[11] The term “consumer” refers to both the immediate user of the product and to any uninvolved third parties present while the product is being used.

3.3 The criteria

The criteria are grouped into four blocks: “Probability of exposure”, “Physico-chemical properties”, “Behaviour in the environment”, and “Toxicology and eco-toxicology”. The structure of the table setting out the questions on the criteria for completion by the user is shown below based on the example of the criterion “Production volume” in the block “Probability of exposure”. The table structure is identical for all four blocks of criteria. The table for “Production volume” is followed by a list of all the other questions and explanations for each of the blocks of criteria: “Probability of exposure”, “Physico-chemical properties”, “Behaviour in the environment”, and “Toxicology and ecotoxicology”.

Table 1: Format of the criteria based on the example “Production volume”

Criterion	**Protection target**[12]	**Explanation**	**Further consideration / Need for precautionary measures / Cause for concern**[13]	**No immediate need for precautionary measures / No cause for concern** [14]	**Data gap**[15]	**Documentation / basis for decision**
Production volume	AVU	Is the volume of nanomaterial manufactured > 100 kg/year?				
		Yes	□			
		No		□		
		Cannot answer / do not know			□	

Probability of exposure

- Production volume (AVU):
  Is the volume of nanomaterial manufactured > 100 kg/year?
- Manufacturing/processing (AU)
  Is the material handled in closed facilities?

[12] Protection targets are abbreviated in the table, as follows: A = Arbeitnehmer (employees), V = Verbraucher (consumers), U = Umwelt (environment).

[13] Here “Further consideration” is taken to mean that closer examination of the criterion is question is considered essential, and hence more information must be generated and, where relevant, risk management measures put in place. The term “Concern” was adopted from the first Nanodialogue phase. In the first dialogue phase the following criteria were deemed relevant for concern: “indications of an expected high level of exposure (to the point of irretrievability), potential problematic effects, and also problems with providing evidence for and with the tracing of released nanomaterials.” In the context of these criteria it is not possible to make definitive or comprehensive statements regarding “Concerns”, since individual aspects are examined separately. A concern is to be seen as an indication that further consideration is needed on precautionary grounds.

[14] The term “No cause for concern” was adopted from the first Nanodialogue phase. In the first dialogue phase the following criteria were deemed relevant for “No cause for concern”: “indications that nanomaterials in the respective application are either permanently firmly bound in matrices, or that they rapidly lose their potentially problematic nano-properties, e.g. through good solubility or rapid degradability”. In the context of the present table of criteria, a rating of “No cause for concern” is to be interpreted as meaning that taking further steps is less necessary and less urgent than in the case of a “Concern” rating. Only a scientific risk evaluation can establish whether a nanomaterial is completely without cause for concern, in other words safe, in a particular application. An assertion of this sort cannot be made on the basis of the criteria.

[15] Data gap: the user of the criteria does not have access to further information is available or there is no data available in general. Knowledge gaps should be classed as grounds for concern as a matter of course.

- Manufacturing/processing (AU)
  Is the material easily released (dust, aerosol formation, waste water)?
- Product use (V)
  Is the material used or intended for use in a consumer product?
- Product use (U)
  Is the material released intentionally into the environment (e.g. groundwater remediation, agricultural applications)?
- Product use (VU)
  Is the nanomaterial easily released (e.g. dust, aerosol formation, in water, by abrasion)?
- Product disposal/recycling (AVU)
  Is the nanomaterial easily released during product disposal/recycling (e.g. dust, aerosol, water, matrix destruction)?

Physico-chemical properties

- Morphology (AVU):
  Does the nanomaterial have a fibre, tube or rod-like morphology?
  Explanation: applies to lengths > 300 nm
- Surface (AVU):
  Is the surface > 6/100 nm^{-1} (note: volume-specific surface, SCENIHR Opinion, Biocidal Products Directive; Explanation: data in m^2/g can be converted to nm^{-1} units by multiplying by the density)
- Reactivity (AVU):
  Is the nanomaterial known to be chemically, catalytically or biologically reactive, or is the material manufactured specifically to produce reactive properties?
- Solubility in water (AVU):
  Is the material readily soluble in water, resulting in loss of its nanostructure?
  Explanation: definition of “readily soluble”; water: 20°C; > 1000 mg/l (ECHA, IUCLID 5.2); procedure OECD TG 105: Water Solubility
- Dust formation (AVU)
  According to the parameters set for dustiness, can the material’s propensity to generate dust be classified as “minimal”?
  Explanation: ranking according to / based on EN 15051 lists. (See also studies by e.g. the *Institut für Gefarhstoff-forschung* (IGF – Institute for Research on Hazardous Substances) concerning the propensity of nanomaterials to deagglomerate).

Behaviour in the environment

- Degradability (U):
  Is the nanomaterial completely degradable?
  Explanation: in the case of organic materials, biodegradability is particularly relevant (along with corresponding OECD testing procedures). Abiotic degradation may apply to both organic and inorganic materials.

As a rule it should be assumed that degradation does not take place unless the nanomaterials have been specifically designed to do so (green nano).

- Mobility in the environment (U)
  Is the nanomaterial permanently embedded in a stable matrix and hence cannot be released into or move around in the environment?

Toxicology / Ecotoxicology

At the present time there are no clearly accepted criteria indicating no cause for concern in toxicological and ecotoxicological terms. It is therefore not currently possible to make a preliminary assessment in this regard. Full scientific risk evaluation is required. For the purposes of assessment, however, available information such as that from public databases and suppliers should be taken into account as far as possible.

- Toxicology (AV):
  Are there any indications of toxicological effects that are relevant for humans?
  Explanation: If the answer is yes, then human exposure must be investigated more closely (scientific risk evaluation). Please provide details of available information here ("Documentation/basis for decision").
- Ecotoxicology (U):
  Are there any indications of ecotoxicological effects that are relevant for the environment?
  Explanation: If the answer is yes, then environmental exposure and its potential impacts must be investigated more closely (scientific risk evaluation). Please provide details of available information here ("Documentation/basis for decision").

3.4 Evaluating the assessment

The criteria table is aimed at alerting users to the need for further consideration or possible precautionary measures, and to grounds for concern or factors giving no cause for concern in relation to the nanomaterial or nanoproducts under examination, as well as highlighting gaps in the users' subjective or objective information. Evaluation of the responses does not produce a single communicable result, e.g. in the form of an aggregated quantitative "risk index". Emphasis is given instead to interpreting the significance of each answer.

However, the number of responses for the "blocks" of criteria under examination can of course be used to help set priorities for further work. It must nevertheless be emphasised that this can only be done in addition to, and not instead of, detailed expert examination of the individual criteria.

4 Key discussions

4.1 Putting the criteria in context

The Issue Group's criteria were developed on the basis of the criteria for "Concern" and "No cause for concern" from the first dialogue phase. This entailed simplifying the criteria and adapting them to the level of knowledge and information available to the target group defined by the Issue Group, namely "informed users".

A workshop to which experts from Switzerland were invited was organised by the Issue Group to facilitate an exchange of information on the Swiss Precautionary Matrix. Presentations were given and discussions were held on the development of the criteria and indicators for the Swiss Precautionary Matrix, and on evaluating the results obtained by this method (see documentation in Annex 4).

As in the case of the Swiss Precautionary Matrix, the criteria developed by Issue Group 4 are couched as questions requiring a clear response from the user, unless the necessary information is not available. The Issue Group's criteria, as in the Swiss Precautionary Matrix, can be assessed pragmatically and with relatively little effort. The user ("informed user") is assumed to have some knowledge of fundamental issues relating to assessing potential risks.

In contrast to the Swiss Precautionary Matrix, no attempt has been made to weight the criteria, and aggregation of the results is not envisaged. The intention here is to prevent individual important criteria from being eclipsed by others of less significance. On the other hand, however, when evaluating the results the numbers of identical responses in each block are collated to enable priority-setting.

The following table presents the similarities and differences between the Issue Group 4 criteria and the Swiss Precautionary Matrix.

Table 2: Comparison of Swiss Precautionary Matrix and Issue Group 4 criteria

Aspect	Swiss Precautionary Matrix	Issue Group 4 criteria
General		
Starting point	Conscious decision that nanomaterials are present Definition of nanomaterials: for pragmatic reasons, upper limit 500 nm	Presence of nanomaterial assumed Definition of nanomaterials: NanoKommission definition adopted; size not restricted to upper limit of 100 nm (ISO definition) Bulk material must not already be classified as a hazardous substance
Evaluation	Criteria are weighted	No weighting
	Knowledge gap → worst case assumed	Knowledge gap → regarded as "no information"
	Result expressed in numerical terms	Result expressed verbally
Target group	Industry, commerce, trade associations; national and international	Informed users (e.g. industry, commerce, trade associations, authorities)
Criteria – details		
Life cycle information	Origin, life cycle, contamination	Not given specific consideration, but integrated into questions on exposure
Potential impact	Redox activity, stability under physiological and environmental conditions	• Reactivity details included under "physico-chemical properties" • Where toxicological/ecotoxicological data are available, these should be considered with expert assistance
Exposure	• Physical surroundings: stability, state • Human exposure: mass/frequency of contact • Input into the environment: mass of waste nanomaterial; mass in consumer products • Definition of nanomaterials	• Production phase: production volume, potential for release • Product application: use in consumer products, potential for release into the environment • Disposal/recycling: potential for release
Physico-chemical properties as an indicator of exposure or impact	Not specifically considered	Morphology, surface, reactivity, solubility in water, and dustiness used as indicators of undesirable effects
Behaviour in the environment	Not so far specifically considered; an information sheet is due to be published soon detailing which responses may be used as a basis for drawing conclusions concerning the environment	Degradability, stability as indicator of mobility

The Issue Group stresses that future work on the criteria should continue to take place in a process of exchange with the Swiss Precautionary Matrix.

The Issue Group 4 criteria are intended explicitly as a tool for making a preliminary assessment of nanomaterials in terms of their impact on humans and on the environment. Scientific risk evaluation is the gold standard, and should not be replaced by the criteria set.

4.2 Scope

The participants at the Issue Group's expert workshop found it very helpful that the Swiss Precautionary Matrix identifies "nano-relevance" (i.e. presence of a nanomaterial within the meaning of the definition). This was not, however, adopted in the list of criteria; instead, a brief description of the scope of the criteria is included in the document setting out how to use the guidelines.

The Issue Group agreed that the scope of the criteria should be tailored primarily to nanomaterials as defined in the NanoKommission's first dialogue phase. In line with the precautionary principle, the ISO definition (at least one dimension < 100 nm) was not adhered to, and nanomaterials not corresponding to this size definition were included. The Group also established that assessment of a na-

nomaterial needs to relate to its end-use application in order to be meaningful; planned applications in research and development can also be tested in this way.

4.3 - Criteria hierarchies, weighting and evaluation

Following several discussions in the Issue Group, it was decided not to rank the criteria in any hierarchical order or give them any weighting. The Group ultimately rejected the original idea of a stepped procedure in which questions are asked first of all about more in-depth criteria (for example about potential exposure, analogous to the SCENIHR Opinion). The idea of arranging the criteria according to the user's level of knowledge or to the availability of information was likewise rejected. Instead the Issue Group felt that all the criteria now included in the list should be treated equally. The rationale behind this was to ensure that all available information would be included in the assessment process and to avoid creating the impression that partial information is an adequate basis for assessment.

As a result, the process may also end up producing statements that are highly conservative, since for example criteria that are relatively unimportant may be given the rating "Further consideration / Need for precautionary measures / Cause for concern" for a certain application. The decision not to group the criteria together can also result in similarly conservative outcomes.

In order to generate awareness of the materials under investigation, it was also decided not to formulate termination criteria to exclude the possibility of an assessment being terminated with a "generally safe" verdict (e.g. where there is no exposure).

When evaluating the responses to the criteria, besides the aspects "No immediate need for precautionary measures / No cause for concern", and "Further consideration / Need for precautionary measures / Cause for concern", the response in the column headed "Data gap" should provide a clear indication of a need for more information. Suggested information sources contained in the guidelines are intended to give users of the criteria initial ideas for ways of closing any information gaps. However, the Issue Group also regards expert support as necessary, especially where concerns are identified.

4.4 - The concepts "Cause for concern" and "No cause for concern"

The terminology used for grading the materials ("Cause for concern" and "No cause for concern") was discussed in depth. On the industry side, the prevailing opinion was that consideration of the individual criteria would objectively highlight aspects requiring further thorough investigation to ensure safe use of the material. Industry representatives thought it misleading to have "cause for concern" as an outcome of a preliminary assessment, and they advocated using "Further consideration" or "Need for precautionary measures" instead.

Some representatives of civic associations and other Issue Group members favoured the terms “Cause for concern” and “No cause for concern” as they express both objective and subjective perceptions. Moreover, these terms illustrate the continuity of the NanoKommission’s work. The outcome of these discussions is that all of the proposed terms are used in the table.

4.5 Discussions on evaluation procedure

The Issue Group is agreed that qualitative, detailed evaluation of the responses is an indispensible step when applying the table of criteria. From the outset, all participants in the Group rejected the idea of aggregating the data and setting quantitative indicators (risk index, etc.).

Nevertheless, as the work of the Group was drawing to a conclusion, it was felt that there was a need to provide users of the criteria with an additional evaluation and interpretation aid. This resulted in the evaluation table in which the number of similar answers for each “block” of criteria, divided up according to protected resources, can be collected together and then be calculated as a ratio of the total number of responses.

Several members of the Issue Group expressed reservations regarding this procedure, as they felt misunderstandings could arise if the users were simply to add up the responses and use this sum to draw conclusions. Listing the number of data gaps was the only suggestion supported by all the participants. In their present form, the evaluation table and interpretation aids in the guidelines represent a compromise carried by the whole Group.

4.6 Unresolved issues and future work

Owing to the limited timeframe, the Issue Group was unable to deal with many issues relating to making the criteria more specific and operationalising them. The list of criteria produced by the participants reflects the consensus within the Group concerning criteria that are relevant for a preliminary assessment of nanomaterials. It is not suitable for use as the sole basis for adopting risk management measures or for deciding whether to manufacture or cease production of particular materials. For such purposes, additional information (e.g. on benefit aspects) or a comprehensive scientific risk evaluation are needed. As experience with using the criteria increases, this could be used to help develop the criteria further.

Work on the following issues was not concluded, although it might have helped to make the criteria easier to understand and apply in practice:

- making the criteria more specific through clear definitions of the concepts used
- where appropriate, producing better indicators and advice regarding when a criterion warrants a yes / no response
- specifying measurement methods for relevant parameters (depending on the availability of testing methods for nanomaterials)
- providing advice on how to decide what action needs to be taken for particular criteria, e.g. what additional information needs to be generated, or what risk management measures would be feasible.

Other unresolved issues include the pros and cons of tailoring the criteria specifically to different target groups (whether to omit particular criteria, provide more detail, adjust the phrasing of the criteria, or make specific recommendations for action), and options for visualising the results.

The Issue Group advocates making “Preliminary assessment of nanomaterials” accessible to a broad audience, for example by means of:

- publication on the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) website and on the websites of other relevant ministries and public authorities
- presentations at workshops and information events
- using and publicising it within associations and other institutions.

When doing this or any other sort of publicity work, however, it is important to put the criteria in context and highlight the unresolved issues and prevailing points of dissent. At an international level, the criteria can also be incorporated into relevant dialogue processes or projects and studies aimed at developing tools for assessing nanomaterials.

5 Concluding remarks and recommendations

The work of the Issue Group was marked by a spirit of constructive scientific exchange, but also by a very tight timeframe. It was also shaped by the participants’ desire to produce an objective preliminary assessment tool yielding clear and unambiguous outcomes.

When using the tool developed by the Issue Group, it must be borne in mind that nanomaterials are a highly heterogeneous group of materials which can be used in a broad range of products. Their heterogeneity makes it difficult at present to establish concrete assessment benchmarks that are applicable across the board. Users of the criteria must exercise a significant degree of critical

awareness and responsibility. In addition, the following points also need to be taken into account:

- scientific knowledge is not yet sufficiently advanced to allow generalisations and abstract pronouncements to be made regarding the properties of nanomaterials
- some properties of nanomaterials may increase or reduce a potential risk depending on the context in which they are applied
- the great variety of applications of nanomaterials means that it is impossible establish specific criteria relating to potential emissions and exposures; this in turn makes it impossible to provide specific advice for gathering and interpreting the data on these aspects.

The criteria and guidelines can be used by companies, public authorities, NGOs and other institutions or individuals. In cases where information is lacking, the conclusion (obtain information) is obvious; for other criteria, the course of action to be taken, if any, will depend on who is using the criteria and for what purpose.

The criteria reflect the position reached in the discussions in the given time. To ensure that this criteria set can become successfully established as a simple tool for initial assessment of the potential impact of nanomaterials, it may be helpful to consider the following:

- Experience relating to application of the criteria in practice should be gathered and taken into account when developing the criteria further.
- Users of the criteria should be able to call upon experts to help interpret the results and, where relevant, identify information or appropriate risk management measures.
- Exchange of experience among users of the criteria could be useful.
- Subject to successful practical testing, the criteria could be incorporated into a broader context. For example, this tool could be applied to the context of implementing the principles for the responsible use of nanomaterials,[16] where it could be used particularly to improve risk management and ensure transparency in communication.
- The criteria should also be incorporated at an international level into related dialogue processes or projects and studies aimed at developing instruments for assessing nanomaterials.
- Where possible, work on the criteria should be continued in cooperation with those working on the Swiss Precautionary Matrix and in relation to the issues outlined in section 4.4 above.

The Issue Group also advocates establishing an advisory service. In terms of the criteria devised by Issue Group 4, such an advisory service could carry out the following tasks:

[16] See Report for the first dialogue phase and the present report of Issue Group 1.

- gather experiences of using the criteria and harness these to develop the criteria further
- assist users of the criteria in interpreting the results and, where necessary, seek support in identifying relevant information and appropriate risk management measures
- organise an exchange of experience among criteria users.

Annex 1: List of Issue Group members -

Name	Institution
Spokesperson of the Issue Group: Dr. Kerstin Hund-Rinke	Fraunhofer Institute for Molecular Biology and Applied Ecology (IME)
Dr. Rolf Buschmann	Federation of German Consumer Organisations, North-Rhine Westphalia
Thomas Gebel	Federal Institute for Occupational Safety and Health – BAuA
Dr. Mario Götz	Federal Institute for Risk Assessment – BfR
Dr. Stefan Grötschel	Federal Institute for Occupational Safety and Health – BAuA
Stephan Hackmann	Centre for Environmental Research and Sustainable Technology (UFT), University of Bremen, (Confederation of German Trade Unions – DGB)
Dr. Anke Jesse	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Oliver Kalusch	BBU (Federal Association of Environmental Action Groups)
Dr. Harry Keidel	Ministry of the Environment, Forestry and Consumer Protection, Rhineland-Palatinate
Dr. Nils Krüger	Evonik Degussa GmbH
Dr. Thomas Kuhlbusch	Institute of Energy and Environmental Technology – IUTA
Cornelia Leuschner	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU
Dr. Hubert Meisinger	Protestant Church of Hesse and Nassau / Centre for Social Responsibility – ZGV
Dr. Karin Michel	Henkel AG & Co. KGaA
Prof. Dr. Hartwig Muhle	Friends of the Earth Germany – BUND
Dr. Barbara-Christine Richter	Bayer Material Science AG
Jan Henrik Schlattjan	Land of Hesse Bureau for testing and research in the public health sector – HLPUG
Dr. Katja Stephan	Forschungszentrum Jülich GmbH
Dr. Doris Völker	Federal Environment Agency – UBA
Dr. Karin Wiench	BASF SE
Dr. Petra Wolff	Federal Ministry of Education and Research – BMBF
Dr. Sibylle Zielke	LAUG, Ministry of Social Affairs, Women, Family and Health, Lower Saxony

Annex 2: How the criteria were developed (dialogue phase 1 → dialogue phase 2)

Table 1: How the criteria from the first dialogue phase were translated into the list of criteria in the second dialogue phase

Criteria from the first dialogue phase	Counterpart or questions in the second dialogue phase	Rationale for modification or elimination
Good solubility (in water, body fluids) if this causes the loss of nano-properties	Solubility in water: - Is the material readily soluble in water?	It is not possible to define the term "nano-properties" at present and it was therefore dropped; "Solubility in body fluids" was perceived to be too detailed for a preliminary assessment. This parameter becomes relevant only in the context of a scientific risk evaluation.
Degradability into non-toxic degradation products	Degradability: - Is the material completely degradable?	Since investigation of degradation products would be too detailed for a preliminary assessment, the Issue Group opted for complete degradability instead.
Fixed, permanent bonding in matrices (stability of matrix, type of bond, end-of-life behaviour)	Mobility: - Is the nanomaterial permanently embedded in a stable matrix and hence cannot be released into the environment? Product application: - Is the nanomaterial easily released? - According to the parameters for dust formation, can the material's propensity to generate dust be classified as "minimal"? - Is the nanomaterial easily released during product disposal/recycling?	The original term was formulated as a question and used as an indicator of a material's mobility in the environment. Additional, supplementary questions were formulated to describe the material's release potential. Evidence of fixed, permanent bonding in a matrix can only be produced by means of simulation studies that are sometimes quite laborious and too detailed for the purpose of a preliminary risk assessment.
Presence of firmly bound aggregates	---	The concept of "aggregate" was subsumed under the criterion "surface" because size is the decisive parameter.
Formation of stable agglomerates	---	Agglomerates depend heavily on environmental conditions and hence cannot be used as a basis for assessment.
Nanostructured surfaces that are non-reactive	---	Examination of nanostructured surfaces is not the object of the list of criteria. The criteria relate to nano-objects.
Production volume or quantity used	Production volume: - Is the volume of nanomaterial manufactured > 100 kg?	---
High degree of mobility in nanoform (in organisms, in the environment)	Mobility: - Is the nanomaterial firmly and permanently embedded in a matrix (see above)?	Demonstrating mobility in organisms or in the environment was deemed too detailed for the purposes of preliminary assessment. This parameter becomes relevant in the context of a scientific risk evaluation.
Mobilisation potential	---	This was deemed too detailed for a preliminary assessment. This parameter becomes relevant only in the context of a scientific risk evaluation.
Targeted release	Targeted release: - Is the material released intentionally into the environment?	---

Criteria from the first dialogue phase	Counterpart or questions in the second dialogue phase	Rationale for modification or elimination
Persistence of nano-properties[17]	---	It is not possible to define the term "nano-properties" at present and therefore experimental research on nano-properties is not yet possible.
Bioaccumulation	---	This was deemed too detailed for a preliminary assessment. This parameter becomes relevant only in the context of a scientific risk evaluation.
High degree of reactivity (biological, chemical, catalytic)	Reactivity: - Is the nanomaterial known to be chemically, catalytically or biologically reactive, or is the material manufactured specifically to produce reactive properties?	---
Problematic morphology	Morphology: - Does the nanomaterial have a fibre, tube or rod-like morphology?	---
Indications of problematic interactions	---	This was deemed too detailed for a preliminary assessment, as it can only be determined by elaborate experimental research.
Indications of problematic transformations	---	This was deemed too detailed for a preliminary assessment, as it can only be determined by elaborate experimental research.
Poor verifiability	---	This was deemed too detailed for a preliminary assessment, and will only be established after extensive work to develop detection methods.
Unclear fate	---	This was deemed too detailed for a preliminary assessment. It is an integral part of a scientific risk evaluation.
---	- Is the material used in a consumer product?	This criterion was included in the interests of consumer protection.
---	- Is the material used in a closed facility?	This criterion was included in the interests of occupational safety.
Biological reactivity	Toxicology Ecotoxicology	Available data and new findings generated through national and international research programmes should be taken into account. however, they should only be used with expert help.

[17] BUND points out that this criterion is very important for an assessment and hence should not have been removed from the list. The persistence of nano-properties, in their view, is generally a cause for concern and has considerable regulatory relevance in terms of exposure.

Annex 3: Guidelines and criteria

CRITERIA FOR PRELIMINARY ASSESSMENT OF NANOMATERIALS WITH REGARD TO THEIR IMPACT ON HUMAN HEALTH AND THE ENVIRONMENT

29 SEPTEMBER 2010 -

CONTENT

1 INTRODUCTION ..... 26 -
2 DEFINITION OF TERMS ..... 26 -
3 APPLYING THE CRITERIA ..... 29 -

3.1 PURPOSE AND CONTEXT OF THE CRITERIA 29

3.2 WHAT CAN BE ASSESSED USING THE CRITERIA? 30

3.3 WHO CAN USE THE CRITERIA? 30

3.4 WHAT ARE THE KEY FEATURES OF THE CRITERIA? 31

3.5 BASIS FOR THE CRITERIA 32

3.6 BACKGROUND: HOW THE CRITERIA WERE DEVELOPED 32

4 CONCEPT OF PRELIMINARY ASSESSMENT ..... 34 -
5 THE CRITERIA ..... 36 -
6 EVALUATING THE ASSESSMENT ..... 42 -

6.1 POTENTIAL RISK MANAGEMENT CONTACTS 44

6.2 POTENTIAL TOOLS FOR TARGETED RISK ASSESSMENT 45

7 ABBREVIATIONS ..... 47 -

1 Introduction

The criteria set presented below was developed by Issue Group 4 of the NanoKommission in its second dialogue phase (2009 – 2010) and is based on preliminary work carried out during the first dialogue phase.

The criteria are intended to help make a preliminary assessment of using nanomaterials in terms of their impact on human health and on the environment. This assessment is not comparable to a conventional risk evaluation and should not replace this procedure.

The criteria cover various issues that need to be considered in connection with the impact of nanomaterials on human health and on the environment. They were chosen with the following considerations in mind:

- As an assessment tool, the criteria set should be easy to use and should facilitate a preliminary assessment of the impact of the intended use or foreseeable misuse of nanomaterials on the protected resources environment, employees and consumers, without involving excessive work.
- In many instances the information available on the potential risks, uses and exposures of synthetically manufactured nanomaterials is inadequate or non-existent at present, which means that it is often only possible to make qualitative statements.
- Different user groups, as well as different questions and contexts, require a differentiated assessment of various aspects that may crop up in connection with the life cycle of manufactured nanomaterials.
- The criteria are intended to be applicable to and give a meaningful result for the entire life cycle of a nanomaterial.

To arrive at an outcome supported by all the Issue Group participants, compromise was necessary in some instances. In some cases the differing opinions of some Issue Group members have been included in the footnotes.

2 Definition of terms

In this section we define some of the terms used in this document. These are simply preliminary working definitions, and not legal or universally valid definitions.

Aggregates and agglomerates: An aggregate is an association of primary particles that are irreversibly bonded to one another and whose combined surface is smaller than the sum of the surfaces of the primary particles. An agglomerate, however, is a collection of reversibly bound primary particles, aggregates or mixtures of the two.

Concern: The term “Concern” has its origins in the first nanodialogue phase. “Concern” means that more thorough examination of the criterion is considered necessary; in other words, fur-

ther information must be obtained and, where appropriate, risk management measures put in place.

Bulk material: Bulk material is the non-nanoscale material which has the same chemical identity as the nanomaterial.

Dose: The amount of a substance applied to an organism multiplied by the duration of exposure, whereby "amount" may refer to mass, surface, or number of particles falling within a given particle size range.

No cause for concern: The term "No cause for concern" has its origins in the first nanodialogue phase. A verdict of "No cause for concern" for a nanomaterial based on one of the criteria should not be considered as evidence that the nanomaterial is safe or as approval that its use presents no risk. Rather, "No cause for concern" should be interpreted as an indication that possible further action (obtaining information, risk management measures) does not need to be considered in connection with this criterion or, if it is necessary to prioritise, action may be postponed until a later date.

Preliminary assessment: In this context this refers to the assessment of the potential impact of a nanomaterial on humans and on the environment carried out on the basis of the present, intentionally simple, criteria set by a person belonging to the specified target group (see section 3.3.). This assessment should be seen as distinct from the scientific risk evaluation, which is carried out by experts.

Exposure: This refers to exposure of an organism to a chemical substance or a mixture of substances.

Criteria set: In the present document, the term criteria set refers to the complete list of criteria for preliminary assessment of nanomaterials in terms of their impact on humans and on the environment given in Section 5. The criteria set should not be seen as a rigid matrix.

Matrix: In this context, "matrix" refers to the structure in which the nanomaterial occurs or is embedded or suspended.

Nanomaterials[18] : The term nanomaterials refers to engineered materials in the nano size range which, primarily as a result of the change in surface-volume relationships, often develop new properties. There is, however, currently no internationally agreed definition.

According to the Technical Committee of the International Standardisation Organisation (ISO Technical Committee 229), **nanomaterials** are subdivided into various groups. These include:

- **Nano-objects**: 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 at the nanoscale and generally occur as compound systems of nano-objects. Typical examples are aggregates and agglomerates. According to ISO these are not limited in their physical size or form[19].

[18] This is the NanoKommission's working definition of nanomaterials.

[19] For an explanation of the terms used, see also Technical Specification (ISO/TS27687:2008(E)) of 15 August 2008.

- **Morphology**: The study of form. The morphology criterion has been included with the intention of documenting the form (e.g. fibre, tube, rod) in which the nanomaterial in question occurs. This enables the user of the criteria to identify whether the shape is relevant in (eco)toxicological terms.

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

Reactivity: Here this denotes to the capacity of a nanomaterial to undergo a chemical reaction. Due to the higher surface area to volume ratio, decreasing size means on the one hand that the surface area of the material available for a reaction increases. On the other, it means that the nanomaterial possesses a larger proportion of atoms at the surface than the bulk material, and as a result the surface atoms have fewer immediate neighbours. As a consequence of this, surface atoms in nanomaterials tend to have a greater propensity to form new bonds with other atoms and molecules.

Risk evaluation: Risk evaluation is a process consisting of the following elements: hazard identification (source of threat) and characterisation of the extent of the hazard, impact assessment, exposure assessment and risk characterisation. This is done by comparing expected exposure with the level of harm that could result from the product of the probability of an event that poses a threat to a protected resource occurring and the potential damage that such an occurrence could cause. Risk evaluation is primarily a scientific task as it depends on evaluation of scientific data to describe the form, extent and characteristics of a risk.

Protection target: This refers to resources requiring protection against potential negative impacts of nanomaterials. In this context, these are the environment and humans, the latter being subdivided into consumers (direct users and/or uninvolved third parties) and employees (in industry and commerce).

Need for precautionary measures: Precautionary measures are used to provide prospective protection for humans and the environment. Precautionary measures are required if potential adverse effects on humans and the environment are not yet known and should be prevented from the outset, e.g. in the case of data gaps.

Solubility in water: Solubility in water refers to the property of a substance to disperse homogeneously in atomic or molecular form in water. A substance's solubility in water influences its mobility and fate in a given compartment or medium.

Weight of evidence: Weight of evidence (WoE) is a key concept used in risk assessment practice. Every risk assessment requires the gathering, weighting and evaluation of all available scientific information, a process abbreviated to WoE analysis.

Further consideration: In the context of the criteria this means that a more in-depth examination of the criterion in question is considered necessary; further information must therefore be obtained and, where appropriate, risk management measures put in place.

3 Applying the criteria

3.1 Purpose and context of the criteria

The criteria are intended to help provide a preliminary assessment of using nanomaterials in terms of their impact on human health and on the environment. In this process, knowledge gaps may become apparent. The fewer the knowledge gaps, the more precise the assessment will be. In some cases, more information will need to be obtained. If a scientific risk evaluation has already been carried out, these criteria should not be applied.

Assessment using the criteria is by no means comparable to a scientific risk evaluation or a risk evaluation in the regulatory context. These are based on scientific evidence (testing of physico-chemical, toxicological and ecotoxicological properties and exposure potential), which is often not (yet) available for nanomaterials[20].

If a comprehensive scientific risk evaluation covering the use of nanomaterials is available, then this replaces the preliminary assessment. Even if a comprehensive risk evaluation is available, however, regular reviews should be carried out to check whether the basic information and assessment benchmarks are still appropriate in the light of current knowledge.

As a flexible tool, the criteria set can serve to highlight information gaps or provide indications relating to the responsible use of nanomaterials. Preliminary assessment can thus provide an initial decision-making aid for the manufacture and application of nanomaterials, and also for restricting their use or initiating further testing.

The assessment can help to focus efforts to obtain additional (new) information for a targeted and more precise appraisal, or to enable better characterisation, rebuttal or confirmation of concerns.

[20] In conventional practice, assessment of substances and products normally involves a weight-of-evidence approach in which all the available data are collated, weighted and evaluated. Likewise, in the case of nanomaterials all available knowledge should be gathered and used for the purpose of assessment, taking into account any indications of potential hazards to protected resources and potential damage resulting from intended or accidental exposure, to provide a complete picture (weight of evidence). At present it is assumed that assessment of nanomaterials will have to be done on a case-by-case basis owing to the heterogeneity of the materials and their applications.

The criteria set can also help with decision-making concerning implementation of precautionary risk management measures (including abandoning the use of a material), to ensure that any risks that may arise are promptly controlled. In addition, the criteria can be used to prioritise which nanomaterials or applications most urgently require action.

Preliminary assessment can also be integrated into a more extensive matrix as part of an ethical process for forming judgements. It is beyond the scope of this paper, however, to do more than touch on this possibility.

The assessment is intended to cover the entire life cycle of the nanomaterial. The result should be reviewed regularly to take account of advances in knowledge about nanomaterials and, where relevant, new information.

3.2 What can be assessed using the criteria?

The criteria can be used for all deliberately engineered nanomaterials (see working definition in section 2). These may be nanomaterials at the research and development stage or those already available or in use. In addition they can be used for free nanomaterials[21] and their aggregates and agglomerates, as well as for products which contain nanomaterials bound in a matrix.

When carrying out the assessment, it should be borne in mind that a nanomaterial may have undergone a variety of modifications, (e.g. surface functionalisations, imperfections in the crystal lattice, etc.), or it may be used in different matrices. As such modifications significantly affect the properties of the nanomaterial, the assessment applies exclusively to the modification being examined. Different applications may, for example, entail different exposure probabilities. Each different application or modification therefore needs to be assessed separately in its own right.

An assessment of nanomaterials and their agglomerates and aggregates which fall outside the size range stipulated in the working definition is also recommended, as this is a temporary definition and different (e.g. larger) sizes may be relevant in other contexts or if the precautionary principle is applied.

It is not envisaged that this criteria set will be used for assessing the impact of the production processes of nanomaterials or of possible malfunctions. Furthermore, the criteria are not intended for use in the case of molecules which are in the nano size range in their pure state, but can no longer be identified as such in the finished product.

3.3 Who can use the criteria?

The criteria set is aimed at informed persons with no specialist knowledge. Use of the criteria the user demands background knowledge about the specific na-

[21] This includes nanomaterials that may foreseeably be generated during use, for example by special spray heads in an aerosol spray.

nomaterials in the product as well as about the product that is the subject of the assessment. The information required to answer the questions relating to the criteria may not be accessible to all user groups, and possibly not available at all.

The criteria may be particularly useful for assessing the impact on humans and on the environment of new nanomaterials or those in development, on which little or no ecotoxicological or toxicological research has been done. Potential user groups for the criteria include:

- manufacturers of nanomaterials wishing to make an initial assessment of potential risks, for example for research and product development purposes,[22] or wishing to undertake a comparative assessment of applications of products already on the market
- users of nanomaterials wishing to assess the impact of their products, e.g. to improve the information they provide to customers or enhance their risk management
- those involved in disposal of products which contain nanomaterials, for assessing the potential impact of the materials during waste disposal processes
- distributors of products which contain nanomaterials can use the assessment results e.g. to improve product classification, enhance occupational safety advice and provide information to customers
- occupational health and safety officers, for making assessments to support risk management and communication in the workplace
- compliance evaluators can use the criteria set e.g. as a support for assessment and decision-making; public bodies authorised to manage a product register can use the criteria to make a preliminary assessment of materials submitted to the register
- NGOs such as environmental conservation and consumer organisations can use the product assessments e.g. to provide information to consumers.

3.4 What are the key features of the criteria?

The criteria are intended to be used to help provide an initial assessment of nanomaterials. The key features of the criteria are summarised below:

- Applying the criteria facilitates an initial assessment of nanomaterials early on, even where very little data is available.
- The criteria can be applied by a variety of users; they cover several different protection targets and all life cycle stages.
- The criteria are not a rigid matrix and can be applied irrespective of the amount of information available.

[22] The NanoKommission's "Green nano" Working Group has produced supplementary guidance for this user group in the form of design principles.

- The criteria can serve as a decision-making aid for undertaking further steps towards a risk evaluation as part of a weight-of-evidence approach.
- Comparatively simple criteria have been selected, in order to facilitate use by a broad range of users with varying degrees of knowledge, and so that information available at an early stage of product development can be used.
- To ensure ease of obtaining information, impacts are rated primarily by means of qualitative statements.
- Use of the criteria to assess the impact of new materials has not yet been validated, nor is it established practice. In contrast to a comprehensive scientific risk evaluation, which is based on tried and tested procedures, initial experience with the use of the criteria has yet to be gathered.
- Assessment is voluntary. It cannot be used either to justify wholly, or to revoke or query any official decision.

3.5 Basis of the criteria

The criteria take into account inherent properties of nanomaterials, such as reactivity and solubility in water, as well as aspects that relate to the probability and extent of exposure, e.g. the conditions in which the products are used and the mobility of the nanomaterials. The criteria are arranged into blocks corresponding to scientific fields. Within each block the criteria are arranged according to the amount of effort needed to obtain the required information.

3.6 Background: how the criteria were developed

The criteria presented here were developed on the basis of the criteria for “Concern” and “No cause for concern” produced in the first nanodialogue phase. The criteria set was intended as an easy-to-use tool which, in contrast to the criteria produced in the first dialogue phase, would be more scientific in approach and geared towards informed, but non-expert users. Owing to the choice of target group, it was necessary to focus the criteria appropriately. To do this, the criteria were couched in the form of questions requiring a “yes” or “no” response.

Criteria for which guiding questions were formulated with no difficulty were adopted from the first dialogue phase list without alteration.

Criteria that could not be couched as a simple question, or for which simple measurement methods were not yet available, were modified so as to obtain relevant information. The coupling of the criteria to measurement methods should be questioned given the choice of target group (users of the criteria). Measurement methods are useful particularly for an expert audience which, however, represents only a small minority of the target group or already has the relevant information without the matrix.

If any of the criteria could not be reformulated into guiding questions, then these were classified as belonging to scientific risk evaluation or research and removed from the current list.

Additional criteria were also included to close gaps resulting from modifications made to the list of criteria from the first dialogue phase and in view of the objective "easy to use, target group: informed users".

The list below summarises how the criteria from the first dialogue phase were incorporated into the criteria set produced in the second dialogue phase.

The following criteria from the first dialogue phase were adopted without modification:

Production volume, intentional release, high level of reactivity, problematic morphology, solubility in water.

The following criteria were modified:

- High level of mobility in nanoform[23] → stable bonding in a matrix[24]
- Rapid degradability in non-toxic degradation products → complete degradability
- Stable and permanent bonding in a matrix → stable bonding, minimal release during use and disposal, tendency to dust formation
- Presence of firmly bound agglomerates, or formation of stable agglomerates → surface[25]
- Biological reactivity → toxicological / ecotoxicological effects

Parameters not considered in the context of preliminary assessment because measurement methods are poor or significant research effort would be required:

- Mobilisation potential, persistence[26] of nano-properties[27], bioaccumulation, indications of problematic interactions or transformations, poor verifiability and unclear fate, solubility in body fluids.
- Another parameter not considered was the criterion "nanostructured surface", because the objective of the criteria list is to assess nano-objects (including their agglomerates/aggregates).

[23] Mobility in the environment is an indication of a substance's distribution in the environment and therefore needs to be distinguished from "Release from matrices" in the thematic block "Probability of exposure". Because methods for ascertaining the behaviour of nanomaterials in the environment are lacking, this criterion is limited to binding within a matrix. This should be amended in accordance with technological progress.

[24] Friends of the Earth Germany (BUND) point out that from their perspective a high degree of mobility of a material in nanoform constitutes grounds for concern as a matter of principle. Hence, in their view asking about bonding in matrices does not go far enough.

[25] The concept of "aggregate" was subsumed under the criterion "surface" because size is the decisive parameter. The criterion "agglomerates" is no longer used, as agglomerates depend to a significant extent on the surrounding conditions and hence cannot be used as a basis for assessment.

[26] BUND points out that this criterion is very important for the assessment and hence should not have been removed from the list. Persistence of nano-properties, in their view, is generally a cause for concern and has considerable regulatory relevance in terms of exposure.

[27] It is not yet possible to define the term "nano-properties", so they cannot yet be subjected to experimental research.

A new inclusion is:

- Use in a consumer product; processing carried out in a closed facility.

4 Concept of preliminary assessment

The criteria should not be used to assess nanomaterials in cases where the bulk form is known to be classified or to meet the criteria for classification as a hazardous substance in accordance with the EU Dangerous Substances Directive (No 67/548/EEC) or Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. In such cases a scientific risk evaluation must be carried out.

If a comprehensive scientific risk evaluation covering the intended use of the nanomaterial is available, no assessment should be carried out using the table.

All available information should be used to complete the table.

The criteria are grouped into the following four blocks:

- **Probability of exposure**
  In this block, information is gathered on the volume of nanomaterials used in production and application, along with potential release scenarios in manufacturing processes and during use of the product.
- **Physico-chemical properties**
  In this block, questions are asked regarding indications of inherent[28] properties of the substance. The manufacturer of the material is generally familiar with these.
- **Behaviour in the environment**
  Information in this block is intended to give an indication of the nanomaterial's environmental fate.
- **Toxicology and ecotoxicology**
  Questions in this block relate to whether information on the nanomaterial's toxicity and ecotoxicity are available.

Each of the criteria is formulated as a guiding question requiring a "yes" or "no" answer; each individual answer is assigned to one of the following categories: "No immediate need for precautionary measures / No cause for concern", or "Further consideration / Need for precautionary measures / Cause for concern". In the absence of information to answer the question, the response "Data gap" can be given. The greater the amount of information and therefore the more criteria that can be completed, the more comprehensive and meaningful the assessment. It is envisaged that the user will check all the criteria and fill in any gaps.

[28] Properties which are inherent to or inseparable from the substance.

Each criterion is assigned a letter denoting the protection target(s) for which it is relevant. This is helpful for evaluating the results with regard to particular protection targets. In some cases criteria are accompanied by explanatory notes, e.g. concerning testing procedures. In the last column of the table the user of the criteria is supposed to give details of the basis for his/her decision (e.g. information source) so that this can be clearly understood by third parties, where relevant.

5 The criteria

Before applying the criteria set, the classification of the nanomaterial's bulk form must be established:

Has the raw material (bulk material) been classified (legal status) or does it meet the criteria for classification (self-declaration by distributor) as a hazardous substance in accordance with the EU Dangerous Substances Directive (No 67/548/EEC) or Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures?

- Yes → carry out scientific risk evaluation
- No → proceed with assessment based on this table

Is a comprehensive scientific risk evaluation[29] available covering the intended application of the nanomaterial?

- Yes → assessment based on this table is not required as the conclusions from the scientific risk evaluation provide a more in-depth assessment
- No → proceed with assessment based on this table

When completing the table please ensure that all available information is included, e.g. from public databases, suppliers' information.

[29] Risk assessment is required in various legal contexts, e.g. in the context of substance registrations (e.g. under REACH) or authorisations (e.g. certain food contact materials). If such assessments or, for other reasons, comprehensive scientific risk evaluations are available for the applications in question, then assessment using the table is superfluous, as these risk evaluations are more detailed and better substantiated.

Table 1: Criteria

Criterion	Protection target[30]	Explanation	Further consideration / Need for precautionary measures / Cause for concern[31]	No immediate need for precautionary measures / No cause for concern[32]	Data gap[33]	Documentation / basis for decision
Designation of the substance, details of any modification						
Application of the substance, details and description of the product						
Probability of exposure						
Production volume	AVU	Is the volume of nanomaterial manufactured > 100 kg/year?[34]				
		Yes	☐			
		No		☐		
		Cannot answer / do not know			☐	
Production / processing	AU	Is the material handled in closed facilities?				
		Yes		☐		
		No	☐			
		Cannot answer / do not know			☐	
Production /	AU	Is the material easily released? (dust, aerosol formation, waste water)				

[30] Protection targets are abbreviated in the table as follows: A = Arbeitnehmer (employees), V = Verbraucher (consumers), U = Umwelt (environment)

[31] Here "Further consideration" means that closer examination of the criterion is considered absolutely essential, and hence more information must be obtained and, where appropriate, risk management measures put in place. The term "Concern" was adopted from the first dialogue phase. In the first dialogue phase, the following criteria were deemed relevant for concern: "Indications of an expected high level of exposure (to the point of irretrievability), potential problematic effects, and also problems with providing evidence for and with the tracing of released nanomaterials". In the context of these criteria it is not possible to make definitive, comprehensive statements regarding "concerns", since individual aspects are examined separately. The presence of a concern is to be seen as an indication that further consideration is necessary on precautionary grounds.

[32] The term "No cause for concern" was adopted from the first dialogue phase. In the first dialogue phase, the following criteria were deemed relevant for "No cause for concern": "Indications that nanomaterials in the respective application are either firmly bound in matrices, or that they rapidly lose their potentially problematic nano-properties, e.g. through good solubility or rapid degradability". In the context of the present table of criteria, a rating of "No cause for concern" is to be interpreted as meaning that taking further steps is less vital and less urgent than in the case of a "concern" rating. Only proper scientific risk evaluation can establish whether a nanomaterial is completely without cause for concern, in other words safe, in a particular application. An assertion of this sort cannot be made on the basis of the criteria.

[33] Data gap: the user of the criteria has no further information, or no data is generally available. Knowledge gaps should be classed as grounds for concern as a matter of course.

[34] Other thresholds discussed by the Issue Group included "10 kg/year" (formerly notification threshold for chemicals) and "1 t" (registration threshold under REACH); when using the criteria, it should be taken into account that the value may be subject to change, e.g. as a result of studies carried out at EU level.

Issue Group 4

Criterion	Protection target[30]	Explanation	Further consideration / Need for precautionary measures / Cause for concern[31]	No immediate need for precautionary measures / No cause for concern[32]	Data gap[33]	Documentation / basis for decision
processing		Yes	☐			
		No		☐		
		Cannot answer / do not know			☐	
Product use	V	Is the material used or intended for use in a consumer product?				
		Yes	☐			
		No		☐		
		Cannot answer / do not know			☐	
Product use	U	Is the material released intentionally into the environment? (e.g. groundwater remediation, agricultural applications)				
		Yes	☐			
		No		☐		
		Cannot answer / do not know			☐	
Product use	VU	Is the nanomaterial easily released? (e.g. dust, aerosol formation, in water, by abrasion)				When answering this question please consider both the intended use and any foreseeable misuse.
		Yes	☐			
		No		☐		
		Cannot answer / do not know			☐	
Product disposal / recycling	AVU	Is the nanomaterial easily released during product disposal/recycling? (e.g. dust, aerosol, water, matrix destruction)				
		Yes	☐			
		No		☐		
		Cannot answer / do not know			☐	

Criterion	Protection target[30]	Explanation	Further consideration / Need for precautionary measures / Cause for concern[31]	No immediate need for precautionary measures / No cause for concern[32]	Data gap[33]	Documentation / basis for decision
Physico-chemical properties						
Morphology	AVU	Does the nanomaterial have a fibre, tube or rod-like morphology?				Applies to lengths > 300 nm
		Yes	☐			
		No		☐		
		Cannot answer / do not know			☐	
Surface	AVU	Is the surface > 6/100 nm^{-1}				SCENIHR Opinion, Biocidal Products Directive (volume-specific surface). Data in m^2/g can be converted to nm^{-1} units by multiplying by the density
		Yes	☐			
		No		☐		
		Cannot answer / do not know			☐	
Reactivity	AVU	Is the nanomaterial known to be chemically, catalytically or biologically reactive, or is the material manufactured specifically to produce reactive properties?				
		Yes	☐			
		No		☐		
		Cannot answer / do not know			☐	
Solubility in water	AVU	Is the material readily soluble in water, resulting in loss of its nanostructure?				Definition of "readily soluble": water: 20°C; > 1000 mg/l (ECHA, IUCLID 5.2); procedure OECD TG 105: Water Solubility
		Yes		☐		
		No	☐			
		Cannot answer / do not know			☐	
Dust formation	AVU	According to the parameters defined for dustiness, can the material's propensity to generate dust be classified as "minimal"?				Ranking according to / based on EN 15051 lists. (See also studies by e.g. the *Institut für Gefahrstoff-Forschung* (IGF - Institute for Research on Hazardous Substances) concerning the propensity of nanomaterials to deagglomerate).
		Yes		☐		
		No	☐			
		Cannot answer / do not know			☐	

Criterion	Protection target[30]	Explanation	Further consideration / Need for precautionary measures / Cause for concern[31]	No immediate need for precautionary measures / No cause for concern[32]	Data gap[33]	Documentation / basis for decision
Behaviour in the environment						
Degradability	U	Is the nanomaterial completely degradable?			In the case of organic materials, biodegradability is particularly relevant (along with corresponding OECD testing procedures from Section 3). Abiotic degradation may apply to both organic and inorganic materials.	
		Yes		☐		
		No	☐			
		Cannot answer / do not know			☐	
Mobility in the environment	U	Is the nanomaterial permanently embedded in a stable matrix and hence cannot be released into or move around in the environment?				
		Yes		☐		
		No	☐			
		Cannot answer / do not know			☐	

Criterion	Protection target[35]	Explanation	Further consideration / Need for precautionary measures / Cause for concern[36]	No immediate need for precautionary measures / No cause for concern[37]	Data gap[38]	Documentation / basis for decision
Toxicology / ecotoxicology						
Note: At the present time there are no clearly accepted criteria indicating no cause for concern with regard to toxicology and ecotoxicology. It is therefore not currently possible to make a preliminary assessment of this. Full scientific risk evaluation is required. Available information such as information from public databases and suppliers should be taken into account as far as possible in the assessment.						
Toxicology	AV	Are there any indications of toxicological effects that are relevant for humans?			If the answer is yes, then human exposure must be investigated more closely (scientific risk evaluation). Please provide details of available information here.	
		Yes	☐			
		No		----		
		Cannot answer / do not know			☐	
Ecotoxicology	U	Are there any indications of ecotoxicological effects that are relevant for the environment?			If the answer is yes, then environmental exposure and its potential impacts must be investigated more closely (scientific risk evaluation). Please provide details of available information here.	
		Yes	☐			
		No		----		
		Cannot answer / do not know			☐	

[35] Protection targets are abbreviated in the table as follows: A = Arbeitnehmer (employees), V = Verbraucher (consumers), U = Umwelt (environment)

[36] Here "Further consideration" means that closer examination of the criterion is considered absolutely essential, and hence more information must be obtained and, where appropriate, risk management measures put in place. The term "Concern" was adopted from the first dialogue phase. In the first dialogue phase, the following criteria were deemed relevant for concern: "Indications of an expected high level of exposure (to the point of irretrievability), potential problematic effects, and also problems with providing evidence for and with the tracing of released nanomaterials". In the context of these criteria it is not possible to make definitive, comprehensive statements regarding "concerns", since individual aspects are examined separately. The presence of a concern is to be seen as an indication that further consideration is necessary on precautionary grounds.

[37] The term "No cause for concern" was adopted from the first dialogue phase. In the first dialogue phase, the following criteria were deemed relevant for "No cause for concern": "Indications that nanomaterials in the respective application are either firmly bound in matrices, or that they rapidly lose their potentially problematic nano-properties, e.g. through good solubility or rapid degradability". In the context of the present table of criteria, a rating of "No cause for concern" is to be interpreted as meaning that taking further steps is less vital and less urgent than in the case of a "concern" rating. Only proper scientific risk evaluation can establish whether a nanomaterial is completely without cause for concern, in other words safe, in a particular application. An assertion of this sort cannot be made on the basis of the criteria.

[38] Data gap: the user of the criteria has no further information, or no data is generally available. Knowledge gaps should be classed as grounds for concern as a matter of course.

6 Evaluating the assessment

The criteria table is aimed at alerting users to potential grounds for concern and factors giving no cause for concern in relation to the nanomaterial or nanoproduct under examination, as well as highlighting gaps in the users' subjective or objective information.

Evaluation of the assessment carried out does not produce a single communicable result, e.g. in the form of an aggregated quantitative "risk index".

At the end of the evaluation emphasis is given instead to an individual interpretation of the significance of each answer. This can be achieved by holding in-house discussions or through dialogue with experts, other users of the criteria or stakeholders.

Individual criteria may have particular weight depending on the type of application of the nanomaterial/nanoproducts. However, differences in the weighting of criteria are difficult to take into account in a simple qualitative assessment scheme. Moreover, it is intended that some of the criteria should be considered in relation to certain others. For example, where an indication of (eco)toxic effects is coupled with a low probability of release/exposure to nanomaterials, this results in a lower potential risk rating than in the case of the combination "high probability of exposure" plus "high (eco)toxicity". Therefore, because of overlaps, attempting to make a quantified evaluation can result in false conclusions.

The number of responses for the block of criteria under examination can, however, be used as pointers to help interpret the results. Using an evaluation table (Table 2, page 19), this interpretation can be carried out for the protected resources taken together or for each protected resource separately. It must be emphasised, however, that this interpretation of the results merely helps with priority-setting, and is done in addition to, not instead of, detailed expert examination of the individual criteria. It must also be borne in mind that the examination must always relate to the planned application of the nanomaterial or product. If new information is obtained, a new examination of the relevant criteria must be carried out to bring the assessment up to date.

The guidance for initial interpretation set out below is not definitive and is subject to the provisos outlined above:

- The proportion of responses in the "Data gap" field within each block gives an indication of the extent to which the user of the criteria lacks knowledge concerning the relevant use of the nanomaterial / nanoproduct. It can therefore be used as an indicator of uncertainty in the completed assessment. It also indicates the areas in which there is a need for more detailed information. (See suggestions in section 0 regarding potential information sources.)

- The number of responses in the field “Further consideration / Need for precautionary measures / Cause for concern” within a given block indicates that additional or more detailed information needs to be obtained in order to re-examine the criteria in question in a more differentiated manner. This may take the form of closer examination of exposure scenarios, for example, or of detailed research into toxicological information[39]. Likewise, measures such as modifications to the material or steps to reduce exposure may change the situation and hence the nature of the investigation. The objective of further examination is either to eliminate the need for additional investigation (if information is available, the user can place a cross in the box “No immediate need for precautionary measures / No cause for concern”), or to establish clearly that further investigation is indeed necessary, and if necessary to draw upon other instruments for this. “Further consideration” requires more in-depth information, but not to the same degree as a professional investigation. Suggestions for instruments that could potentially be used to generate more detailed information or undertake further (more specific) investigation, as well as contact persons for discussing options for action are listed in section 0.
- The number of responses in the “No immediate need for precautionary measures / No cause for concern” field within a given block provides an indication of whether and to what extent the suspicion of potential impacts arising from the use of the nanomaterial in question can be allayed. Here too, however, detailed examination of the nanomaterial in the context of its specific field of application is essential, in order to take account of any prevailing differences in weighting given to particular criteria.
- A large number of responses in the “No immediate need for precautionary measures / No cause for concern” field in the "Probability of exposure" block (minimal probability of exposure) can be considered to indicate (increased) likelihood that there is no cause for concern, since lack of exposure means that no effects are to be expected. This trend should likewise be interpreted with caution, taking into account differences in weighting given to particular criteria.

A growing number of ecotoxicological and toxicological studies are being carried out and published. **The findings of these studies must be taken into consideration**. This, however, requires expert knowledge. It may therefore be necessary to seek support from experts in the relevant field in order to take these research findings into account in the assessment.

[39] In this sense, “further examination” goes beyond the questions asked in the list of criteria, but this does not necessarily mean using ADDITIONAL or NEW criteria in the assessment.

Information sources

If the user of the criteria identifies information gaps, the obvious course of action required is to obtain information. Potential information sources for each of the thematic blocks are listed below:

Information on probability of exposure

- Manufacturer of the nanoproduct (depending on how the nanomaterial is incorporated into the product and on the product's field of application)

Information on physico-chemical properties

- Manufacturer of the nanomaterial
- Safety Data Sheet

Information on behaviour in the environment

- Manufacturer of the nanomaterial (criterion concerning degradability)
- Safety Data Sheet of the nanomaterial or the chemical product containing the nanomaterial
- Manufacturer of the nanoproduct (criterion concerning release)

Information on toxicology and ecotoxicology

- Manufacturer of the nanomaterial[40]
- Safety Data Sheet of the nanomaterial or the chemical product which contains the nanomaterial

6.1 Potential risk management contacts

If the user of the criteria identifies potential grounds for concern in the use of the nanomaterials, s/he could firstly discuss and verify the result of his/her assessment with expert help. Potential contacts could include the manufacturer, the manufacturer's (eco)toxicology departments (if such exist), and public authorities.

In principle, guidelines and documents providing advice on risk management in dealing with chemicals may also be used. However, these should be checked to establish whether they meet the specific requirements of nanomaterials[41].

[40] The manufacturer can only make a statement on this if an examination has been carried out in accordance with nano-specific testing requirements (physico-chemical testing, production of suspensions, etc.).

[41] The Federal Institute for Occupational Safety and Health (BAuA), for example, has collaborated with the German Chemical Industry Association (VCI) to develop guidelines for activities involving nanomaterials in the workplace. This is available on the Internet.

6.2 Potential tools for targeted risk assessment

If the assessment indicates “Further consideration / Need for precautionary measures / Cause for concern”, options for conducting a scientific risk evaluation of (this use of) the nanomaterial should be explored. In the event of a concern arising, e.g. relating to the environment, but no concerns are identified for employees and consumers using the nanomaterials, the scientific risk evaluation can include a “targeted risk assessment” focusing on the specific protected resource.

The purpose of the following evaluation table is solely to obtain an overview of the responses in order to help set priorities for further work. It therefore complements the detailed examination of the individual responses.

Table 2: Evaluation table for the criteria list

Block	Number of criteria for which no response was given (data gaps) compared with the maximum possible number [1,2]				Number of criteria for which the response "Further consideration / Need for precautionary measures / Cause for concern" was given compared with the maximum possible number [1,3]				Number of criteria for which the response "No immediate need for precautionary measures / No cause for concern" was given compared with the maximum possible number [1,3]			
	G	A	V	U	G‘	A‘	V‘	U‘	G‘	A‘	V‘	U‘
Core question	(Classification available? Scientific risk evaluation carried out?)											
Probability of exposure	/ **7**	/ 4	/ 4	/ 6	/	/	/	/	/	/	/	/
Physico-chemical properties	/ **5**	/ 5	/ 5	/ 5	/	/	/	/	/	/	/	/
Behaviour in the envronment	/ **2**	- / -	- / -	/ 2	/	/	/	/	/	/	/	/
Toxicology / ecotoxicology	/ **2**	/ 1	- / 1	/ 1	/	/	/	/	[4]			

[1] G = (Gesamtzahl) Total number of criteria per block with the relevant response; A, V, U (A = Arbeiter (employees); V = Verbraucher (consumers); U = Umwelt (environment)): number of responses for the various protection targets; as each of the criteria may be linked to more than one protection target, the total number of responses for the individual protection targets may be greater than the total number of criteria per block.

[2] The maximum possible number here relates to the total number of criteria (since this is fixed, it is a given).

[3] The maximum possible number here is determined by the number of criteria for which a response was given in the left-hand block (no data gap). In other words, in column G‘ the figure to be entered as the total number is the number of criteria listed in the left-hand block under G minus the number of criteria for which a data gap was identified under G. The same principle applies to the number of responses concerning protected resources A‘, V‘ and U‘. If, for example, no response is given to 2 of the questions concerning physico-chemical properties under the protected resource “Arbeiter” (employees), then in the 2nd and 3rd block in the row “physico-chemical properties”, the total number of criteria should be given as (G‘) 5-2 = 3.

[4] Under toxicology and ecotoxicology it is not possible to give the response “No immediate need for precautionary measures / No cause for concern”

7 Abbreviations -

A	Arbeitnehmer / Arbeiter (= employees)
ECHA	European Chemicals Agency
EN	European Standard
ISO	International Organization for Standardization
IUCLID	International Uniform Chemical Information Database
NGO	non-governmental organisation
NM	nanomaterial
nm	nanometer
NP	nanoparticle
OECD	Organisation for Economic Co-operation and Development
REACH	Acronym for the European Union's Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
TWG	Technical working group
U	Umwelt (= environment)
V	Verbraucher (= consumers)
WoE	Weight of evidence

Annex 4: Minutes of the Expert Workshop -

MINUTES OF THE EXPERT WORKSHOP

COMPARISON OF THE SWISS PRECAUTIONARY MATRIX AND THE CRITERIA DEVISED BY ISSUE GROUP 4

7 January 2010
Berlin, 10.45 a.m. to 4 p.m.

Ökopol
Institut für Ökologie und Politik GmbH

1 Introduction and objectives

Assessing nanomaterials in terms of their potential impact on human health and on the environment is one of the priority issues under examination in the second dialogue phase of the NanoKommission. The objective of the Issue Group working on this issue is to refine the criteria for the assessment of nanomaterials developed during the first dialogue phase by bringing them up to date, making them more specific and operationalising them.

The aim of the Expert Workshop is to enable an exchange of ideas on developing and structuring assessment tools and to integrate experience already gained from practical implementation of the Swiss Precautionary Matrix into the next stage of Issue Group 4's work. In effect, then, the objective of the Workshop is to compare the two systems, and to exchange information about background factors, challenges and successes.

In addition to Issue Group 4, members of other Issue Groups members are also taking part in the Expert Workshop, as the assessment of potential risks is a cross-cutting issue that is important for all other areas of work.

2 Presentation of the criteria developed by Issue Group 4

2.1 Presentation content

Ms Hund-Rinke presented the Issue Group's work as it currently stands (see slides). She set out the context of the criteria and explained that the criteria form part of an explanatory document. The criteria are structured according to the product life cycle on the one hand, but also according to the feasibility of obtaining the information required to obtain a response to the criteria.

The table of criteria is organised as follows: the first column contains the name of the criterion; the second gives an indication of any technological or scientific limitations concerning its application; suggestions for potential measurement parameters and, where appropriate, available or suggested measurement methods and information sources appear in columns 3 and 4. The fifth column contains suggestions on how to assess a criterion; assessment indicators are quantitative, qualitative or not yet available (this is a work in progress), and should be formulated in terms of "No cause for concern" (this indicates that there is no increase in potential risk) and "Cause for concern" (indicating that a potential risk exists). An additional column presents six parameters which may be marked with a cross, thereby providing a picture of the areas which the criteria can be used to assess. The last column states the protected resources for which the criterion is relevant.

The criteria table presented is still in the process of development and the version circulated contains a variety of proposals and approaches that have not yet been discussed in the Issue Group. Subsequent work will focus on developing and formulating assessment indicators and on how to present the results to give an overall assessment.

2.2 - Summary of questions, responses and comments on the Issue Group 4 criteria

The target group or intended audience of the criteria devised by Issue Group 4 is not clear. Irrespective of the intended audience, however, it was emphasised that providing a guide or other assistance explaining the criteria and how to apply them is vital. Plans are in development to incorporate the criteria list into an explanatory document to provide guidance on how to assess nanomaterials. In addition, the criteria are to be tested on the basis of examples and, if appropriate, these could also be published alongside the criteria and guidelines.

Consumers are neither explicitly mentioned nor explicitly excluded as a target group for the criteria. In principle, consumers should be able to use the criteria too, but they will often lack access to the information required in order to calculate the values for the individual criteria.

Issue Group 4 based the criteria on the NanoKommission's working definition of nano-objects. This does not mean that nanomaterials which do not correspond to the definition cannot be assessed as well. According to the ISO definition, nano-objects include nanoparticles, nanorods (nanowires) and nanoplates, as well as any agglomerates.

Concerning the criteria on toxicity to humans, the criteria currently indicate that "endpoints in accordance with REACH" should be checked. It should be noted, however, that in the case of nanomaterials neurotoxicity and immunotoxicity are particularly important and the provisions of REACH do not adequately cover these.

3 Presentation of the Swiss Precautionary Matrix

3.1 Presentation content

Mr Höck gave a presentation on the Swiss Precautionary Matrix (see slides), which is intended for use by anyone handling nanoparticles and nanorods (NPR[42]) at any stage in their life cycle. The matrix helps to identify any need for precautionary measures[43] and to highlight knowledge gaps. A distinction is drawn between three types of criteria:

- background conditions (nano-relevance and level of knowledge – S1 and S2)
- potential effect (expressed as reactivity and stability – W1 and W2)
- potential exposure, comprising

  physical surroundings of NPR (gas/liquid/solid or various types of bonding in a matrix)

  the probability of human exposure (volume used and frequency of use – E)

  the environment (production volume and waste management).

A formula is used to relate these parameters to one another and aggregate them to give a numerical value. This number may be between 0 and 7000.

All the stakeholders feel that the decision tree used to test for “nano-relevance” is central and very helpful. In keeping with a precautionary approach, materials whose size exceeds that stipulated in the current definitions[44] are also considered NPRs (i.e. the size range between 100nm and 500nm is also considered relevant).

The Swiss Precautionary Matrix is applied as an IT tool as this enables the formulas to be embedded into the table, and this format facilitates structured information gathering (i.e. enhances its practicability). A system of scoring on a scale of 1 to 9 was adopted to enable adjustment of the matrix in accordance

---

[42] NPR, meaning nanoparticles and nanorods, is used in the context of the Swiss Precautionary Matrix for all materials that can be assessed using the Matrix. This term, however, can also include agglomerates and nanostructured materials, (the latter because/if they contain nanoparticles or rods/wires). The term is used here in relation to the Matrix.

[43] The need for precautionary measures is not an indication of actual risks. Identifying the need for precautionary measures should prompt users of the matrix to consider whether existing protection measures adequately meet this need, or whether additional measures are necessary.

[44] For example agglomerates up to a size of 10 µm are considered to be nano-relevant if they are unstable and occur in applications where they could potentially be inhaled. In the case of disintegration, the mere fact that disintegration can occur is sufficient, so the length of time this takes or the point at which it starts are not considered. Although potentially also important for the environment, instability of agglomerates is only discussed in relation to humans in order to avoid over-complicating the assessment process, and also because current knowledge is inadequate for establishing appropriate indicators.

with advances in knowledge and, where relevant, permit more differentiated assessment.

3.2 - Summary of questions, responses and comments on the Swiss Precautionary Matrix

Some participants have commented that they feel both the method and assessment criteria are “too broad” to provide a reliable indication of potential problems or any indication that there is no increased need for a precautionary approach. This relates to the fact that completion of some of the parameters is (may be) done “by intuition”, that assessment of toxicity and ecotoxicity is not covered, and that the rating “A – no need for precautionary measures” can be given at all on the basis of so very little information. It has also been commented that a matrix can be completed “in a careless fashion”.

The response to this is that the matrix does not attempt to give an indication of risk, only of the need for precautionary measures. It is also intended to foster responsible behaviour on the part of industry and commerce, and an “irresponsibly” completed matrix would be damaging to the very person carrying out the assessment. The matrix is intended to cover nano-specific aspects and does not absolve the user from testing a substance’s properties under the legislation on chemicals. For this reason, reactivity and stability are deemed to be the crucial additional parameters that permit an appraisal of potential impact. Moreover, “A”-rated NPRs have so far never proven to have been underestimated, e.g. in the light of new information generated by testing.

The matrix does not take account of whether or not risk management measures have been put in place, partly because a great many scenarios would need to be depicted (complexity), and partly because it cannot be assumed that measures are (correctly) implemented. This is also the reason why the matrix cannot be used to assess malfunctions and non-intended uses of NPRs or products which contain NPRs.

By looking at worst-case scenarios, the aim among other things is to highlight that it is important to consider not only the amount of NPRs an employee handles directly, but also the volume of NPRs stored in proximity to employees or handled by other persons. Worst-case scenarios include, for example, accidents. Some workshop participants view this scenario in particular with considerable criticism, since one would also have to assume for example that a closed facility might explode. The response to this criticism is that the matrix is aimed at identifying the need for precautionary measures and the person carrying out the assessment then needs to gauge whether his/her precautionary measures are adequate, as they would be in the case of closed and effectively secured facilities.

The item “nano-specific waste management” is not specified in detail at present. The aim here is basically to ascertain whether waste which contains NPR should be considered diffuse source or point source emissions.

In the Swiss Precautionary Matrix it is envisaged that (at least) one matrix will be completed for each life cycle stage. This allows the various life cycle stages to be considered individually, and any indications of relevant critical processes or stages to be identified.

The fact that the results are aggregated to produce a number means that it is not possible to gain a differentiated picture of the need for precautionary measures; being able to gauge this need for precautionary measures reliably is especially important in the field of consumer protection. The number, however, is only an indicator that is intended to facilitate classification of an NPR. More important information is obtained from evaluation of the individual parameters. A very clear line is drawn between a class A and a class B rating (A = up to 20 points; B 21-7000 points). If data are completely lacking, therefore, an A rating cannot be given. Class A includes products such as milk, so in effect this rating is only applied to exclude clear-cut cases.

A question has been raised as to why the level of information available (S2) is only incorporated into the outcome “need for precautionary measures” as an additional factor. The Swiss experts explained that areas where knowledge is lacking in fact have to be shown in each individual criterion, e.g. in the form of information on whether a criterion has been assigned a particular score on the basis of available data or lack of data. Further consideration will be given to this issue when the matrix is being developed in future.

Some participants feel that assessing toxicity on the basis of the parameters reactivity and stability was overly narrow. In addition, gauging toxicity on the basis of an “intuitive decision”, e.g. by comparison with example compounds, is thought to be inappropriate, and would cast doubt on the quality of the results. Experience from Switzerland has shown that data on toxicity in particular is largely absent (lack of testing methods). For this reason the worst-case scenario[45] is always assumed, and it is impossible to make the criterion more differentiated. By including only reactivity and stability, as more nano-specific parameters, differentiation becomes possible. This is seen merely as an approximation and information from tests or similar procedures should be used instead as soon as they become available.

Indicators concerning relevant volumes in relation to the environment were taken from the tonnage thresholds laid down in REACH. In the field of occupational safety, quantities have been calculated on the basis of the surface ratios; in the lowest category these are around < 1200µg.

Demand for the precautionary matrix certainly exists, especially among small and medium enterprises (SME). Larger enterprises also use the matrix, however, to identify and analyse discrepancies in their management systems, for example.

[45] According to the directions for using the Swiss Precautionary Matrix, if no information is available the highest value should always be assumed. In keeping with the precautionary principle, this ensures that underestimation is ruled out.

The matrix is useful for companies because it provides a structured introduction to the issues involved and makes it clear that different processes and applications of an NPR need to be considered separately. Some industry representatives report, for example, that the matrix has strengthened the hand of occupational safety officers when it comes to implementing measures within the company. They also point out some difficulties in communicating the results of the assessment (numbers).

4 How Swiss retailers use the Precautionary Matrix

4.1 Presentation content

Mr Gude presented various activities of the Swiss retail industry concerning products which contain nanomaterials (see slides). The retail industry sees itself as an important bridge between consumers and manufacturers of consumer products in terms of communication and information. In this regard the Swiss retail sector also assumes a degree of responsibility for products, albeit in an informal, non-legal sense. He pointed out that in commerce, risk aspects relating to placing products on the market are weighed against marketing and sales figures, and interests depend on a variety of parameters.

The Swiss retail industry association has conducted a survey of suppliers in the non-food sector which first of all asked the question whether they have any “nanoproducts” or products labelled “nano” on the market. If the answer was “yes”, the respondent was asked to answer a number of other questions (on availability of information, knowledge relating to risks, etc.). The quality of the completed questionnaires was variable.

Enterprises can tell by the way in which the questionnaire (or precautionary matrix) is completed whether the supplier is acting responsibly and selecting the information with care, or whether he is just “ticking boxes”. In particular, the column headed “Rationale” in the precautionary matrix is important in this regard, since this is where respondents disclose their reflections, assumptions and information sources.

Using the responses to the questionnaires, the Swiss retail industry association is producing lists of nanoproducts, which will soon be made available on the Internet. No detailed information from the questionnaire survey or precautionary matrix will be published.

4.2 Summary of questions, responses and comments

The Swiss retail industry association sent questionnaires to around 8000 suppliers worldwide. Around 800 were returned, a 10% response rate. In most cases the respondent replied in the negative: he did not use or distribute nano-

materials. The food industry was not included in the survey because the use of nanomaterials in food is currently avoided. (According to a study by the Institute of Applied Ecology (Ökoinstitut), there are no foods containing nanomaterials on the market in Switzerland at present.) So far very few conclusions have been drawn from the survey as the results are still being analysed.

It is pointed out once again that the Swiss retail industry association sees itself in a different role to that of its German counterpart, as it takes on a higher degree of responsibility. Product liability, however, remains with the product manufacturer. This was achieved by ensuring that the information provided in the questionnaire had to be signed. The Precautionary Matrix provides a good structure for enquiring about products. Ultimately, however, the reasons for the decision do not only depend on the information provided in the matrix.

The objective of the questionnaire survey was to obtain more information about products and also to avoid repeating what happened with products containing genetically modified organisms (GMO), for example. It also helps to maintain the good reputation of the retail chain in question.

The publication of product lists based on information provided using the matrix is viewed critically because this information does not meet scientific standards, such as of a complete risk evaluation. Although the retail industry body concedes that this is the case, there is no other alternative to this procedure at the present time, since there is no sound information on which to base an assessment. The Swiss retail industry association has no desire to publish details of products for which no information has been provided. Products which contain nanomaterials and for which information is available, e.g. in the form of a completed matrix, will certainly remain on the market if the potential risks are acceptable – such as in the case of silicon dioxide as an anti-caking agent in table salt – especially if the substances contained in nanoform have already been approved.

The role of the retail industry association was discussed and it was noted that in effect this had been a product surveillance exercise. Some participants perceive this to be in competition with the activities of the public authorities, while others see it as useful and complementary, since not all products can be inspected by the authorities.

5 Conclusions / pointers for the work of Issue Group 4

It is important to avoid duplication of effort when devising assessment tools. In this respect the criteria developed by Issue Group 4 can be considered a better/more precise method of assessment which can be used, for example, if assessment using a precautionary matrix identifies a significant need for precautionary measures. The first of the Issue Group 4 criteria correspond to the precautionary matrix criteria, while the rest are more detailed. One possible area of

future work would be to put the two assessment tools one overall framework. This would help to cover the middle ground between the precautionary matrix (highly simplified) and a conventional risk assessment (REACH) and, where relevant, integrate into the appraisal any detailed information available, e.g. relating to toxicity. In this sense the precautionary matrix would be useful for carrying out initial screening of a product, while Issue Group 4's criteria could be used for initial product ranking.

Several participants emphasise that the Issue Group needs to refine and specify more clearly the objectives of the criteria and who they are intended for. The feeling is that the target group should be companies (users of products) rather than consumers or distributors, for example.

Another point that warrants consideration is that there is a need for communication along the supply chain via appropriate information, both from manufacturer to user[46] and from user to manufacturer (concerning a product's applications), and this could be enhanced by an instrument of this sort.

The experiences gained from use of the Swiss Precautionary Matrix should be taken into account as background information for developing the criteria.

The structured procedure provided by the Swiss Precautionary Matrix, and especially the decision tree for ascertaining nano-relevance, are considered valuable and should be discussed by Issue Group 4. It is also important to include a criterion for terminating the assessment. At present the decision that a nanomaterial or nanoproduct should be assessed using the criteria is taken for granted within the Issue Group.

Presentation of the need for precautionary measures in graphic form is helpful as it very quickly becomes clear in which areas potential problems could arise.

Examining the different stages in a product s life cycle separately is also helpful. At present this is only assessed "in an integrated manner" in the Issue Group 4 criteria, which means that the results are not specific to a particular stage or process.

[46] Safety Data Sheets do not always contain the relevant information on the nanomaterials themselves. Moreover, the applications in which a material is used are a decisive factor.