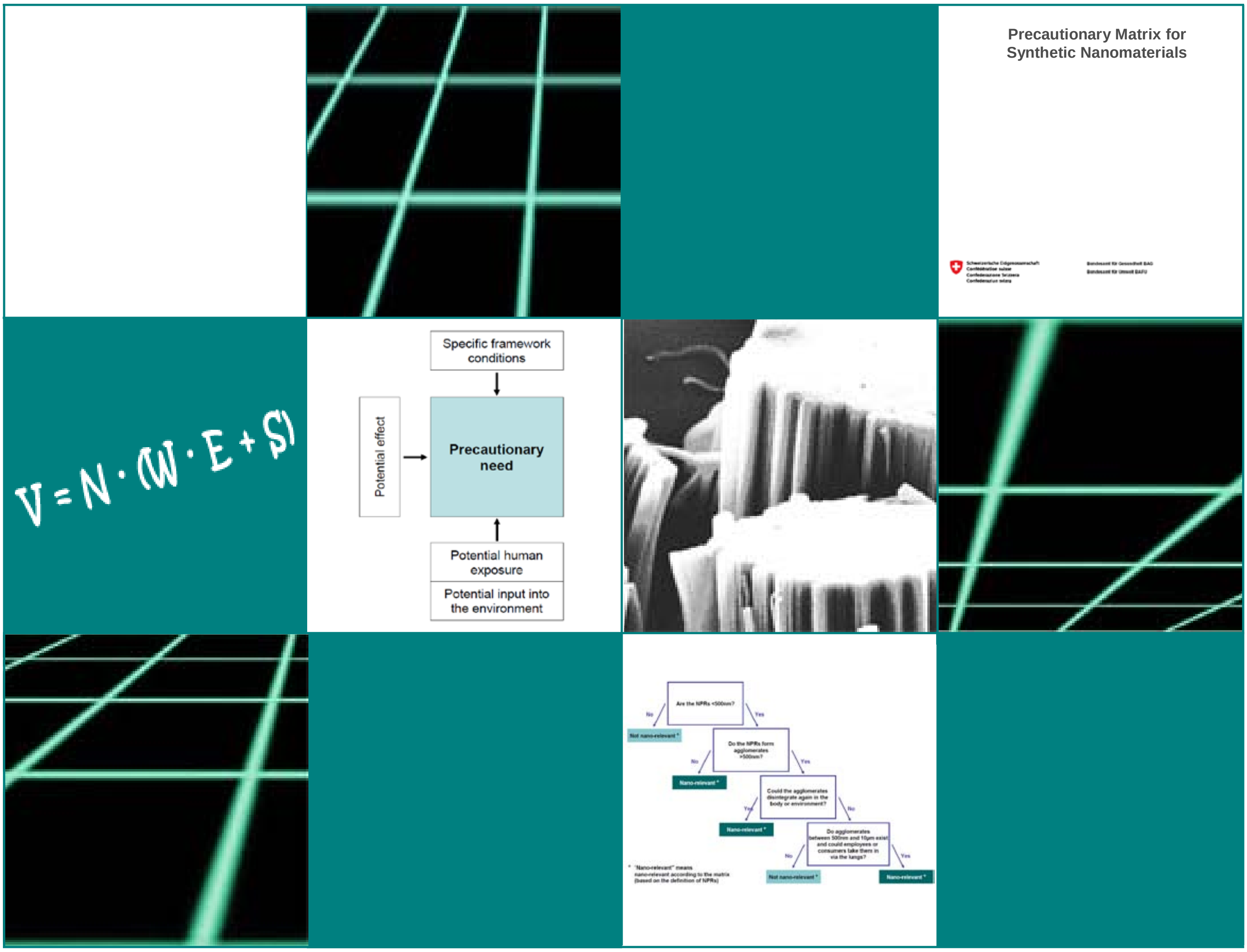
Guidelines on the Precautionary Matrix for Synthetic Nanomaterials



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Contents

1 Context

Although synthetic nanomaterials are not dealt with specifically in present legislation, all regulatory areas implicitly include synthetic nanomaterials. This is the conclusion of both the Swiss and the European authorities. Responsibility for the safe handling of synthetic nanomaterials therefore rests with the private sector (industry, commerce and trade).

Moreover, the scientific and methodological preconditions (e.g. special testing requirements) do not yet exist to enable us to define requirements that go beyond the current general provisions to protect health and the environment.

This situation is causing businesses considerable uncertainty about how to act and whether to invest, and it makes it difficult to have a public debate on the opportunities and risks presented by nanomaterials.

In the light of this general situation, the Federal Council adopted the **Swiss Action Plan Synthetic Nanomaterials**[1]. Focusing on the following priority actions,

- creating the scientific and methodological preconditions to recognise and prevent the possible harmful impacts of synthetic nanoparticles on health and the environment,
- creating the regulatory framework for responsible handling of synthetic nanomaterials,
- promoting public dialogue about the opportunities and risks of nanotechnology and
- better use of existing promotional instruments for the development and market launch of sustainable applications of nanotechnology

this action plan aims to develop a precautionary matrix for products and applications that involve synthetic nanomaterials as the core measure for empowering industry, commerce and trade to take greater responsibility in this area and to apply the precautionary principle in a targeted and cost-effective manner.

[1] This can be downloaded free of charge from: www.umwelt-schweiz.ch/div-4002-e

2 Objective and Area of Application

2.1 Objective

The present precautionary matrix helps businesses to assess the need for nanospecific measures (precautionary need) for synthetic nanomaterials and their applications for employees, consumers and the environment, based on selected parameters[2]. In addition it helps in the identification of possible sources of risk in the development, production, use and disposal of synthetic nanomaterials. However, this pragmatic approach should not in any way be compared with a risk assessment process.

The risk potential can be classified to show what action is appropriate:

"Class A": The nanospecific need for action can be rated as low, even without further clarification.

"Class B": Nanospecific action is needed. Existing measures should be reviewed, further clarification undertaken and, if necessary, measures to reduce the risk associated with development, manufacturing, use and disposal implemented in the interests of precaution.

As regards further clarification, users of the precautionary matrix can carry out their own investigations on human exposure, inputs into the environment and the effects of nanomaterials. They may also, if applicable, draw on data from the literature and experts.

Applications that require clarification can thus be identified independently using the precautionary matrix, and the need for measures for protecting health and the environment can then be reviewed and estimated. As such the precautionary matrix is an instrument that industry, commerce and trade can use for duty-of-care and self-supervision purposes[3] associated with the production and marketing of synthetic nanomaterials. The precautionary matrix is also intended to assess the precautionary need of existing or new products and processes. The matrix facilitates a structured approach and allows the major potential sources of risk to be identified. Thus it also provides the basis for early decision-making on whether to proceed with new projects.

The classification of the precautionary need allows a differentiated and objective approach to the opportunities and risks presented by nanotechnologies.

The precautionary matrix functions simultaneously as a differentiation aid, a detector of gaps in knowledge and an early warning system. The precautionary matrix is freely available and free of charge.

[2] The scientific and technological basis for a solid assessment of the risks presented by synthetic nanomaterials to human beings and the environment is still largely lacking. In the environmental area, the input of nanomaterials into different compartments and their distribution between compartments have not been clarified. Also, only a small amount is known about the possible harmful effects of nanoparticles on the body, as test systems have not yet been established

[3] According to the Chemicals Law (SR 813.1), Environmental Protection Law (SR 814.01) and the Chemicals Ordinance (SR 813.11)

2.2 Area of application

In the precautionary matrix it is assumed that nanospecific risks arise only if there is a possibility of two-dimensional (nanorods) or three-dimensional (nanoparticles) nanoscale particles or their agglomerates being released[4]. The precautionary matrix consistently refers to these two types of particles as **nanoparticles and nanorods (NPRs)[5]**. For the purposes of the precautionary matrix, the nanoscale should ideally be extended to 500nm (see section 4.3 for reasons).

The precautionary matrix definition of NPRs also covers nano-objects defined by the ISO as nanoplates[6] (for derivation see appendix 6.1), where these are within the nanoscale in two or three dimensions. Bearing in mind the abovementioned 500 nm, this means that a platelet with e.g. 200 x 200 x 10 nm is defined as an NPR in the sense of the precautionary matrix.

In other words: **NPRs are nano-objects with at least two nanometre-scale dimensions**.

As Figure 1 shows, it is important when using the precautionary matrix to make a clear distinction between the terms "nanotechnology(-ies)", "nanomaterials", "nanostructured materials", nano-objects" and NPRs. The precautionary matrix focuses on NPRs, and discussions of precautionary need are based solely on this definition.

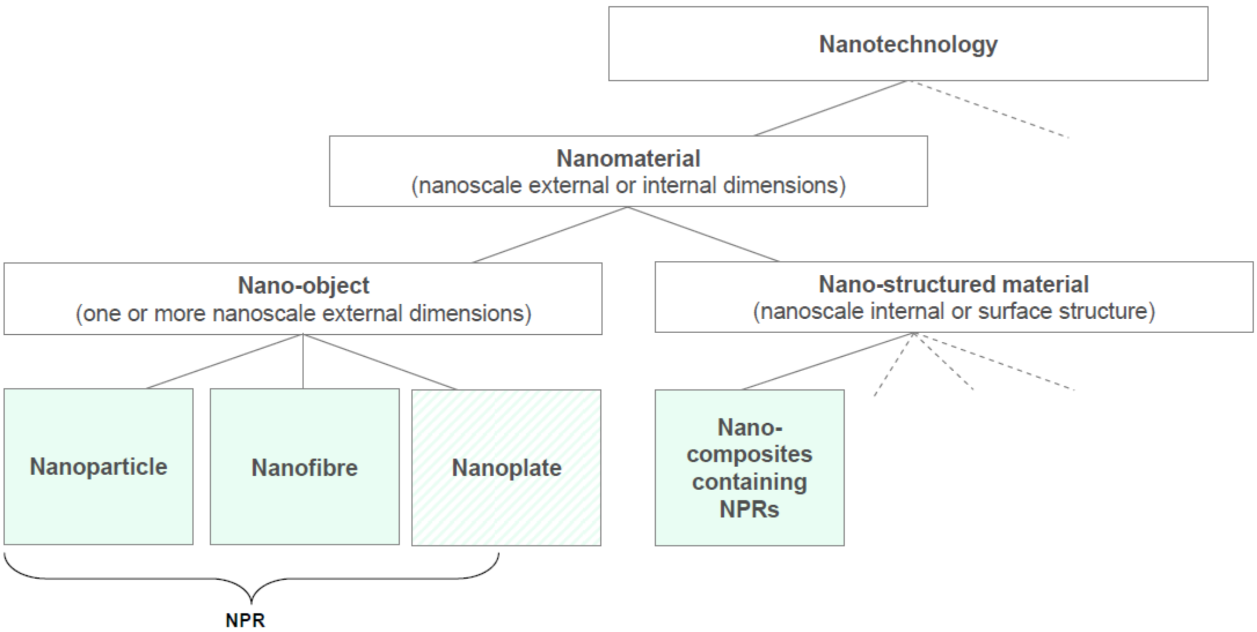

Figure 1: Differentiation of nano-relevance in the precautionary matrix (Source:ISO TS 27687)

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[4] The precautionary matrix uses the ISO nomenclature and definitions (Technical Specification ISO/TS 27687, Nanotechnologies — Terminology and definitions for nanoparticles, Proof, © ISO 2007).

[5] The current ISO document ISO/TS 27687 (Technical Specification ISO/TS 27687, Nanotechnologies — Terminology and definitions for nano-objects — Nanoparticle, nanofibre and nanoplate, corrected version 2009-02-01, © ISO 2009) now uses the term nanofibres instead of nanorods. Since the name definition process has not yet been completed, the terms used in the precautionary matrix have not been changed and the abbreviation "NPF" is not used

[6] According to ISO/TS 27687 nanoplates are defined as nano-objects that measure <100nm in one dimension but are significantly larger in two dimensions

It follows, therefore, that only those materials containing NPRs are considered to be relevant to the precautionary matrix. These are described as "nano-relevant" in the following and in the associated accompanying documents. However, this does not imply any generally valid definition of nano-relevance and applies only in connection with the precautionary matrix.

The precautionary matrix focuses exclusively on nanomaterials or applications containing synthetic NPRs. The precautionary matrix does not record the possible nanospecific risks of surface structures and coatings in the nanometre thickness range if they do not comprise any NPRs. Regardless of whether a nanomaterial is present, nanometre-size particles can also be produced by abrasion or combustion, and by the loosening of fragments (nanoplates) from coatings. The resultant possible risks are dealt with under the heading of fine/ultrafine particulate matter and are not considered by the precautionary matrix. The precautionary matrix is not influenced by non-nanospecific risks to health or the environment, e.g. risks resulting from the toxicity of an NPR's chemical composition (classical "chemical toxicity") or its specific structure (e.g. toxicology of biopersistent fibres longer than 15µm[7]). These risks must be assessed by conventional standard procedures.

The precautionary matrix can be used to estimate the precautionary need for the health of employees and consumers and for the environment throughout the entire life cycle of nanomaterials. The following processes in a nanomaterial's life cycle are considered (see Figure 2):

- Research and development
- Production (including primary production, further and final processing, storage, packaging processes and transport)
- Use
- Recycling
- Disposal.

[7] See e.g. Technical Rules for Hazardous Substances TRGS 521: Fibrous dust. Version: May 2002. (BArbBl. 5/2002 S. 96 or J. R. Soc. Interface published online 2 September 2009; Anthony Seaton, Lang Tran, Robert Aitken and Kenneth Donaldson; Nanoparticles, human health hazard and regulation http://rsif.royalsocietypublishing.org/content/early/2009/08/31/rsif.2009.0252.focus.abstract

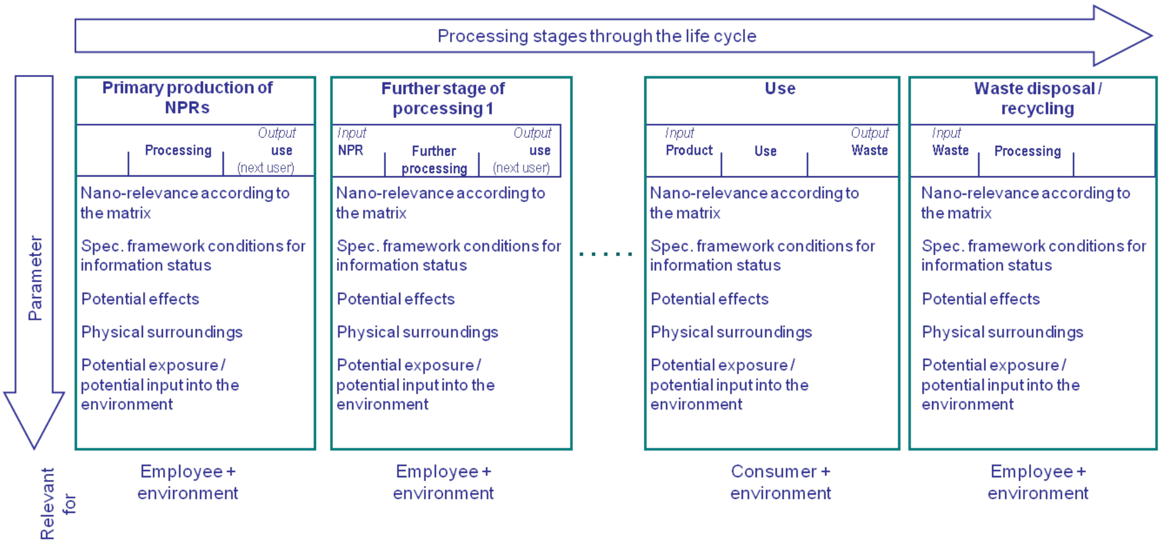

Figure 2: Processing stages as part of the entire life cycle

As a general rule, a precautionary matrix applies to just one specific type of NPR in a precisely defined environment. If the physical environment (e.g. solvent, matrix/substrate, state of aggregation, etc.) or the conditions of use change, a new precautionary matrix has to be completed for this situation. A new matrix also has to be completed if the original NPRs are changed into defined new NPRs during use, for instance through rapid dissolution of a coating.

The precautionary matrix is based on a limited number of evaluation parameters. The **potential effect**[8] is estimated on the basis of the NPRs' **reactivity** and **stability**[9] . The probability and degree of exposure (= "**potential exposure**") of humans and the **potential input into the environment** are determined through data on the **physical surroundings** of the NPR, on the **amount of the handled NPR**, on the **frequency**, on the **amounts in consumer products,** or the **amount of disposed NPR**, or the **amount in exhaust gases, wastewater or solid waste** from development, production or use. In addition, specific limiting conditions are surveyed for the current information. The precautionary matrix is made up of modules for these evaluation parameters. This structure ensures that new scientific information on effects, human exposure or input into the environment can be taken into account at any time.

Note:

A computerised version of the precautionary matrix exists which includes automatic evaluation of entries[10]. This simplifies processing and evaluation and saves a lot of time. These guidelines incorporate basic deliberations about the concept of the precautionary

[8] Capacity of the NPRs to act upon their surroundings (humans, environment)

[9] In the context of the precautionary matrix, NPR stability is to be understood to be the persistence of an NPR as such in the surroundings in question (e.g. resistance to dissolving, chemical or physical change, sintering to bulk material, breakdown etc.)

[10] http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=de

matrix and describe the evaluation algorithms. These explanations are helpful, but not necessarily essential, for using the computerised version of the precautionary matrix.

3 Procedure for Completing the Precautionary Matrix

The precautionary matrix should be completed according to the procedure explained below and evaluated in terms of the possible risks to health and the environment. A template for the precautionary matrix is available as a hard copy and as a computerised version. Explanations and guidance on completing the precautionary matrix are provided in section 4. "Concept of the Precautionary Matrix", for the evaluation of the precautionary matrix in section 5 "Linking of Parameters and Estimation and Classification of the Precautionary Need". The evaluation is always linked to specific processes.

Procedure:

1. **Make an inventory of materials / products / applications**, which are to be tested for nano-relevance to the precautionary matrix and the precautionary need. Include any materials / products / applications where there is doubt about whether nanomaterials are involved.
2. **Check the nano-relevance** of each material / product / application listed in the inventory on the basis of the parameters described in section 4.3. Exclude materials / products / applications that are not nano-relevant. It is recommended that 500 nm be used as the limit of the nanoscale so as to avoid excluding any possible nano-specific risks.

   If the same material / product contains several NPRs, or if several are used in the same application, then a separate matrix must be filled in for each NPR. If the NPRs are capable of changing specifically in the body or in the environment (e.g. dissolving a coating, oxidation etc.) and could be present at the same time in these new forms, a separate matrix must be completed for each of these NPRs.
3. **Find and divide up (process) steps** for all nano-relevant materials / products / applications that are covered for assessment by the precautionary matrix (no change in the physical surroundings of the NPRs). A separate matrix must be completed for each step.
4. **Position each (process) step found in the value chain** using Figure 2: Decide on the groups – employees, consumers and the environment – for which a matrix should be completed.

   If appropriate, separate matrices must be completed for workers with different activity profiles in the same (process) step, or for different groups of consumers.
5. **Enter general information in the relevant matrix**. Define the person responsible / contact person in the company for any external contact.
6. **Complete the technical part of the precautionary matrix**, following the parameters described in section 4 as far as possible.
7. **Specify information sources**: give the name of the person in charge in case any data or information is missing (e.g. suppliers, research departments, universities, experts etc.).
8. **Obtain information** using the relevant questions from the matrix.

9. **Finish the matrix**, delimit the relevant precautionary need and determine the classification.
10. **Clarify any need for action** and, if appropriate, initiate measures (commence further clarifications, additional measures, protection measures and measures to provide information, communication, etc.).

The precautionary matrices are logically completed and evaluated in two iterative steps:

1. A first rapid evaluation demonstrates knowledge gaps and uncertainties and leads to a preliminary precautionary matrix
2. Exact clarifications on the fundamentals of the results from step 1 and the specific answers to the knowledge gaps afford the finished, evaluated, definitive precautionary matrix

4 Concept of the Precautionary Matrix

This section describes the structure of the precautionary matrix and the parameters used. The tables illustrate queries and possible responses in the precautionary matrix (grey background) and the resulting numerical values for the estimation of the precautionary need. The linking of the numerical values is described in section 5, as are the metrics and the evaluation of the precautionary matrix.

4.1 Principles

The precautionary need is represented primarily in relation to the potential effect (W) on the one hand and the potential exposure of humans or inputs into the environment (E) on the other. "Specific framework conditions" (S) are introduced as additional parameters. These factor in uncertainties that take account of gaps in knowledge about the background and the future life of the nanomaterials, or of lack of clarity in the system under consideration (impurities or inaccurately determined size distribution of NPRs, etc.). "Nano-relevance according to the precautionary matrix" (N)[11] is introduced as a criterion for deciding whether the use of the precautionary matrix is indicated:

Precautionary need = f(N, W, E, S)

where:

W: Potential effect (section 4.5)

E: Potential human exposure / potential input into the environment (section 4.6)

N: Nano-relevance according to the precautionary matrix (section 4.3)

S: Specific framework conditions: Information about the life cycle (section 4.4)

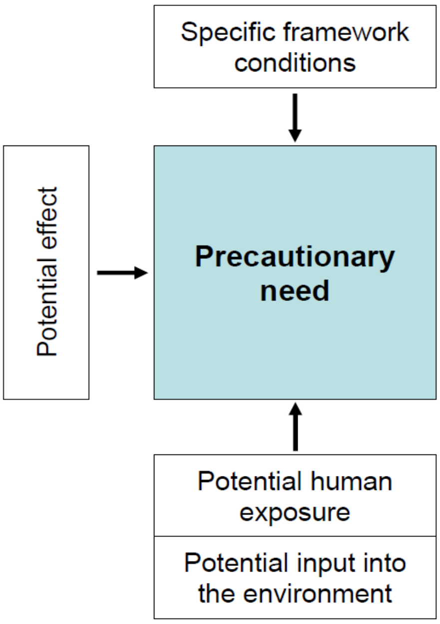

Figure 3: The concept for estimating precautionary need

[11] A system is considered to be relevant in the context of the precautionary matrix if it contains NPRs

Potential effect, potential human exposure, potential input into the environment and specific framework conditions are each evaluated using a parameter selected for the class, and related together to determine the precautionary need. To this end, tables of relationships and corresponding parameter-dependent functions are both used. See section 5 for details on evaluation.

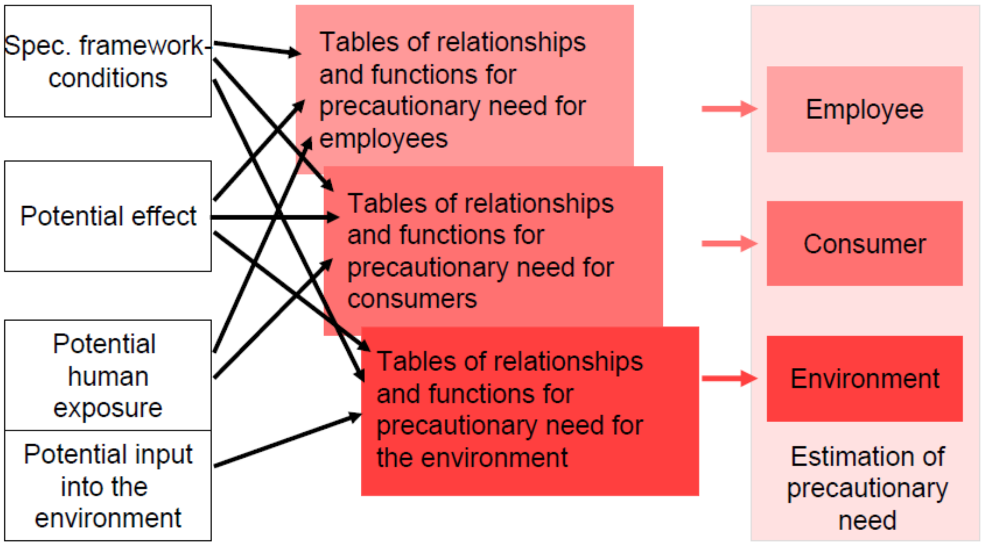

Figure 4: Parameters for estimating the precautionary need

For employees, a “worst case” (WC)[12] is also defined, based on the consideration: in otherwise identical conditions and the same precautionary need for the normal exposure to the NPR, two employees in different companies can have a significantly different precautionary need in an accident, in the case when a significantly greater amount of NPR is stored in one of the companies.

For the purposes of calculating precautionary need, the input parameters are scored from 1 to 9 (the following ratings are currently used: low = 1, medium 5, high = 9. In all cases in which it is not possible to conduct an assessment according to the guidelines in the matrix (e.g. low, medium, high) because the information is not available, the value that would ultimately give the highest precautionary need must be used.

[12] Worst case scenarios are considered to be relevant for the precautionary matrix only if they involve accidents during production, storage, packaging and transport which lead to an increase in exposure in the workplace. The precautionary matrix cannot take account of natural disasters and attacks. Since incorrect use of materials and products falls within the sphere of responsibility of employees and consumers, it is not considered in the matrix. The effects of major accidents on the population are not considered.

4.2 Parameters

The parameters and their sub-divisions are summarised in Table 1: Classification of the parameters used.

Nano-relevance	**Nano-relevance according to the precautionary matrix (i.e. contains NPR)**	N
	Size of the primary particles (NPRs) in the materials (free, bound, aggregated or agglomerated)	N1
	Do the NPRs form agglomerates >500nm?	N1a
	Only if N1a = yes: Does deagglomeration of agglomerates (or aggregates) to primary NPRs or agglomerates <500nm occur under physiological conditions?	$N2_{A,V}$
	Only if N1a = yes: Does deagglomeration of agglomerates (or aggregates) to primary NPRs or agglomerates <500nm occur under the respective environmental conditions?	$N2_U$
	Only if $N2_{A,V}$ = no: If agglomerates between 500nm and 10µm are present, can employees or consumers take these in via the lungs?	N2a
Spec. framework conditions	**Specific framework conditions for information status**	S
	Is the origin of the (nanoscale) starting materials known?	S1
	Is sufficient information on nanoscale starting materials available to complete the precautionary matrix?	S2
	Are the next users of the considered NPRs known?	S3
	How accurately is the material system known, or can disturbing factors (e.g. impurities) be estimated?	S4
Potential effect	**Potential effect**	W
	Redox activity and/or catalytic activity of the NPRs present in the nanomaterial	W1
	Stability (half-life) of the NPRs in the nanomaterial in physiological conditions	$W2_{A,V}$
	Stability (half-life) of the NPRs in the nanomaterial under environmental conditions	$W2_U$
Potential human exposure / potential input into the environment	**Physical surroundings**	E1
	Potential for release related to human exposure	$E1_{A,V}$
	Potential for release related to the environment	$E1_U$
	Maximum possible human exposure	E2
	Amount of NPRs handled by an employee per day	E2.1
	Amount of NPRs with which an employee could come into contact in the worst case	E2.2
	Frequency with which an employee handles NPRs	E2.3
	Amount of NPRs handled by a consumer per day via the utility product	E2.4
	Frequency with which a consumer uses the utility product	E2.5
	Maximum possible input into the environment	E3
	Amount of NPR reaching the environment from wastewater, exhaust gases, solid waste per year	E3.1
	Annual amount of NPRs in utility products	E3.2
	Amount of disposed NPR per year	E3.3

Table 1: Classification of the parameters used

4.3 Nano-relevance according to the precautionary matrix (N)

Parameters N1 and N2 examine the nano-relevance of the system. This is derived from the size of the primary particles (= primary NPR) that are present – free, bound or as aggregates[13] or agglomerates[14] – in the nanomaterials being evaluated. In particular for the aquatic environment, these primary particles are understood in the sense of the "smallest dispersible units".

When using the precautionary matrix, it is recommended for the purposes of determining nano-relevance to include NPRs up to 500nm. The maximum size distribution value is used as a unit for measuring the size of primary particles (N1)[15]. Accordingly, the following should be taken into consideration:

- NPR size distributions with a maximum of 500 nm can extend into the low nanometre range
- nano-specific interactions can occur up to around <300 nm[16].

The limit of 500nm therefore includes a certain safety margin in line with the precautionary thinking.

Ranges of sizes of primary particles (NPRs) contained in the materials (free, bound or as aggregates or agglomerates)	>1nm, <100nm	>100nm, <500nm	>500nm
N1	1	1	0
Do the NPRs form agglomerates >500nm.	yes	no	not known
N1a	1 (proceed to N2)	1	1

Table 2: Nano-relevance

The division into three ranges of particle size reflects the consideration that:

- There is a range of sizes in which the nanoscale character has a dominant physical and chemical influence (e.g. quantum effects) on the properties and thus a causal effect on biological interactions[17]
- Particles above a particular size in living organisms are treated like bulk materials (no nano specific effects)

[13] According to ISO: Particles from rigidly joined or molten particles in which the resulting surface area can be much smaller than the sum of the calculated surface areas of the individual constituents
[14] According to ISO: Loose arrangement of particles or aggregates or mixtures of the two in which the resulting surface area is similar to the sum of the surface areas of the individual constituents
[15] A more detailed consideration would have to be based on the exact size distribution. However, this is not currently done for practical reasons.
[16] Personal communication: P. Gehr, University of Berne
[17] This corresponds to the nanoscale range of 1-100nm as defined by the ISO

- There is a zone between these ranges, in which the quantum effects act in the background, for which, however, nanospecific size effects play a relevant role on exposure and dispersion in organisms.

If the primary particles (<500nm) are in an aggregated or agglomerated form >500nm (N1a), the key factor for determining their "nano-relevance" is whether these aggregates or agglomerates are capable of disintegrating into primary particles or smaller agglomerates (< 500nm) (N2) under ambient conditions (in the body or the environment). If there are stable agglomerates as well as free primary particles, parameter N2 must always be designated with 1.

An NPR's stability in the body is important for assessing the precautionary need for health ($N2_{A,V}$), while stability under ambient conditions is important for assessing the precautionary need for the environment ($N2_U$).

Even for stable agglomerates >500nm, structural elements (nanoscale side branches) which have nano-specific toxicity when in contact with biological tissues can be produced. The cases should be treated as N2a in the precautionary matrix.

Only if N1a = yes: Does deagglomeration of agglomerates (or aggregates) to primary NPRs or agglomerates <500nm occur in the body?	yes	no
$N2_{A,V}$	1	1 (proceed to N2a)
Only if N1a = yes: Does deagglomeration of agglomerates (or aggregates) to primary NPRs or agglomerates <500nm occur under the respective environmental conditions?	yes	no
$N2_U$	1	0
Only if $N2_{A,V}$ = no: If agglomerates between 500nm and 10µm are present, can employees or consumers take them in through their lungs?	yes	no
N2a	1	0

Table 3: Nano-relevance of agglomerates

The process for establishing nano-relevance is summarised in simplified form in the following diagram. For a more detailed description see appendix 6.2:

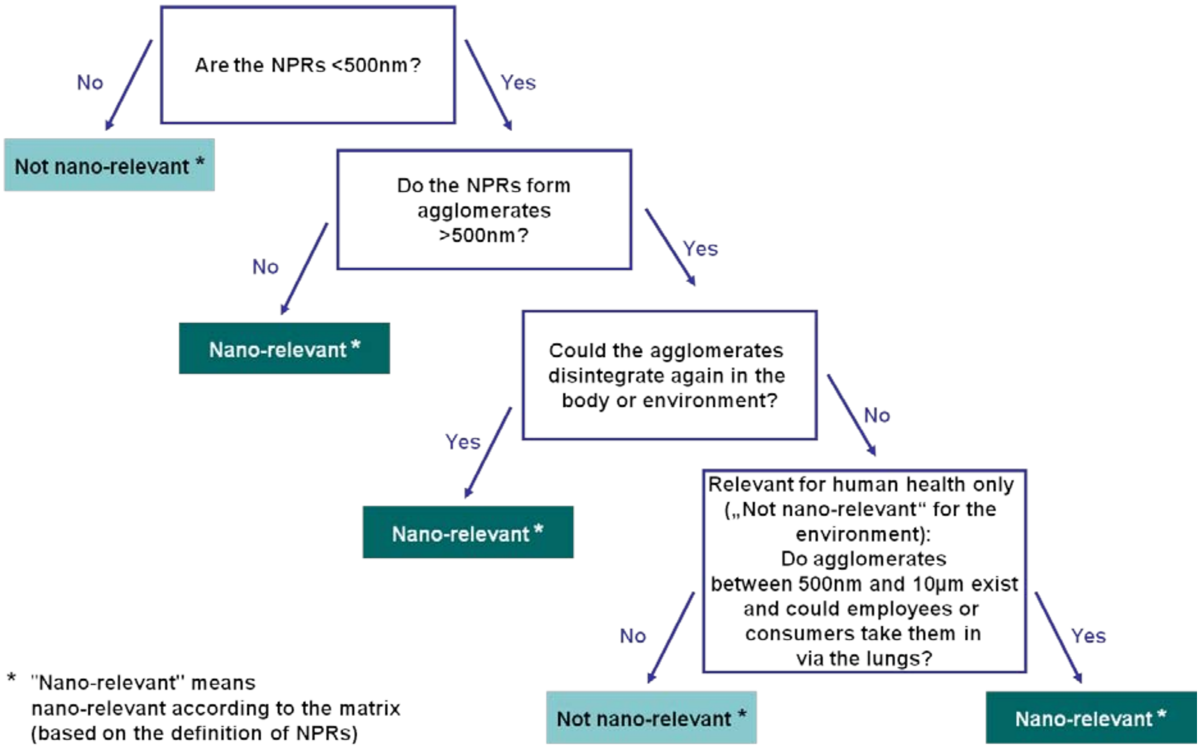

Figure 5: Process for establishing nano-relevance

4.4 Specific framework conditions for information status (S)

Parameters S1 to S3 evaluate the uncertainties that result from gaps in knowledge about the background of the nanomaterials and of their future life cycle. This also includes knowledge of other likely effects on the nanomaterial during its life cycle. S4 takes account of uncertainties about the system under consideration, including impurities, inaccurately determined NPR size distribution, etc.

The sum of parameters S1 to S4 gives the factor S.

Is the origin of the (nanoscale) starting materials known?	yes	partly	no
S1	0	3	5
Is sufficient information available to complete the precautionary matrix for nanoscale starting materials?	yes	partly	no
S2	0	3	5
Are the next users of the considered NPRs known?	yes	partly	no
S3	0	3	5
How accurately is the material system known, or can disturbing factors (e.g. impurities) be estimated?	accurately	not accurately	not known
S4	0	3	5

Table 4: Information about the life cycle

For primary manufacturers of NPRs S1 and S2 should be completed as follows:

- S1: Answer the question for non-nanoscale starting materials
- S2: Answer 'yes' for this parameter if no nanoscale starting materials are present

4.5 Potential effect (W)

The potential effect of NPRs on health and the environment is estimated by:

1. Redox activity and/or catalytic activity[18] of the NPRs present in the nanomaterial (W1)
2. Stability of the NPRs present in the nanomaterial under the relevant conditions in the body ($W2_{A,V}$) or the environment ($W2_U$)

There are currently no internationally approved methods for determining the **nanospecific redox activity** or **catalytic activity** of NPRs. An important factor in assessing this parameter is the ability of an NPR to react with its environment by electron exchange or catalysis (without electron transfer). Until such time as this parameter can be better quantified on the basis of new findings, an approximate evaluation can be achieved with the following illustrative listing of comparative NPRs (Figure 6).

NPR reactivity	low (1)	medium (5)	high (9)
Micelles	X		
Lipid drops	X		
Vesicles	X		
Polymer, unfunctionalised	X		
All other nanoparticles (excluding nanorods) <10nm			X
Gold >10nm	X		
TiO_2, uncoated >10nm			X
TiO_2, silica-coated >10nm	X		
ZnO, uncoated >10nm		X	
All other CNTs, unfunctionalised			X

Figure 6: Illustrative evaluation of W1 for various classes of NPR

As already discussed in section 2.2 above, biopersistent fibres of more than 15 micrometers in length that can be regarded as NPRs should be investigated in a separate analysis**Fehler! Textmarke nicht definiert.**.

[18] This also includes photochemical and photocatalytic activity

In the present context, **stability** takes into account the stability of the employed synthetic NPRs towards dissolution, chemical or physical transformation (for example silver nanoparticles to silver sulfide nanoparticles in wastewater treatment plants), sintering, sorption, agglomeration/aggregation or particle degradation. The last applies for complete or partial degradation, for example, if a coating dissolves.

Since conditions (and hence stability) in the body under physiological surroundings and different environmental compartments can diverge from each other, stability was apportioned to both areas. Care should be taken that the respective conditions for the inspection with the precautionary matrix must be exactly defined:

- Conditions in the body: in certain circumstances it is necessary, depending on the type of exposure, transport, chemical transformation and separation, to complete several precautionary matrices for the respective different conditions (pH, temperature, presence of proteins…)
- Environmental conditions: the possible conditions in the environment vary strongly with the respective considered compartment as well as with the physical and chemical factors that prevail there. Here the relevant scenarios should be worked out first and then each evaluated with new precautionary matrices.

Strictly speaking, for the environment a differentiation must be made between biotic and abiotic systems. Biotic systems in most cases can be estimated using the same stability as applied for humans. A differentiation of both environments is consequently conceivable mainly when considering abiotic environments. If there is no evidence to suggest that stability differs between the two surroundings, then $W2_{A,V}$ and $W2_U$ are assigned the same value. The value should be chosen from the available data for either the physiological or environmental conditions of the exposure under review.

Redox activity and/or catalytic activity of the NPRs present in the nanomaterial	low	medium[19]	high
W1	1	5	9
Stability (half-life) of the NPRs present in the nanomaterial in the body	hours	days-weeks	months
$W2_{A,V}$	1	5	9
Stability (half-life) of the NPRs present in the nanomaterial under environmental conditions	hours	days-weeks	months
$W2_U$	1	5	9

Table 5: Potential effect

If an NPR becomes unstable during a processing step or during use / application, resulting in the complete disappearance of the NPR and its agglomerates, further evaluation for the

[19] Because of their special toxicokinetics NPRs may be able to reach sites in the organism that are not normally accessible for the underlying chemical substances in dissolved form. If the NPRs reach these sites in solution, high local concentrations of these chemical substances may arise, with new toxic effects. In the present context, this possible influence on the potential effect is not considered as sufficient data are not currently available.

subsequent steps is not necessary. If a novel NPR is produced as a result, a separate precautionary matrix must be completed for it.

The presence of a coating or other functionalisation represents a special case for analysing the stability of the NPR. If a coated or otherwise functionalised NPR is present[20], a distinction must be made between the following cases[21]:

- If the coating/functionalisation is stable, the precautionary matrix is completed on the basis of the coated/functionalised NPR's W1 and W2.
- If the coating/functionalisation is conceived in such a way that it dissolves very rapidly in use and thus is not expected to have any impact on the properties of the NPR, the potential effect is to be based on the resultant uncoated/unfunctionalised NPR's W1 and W2 parameters.
- If the coating/functionalisation dissolves during use or application (or in the body / the environment) during a period that leads to the existence of coated/functionalised NPRs as well as uncoated/unfunctionalised NPRs, a precautionary matrix must be completed for the coated/functionalised NPR in addition to the matrix for the coated/functionalised particles.

In the case of soluble NPRs, the underlying chemical substance may exhibit greater or more rapid bioavailability than when present in the non-nanoscale form. This could result in increased acute toxicity, which can be detected by the classical toxicity tests for chemical substances (even if only at fairly high dosages). This possible impact on the potential effect has therefore been omitted from the precautionary matrix.

4.6 Potential exposure of humans / potential input into the environment (E)

Two groups of parameters are used to estimate potential human exposure and potential input into the environment:

1. the physical surroundings of the NPR in the nanomaterial or in its application as a measure of the availability of the NPR (E1)
2. the maximum possible extent of human exposure (E2) or the input into the environment (E3) in the worst case

The fundamental idea is the following: the maximum possible extent of the exposure corresponds exactly to the total amount of material handled. This worst-case reasoning underlines the precautionary thinking. This maximum possible exposure in the worst case is limited and simultaneously “scaled” by taking into consideration the respective physical surroundings of the NPR and consequently the probability of an exposure according to the different availability of the NPR.

[20] In this precautionary matrix the term 'coating' also covers all other types of surface functionalisation

[21] These considerations apply in a similar way if, during the production or use of the NPR, new defined NPRs can be produced by chemical reactions (e.g. oxidation)

4.6.1 Physical surroundings

The potential availability of the NPR differs depending on the physical surroundings (Table 6). Only one of the given surroundings can be (accurately) selected per matrix. Selecting the physical surroundings assigns predefined values for availability in relation to the potential human exposure ($E1_{A,V}$) and input into the environment ($E1_U$).

Physical surroundings	**$E1_{A,V}$**	**$E1_U$**
Air	1	1
Aerosols <10 µm	1	1
Aerosols >10 µm	0.1	1
Liquid media	0.1	1
Solid matrix, not stable under conditions of use	0.1	1
Solid matrix, stable under conditions of use, NPR mobile	10^{-2}	10^{-2}
Solid matrix, stable under conditions of use, NPR not mobile	10^{-4}	10^{-4}

Table 6: Physical surroundings

In the case of human exposure, a distinction is made between possible exposure of the lungs ($E1_{A,V}$ =1) and other target organs[22] ($E1_{A,V}$ = 0.1) when evaluating NPRs in the air and liquid media (including aerosols). No such distinction is relevant for the environment. In the case of aerosols, the change in aerosol sizes over time ("aerosol ageing" should be taken into account where appropriate.

If the NPRs are within or bound to a solid matrix (plastic, ceramic, metal), they are always evaluated on the basis of the matrix's stability under the particular conditions of use[23] and the strength of the NPR's bond to the matrix[24] regardless of the exposure path (only relevant for stable matrices).

When estimating potential exposure, parameters $E1_{A,V}$ and $E1_U$ have a multiplicative effect on the extent of exposure.

4.6.2 Maximum possible human exposure

For employees and consumers, the maximum possible exposure is estimated via the amount of NPR with which those people come in contact per day, and the frequency with which this occurs.[25] The associated parameters are evaluated as shown in Table 7.

[22] It should be noted that evidence exists to indicate that exposure via the skin does not have the same importance as exposure via the GIT. The precautionary matrix makes no further differentiation on this point at present

[23] An example of an "unstable" matrix would be wax for skis, while a bicycle frame would be a "very stable" matrix

[24] If the NPRs are not in the presence of a substance that promotes dissolution in the matrix, they can be designated as strongly bound. Surface-bound NPRs cannot be classified *a priori.* Clarification is needed in such cases

[25] Since failure to wear or the wearing of inadequate personal protective equipment falls within the sphere of responsibility of employees and consumers, this is not considered in the precautionary matrix.

Amount of NPR which a worker[26] handles per day[27]	<1.2mg	<12mg	>12mg
E2.1	1	5	9
Amount of NPR with which a worker could come into contact in the "worst case"	<12mg	<120mg	>120mg
E2.2	1	5	9
Frequency with which a worker handles the NPR(s)	monthly	weekly	daily
E2.3	1	5	9
Amount of NPR which a consumer handles daily through the utility product	<1.2mg	<12mg	>12mg
E2.4	1	5	9
Frequency with which a consumer uses the utility product	monthly	weekly	daily
E2.5	1	5	9

Table 7: Potential human exposure

The extent of potential exposure is then estimated by factoring in the availability of the NPRs as a function of their physical surroundings (section 4.6.1). This is done separately for employees and consumers.

4.6.3 Maximum possible input into the environment

Environmental inputs during the production phase (including manufacture, processing, packaging, transport and disposal) and consumer phase are considered separately. In the consumer phase, two different scenarios also have to be considered (use **with** and **without** specific waste disposal[28]). Subsequent to the consumer phase with specific disposal, the disposal process has to be evaluated once more in a separate precautionary matrix.

The following graphic presents the procedure for handling the possible environmental inputs and subsequent matrix-relevant processes:

[26] If different employees are subject to markedly different exposures, it is recommended that separate precautionary matrices be completed for these employees

[27] For the derivation of the specified values see appendix 6.1. In this context "handle" means the physical presence of the material in the vicinity of the employee or consumer without taking account of specific protective measures

[28] the FOEN working group for "Environmentally compatible and safe disposal of nanomaterial waste products" is preparing a guide that will provide information on the disposal of industrial and commercial waste. Contact: FOEN, Industrial chemicals Section, ernst.furrer@bafu.admin.ch

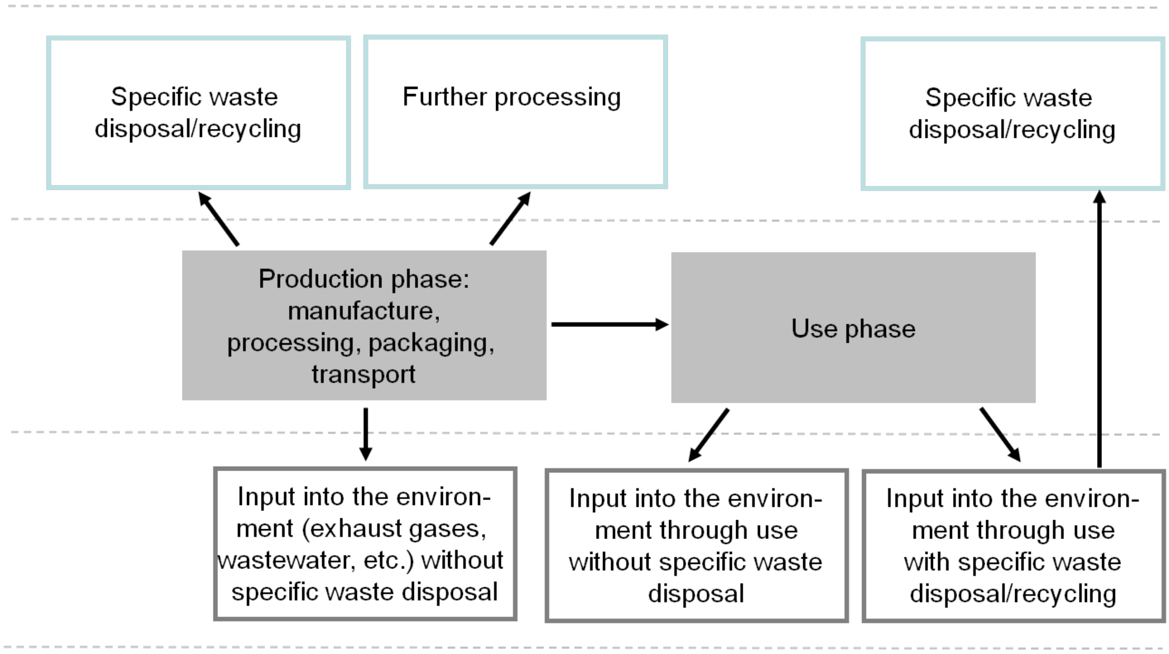

Figure 7: Environmental input scenarios

1. **Production phase (manufacture, processing, packaging, transport, disposal)**

   During the nanomaterial production phase, input of NPRs into the environment may occur via exhaust air, wastewater or unspecific waste disposal. This is assessed in the precautionary matrix by the disappearance of NPRs during the process under consideration (E3.1).

   Any input during specific waste disposal, recycling or further processing occurs in a separate process step and must be estimated in its own precautionary matrix. The estimate in this case is made for the quantity of disposed NPR per year (E3.3). In order to select a suitable disposal method it is recommended to fill out the precautionary matrix in collaboration with a suitable waste disposal company. In regard to this, see also the activities in the context of disposal of nanowaste[30].

2. **Use phase**

   Here there are two separate scenarios:

   a) In the case of use **without specific waste disposal** (e.g. of utility products) it is often difficult to quantify input into the environment. The estimation is based on the total amount of NPRs in the marketed utility products (E3.2). Estimated input into the environment does not include the physical surroundings ($E1_U$) since, when looked at in the long term, all NPRs are introduced into the environment independently of their physical surroundings.

   b) For use **followed by specific waste disposal**, only inputs during use are considered. Input is estimated via the total amount of NPRs in the marketed utility products (E3.2) taking account of the physical surroundings ($E1_U$).

Since environmental inputs via a specific method of disposal or recycling after use represent individual process steps, these are estimated in their own precautionary matrix. The parameter E3.3 is also applied in this case.

The environmentally relevant parameters are evaluated as follows:

Annual quantity of NPR that reaches the environment via wastewater, exhaust gases or solid waste[29]	< 5kg	< 500kg	>500kg
E3.1	1	5	9
Annual quantity of NPRs in utility products	< 5kg	< 500kg	>500kg
E3.2	1	5	9
Annual quantity of disposed NPR	< 5kg	< 500kg	>500kg
E3.3	1	5	9

Table 8: Input into the environment

[29] The listed values are derived according to Appendix 6.4

5 Linking of Parameters and Estimation and Classification of the Precautionary Need

The linking of the parameters presented and explained in section 4, the estimation of the consequent precautionary need and its classification are presented in the following sections. This section is only intended to provide supplementary information and is not essential for using the computerised version of the precautionary matrix.

5.1 Linking and estimation of parameters

5.1.1 Nano-relevance according to the precautionary matrix

Nano-relevance is determined using the flow diagram in section 4.3, where:

$$\mathbf{N = N1 \cdot N1a^{30} \cdot N2^{31} \cdot N2a}$$

N = 1: "nano-relevant" according to the precautionary matrix

N = 0: not "nano-relevant" according to the precautionary matrix

5.1.2 Specific framework conditions for information status:

The sum of parameters S1 to S4 gives the factor S:

$$\mathbf{S = S1 + S2 + S3 + S4}$$

5.1.3 Potential effect

The overall potential effects $W_{A,V}$ on humans and W_U on the environment are estimated using the following equations:

$$\mathbf{W_{A,V} = W1 \cdot W2_{A,V}}$$

$$\mathbf{W_U = W1 \cdot W2_U}$$

5.1.4 Potential Exposure of Humans

Potential Exposure of Workers:

$$\mathbf{E_A = E1_{A,V} \cdot E2.1 \cdot E2.3}$$

additionally in the "worst case": $\mathbf{E_A^{WC} = E1_{A,V} \cdot E2.2}$

where:

$E1_{A,V}$: Physical surroundings, specific for the "workers/consumers" target groups (section 4.6.1)

E2.1: Amount of NPR with which a worker comes into contact per day

E2.2: Amount of NPR with which a worker could come into contact in the "worst case"

E2.3: Frequency with which a worker comes into contact with NPRs

Potential exposure of consumers:

[30] For N1a = no: N2 and N2a are inapplicable

$$E_V = E1_{A,V} \cdot E2.4 \cdot E2.5$$

where:

$E1_{A,V}$: Physical surroundings, specific for the "workers/consumers" target groups (section 4.6.1)

E2.4: Amount of NPR with which a consumer comes into contact

E2.5: Frequency with which a consumer comes into contact with NPRs

5.1.5 Potential Input into the environment

Production phase: Input of NPR via exhaust air, wastewater or unspecific waste disposal is assessed by the decrease in NPRs during the process under consideration (E3.1):

$$E_U^P = E3.1$$

where:

E_U^P: Maximum possible input into the environment during the production phase

E3.1: Annual amount of NPR reaching the environment via wastewater, exhaust air, solid waste

Specific waste disposal step after the production phase: Input of NPR via exhaust air or wastewater is estimated from the disposed quantity of NPR during the waste disposal throughout the year (E3.3) factoring in the physical surroundings ($E1_U$):

$$E_U^{PSE} = E1_U \; E3.3$$

where:

E_U^{PSE} maximum possible input into the environment from a disposal step subsequent to production

$E1_U$ physical surroundings specific to the environment (section 4.6.1)

E3.3 annual quantity of disposed NPR (from the production phase)

Use phase, without specific waste disposal: Input into the environment is estimated without factoring in the physical surroundings ($E1_U$). For the real input of NPR from utility products into the environment, weathering and leaching processes are responsible:

$$E_U^G = E3.2$$

where:

E_U^G: Maximum possible input during use without specific disposal

E3.2: Annual amount of NPRs in utility products

Use phase, with specific waste disposal: Input is estimated via the total amount of NPRs in the marketed utility products (E3.2) taking account of the physical surroundings ($E1_U$):

$$E_U^{G,spez} = E1_U \cdot E3.2$$

[31] For N2= yes: N2a is inapplicable

where:

$E_U^{G,spez}$: Maximum possible input during use with specific waste disposal

$E1_U$: Physical surroundings, specific for the environment (section 4.6.1)

E3.2: Annual amount of NPRs in utility products

Specific disposal step subsequent to the use phase: Input into the environment is estimated from the quantity of disposed NPR per year (E3.3) by taking into account the physical surroundings:

$$\mathbf{E_U^{GSE} = E1_U \;\; E3.3}$$

where:

E_U^{GSE} maximum possible input into the environment during the disposal process of utility products

$E1_U$ Physical surroundings, specific for the environment (section 4.6.1)

E3.3 annual quantity of disposed NPR (from the production phase)

5.2 Estimation of the precautionary need (V)

To estimate the precautionary need, the values determined for potential effect W and potential human exposure / input into the environment E are multiplied by each other. Then S is added and the result is multiplied by N:

$$\mathbf{V = N \cdot (W \cdot E + S)}$$

Precautionary need for employees

$$\mathbf{V_A = N_{A,V} \cdot (W_{A,V} \cdot E_A + S)}$$

$$\mathbf{V_A^{WC} = (W_{A,V} \cdot E_A^{WC}) + V_A}$$

Precautionary need for consumers

$$\mathbf{V_V = N_{A,V} \cdot (W_{A,V} \cdot E_V + S)}$$

Precautionary need for the environment

$$\mathbf{V_U^P = N_U \cdot (W_U \cdot E_U^P + S)}$$

$$\mathbf{V_U^{PSE} = N_U \cdot (W_U \cdot E_U^{PES} + S)}$$

$$\mathbf{V_U^{G,spez} = N_U \cdot (W_U \cdot E_U^{G,spez} + S)}$$

$$\mathbf{V_U^{GSE} = N_U \cdot (W_U \cdot E_U^{GES} + S)}$$

$$\mathbf{V_U^G = N_U \cdot (W_U \cdot E_U^G + S)}$$

where:

V_U^P: Precautionary need during production

V_U^{PSE}: Precautionary need during a disposal step of production waste

$V_U^{G,spez}$: Precautionary need during use with specific waste disposal

V_U^{GSE}: Precautionary need during a disposal step of a utility product

V_U^{G}: Precautionary need during use without specific waste disposal

5.3 Classification

Evaluating a precautionary matrix with the metrics used here produces a total score that allows a general classification of the nanospecific need for action:

Score	Classification	Importance
0 - 20	A	The nanospecific need for action can be rated as low even without further clarification.
>20	B	Nanospecific action is needed. Existing measures should be reviewed, further clarification undertaken and, if necessary, measures to reduce the risk associated with manufacturing, use and disposal implemented in the interests of precaution.

The differentiation limit between classes A and B has been defined as 20 both for the case health as well as for the case environment, independently of the different evaluation algorithm. This is based on considerations that appear acceptable to each of the assumed cases and unacceptable (viz. Tables 9 and 10).

The result of the evaluation does not say anything about actual risks. Establishing the precautionary need should motivate the user to think about whether existing protective measures meet this precautionary need or whether further measures are required. In this regard it should be noted that if an NPR is unstable during processing, during use or under the given environmental conditions and these cause the NPR and its agglomerates to totally disappear, then any further evaluation of the subsequent steps becomes unnecessary. However, should a new type of NPR be formed, then its own precautionary matrix would need to be filled out.

In the context of precaution, class B represents an evaluation which, in case of doubt, can be applied to all nanorelevant materials according to the precautionary matrix. The need for action can only be rated as low without further clarification in cases where evaluation using the precautionary matrix produces a score of 20 or less.

Total scores are derived from the estimates that are entered for the specific framework conditions, the potential effect and the potential human exposure / potential input into the environment. An analysis of these chosen estimations of the individual parameters enables a differentiated view of the gaps and uncertainties to be made and results in an additional specification of the handling needs.

By way of illustration, Table 9 shows which combinations of parameters result in which classification of the precautionary need for health for an exposure to air.

	Potential effect			
Potential e exposure of humans		**Low** **Low** redox activity and catalytic activity and **low** stability	**Medium** **Medium** redox activity and catalytic activity and **low** stability Or vice versa	**High** **Medium or high** redox activity and catalytic activity and **medium or high** stability
	Low **Low** amount of NPR handled by a consumer/employee per day and **low** frequency of consumer product use /exposure of NPR to an employee	**Class A**	**Class A**	**Class B**
	Medium **Medium** amount of NPR handled by a consumer/employee per day and **low** frequency of consumer product use/exposure of NPR to an employee Or vice versa	**Class A**	**Class B**	**Class B**
	High **High** amount of NPR handled by a consumer/employee per day and **high** frequency of consumer product use/exposure of NPR to an employee	**Class B**	**Class B**	**Class B**

Table 9: Classification of NPR that results in exposure via the air (aerosols <10µm). A value 0 was used for the specific framework conditions

In the case of a consumer product, this for example would mean the following: since it can be assumed that consumers exposed to NPRs via the air entails a low potential exposure in just a very few cases, only products that contain NPRs with a low potential effect would be rated as class A (low reactivity and low stability).

In analogy with Table 9, Table 10 shows an example for the possible classification of an input into the environment via wastewater from a manufacturing process.

	Possible effect			
Potential input into the environment		**Low** **Low** redox activity and catalytic activity and **low** stability	**Medium** **Medium** redox activity and catalytic activity and **low** stability Or vice versa	**High** **Medium or high** redox activity and catalytic activity and **medium or high** stability
	Low **Low** amount of NPR disposed per year in wastewater, exhaust air or solid waste which reaches the environment	**Class A**	**Class A**	**Class B**
	Medium **Medium** amount of NPR disposed per year in wastewater, exhaust air or solid waste which reaches the environment	**Class A**	**Class B**	**Class B**
	High **High** amount of NPR disposed per year in wastewater, exhaust air or solid waste which reaches the environment	**Class A**	**Class B**	**Class B**

Table 10. Classification of the input of NPR into the environment in wastewater from a manufacturing process. A value 0 was used for the specific framework conditions

Minimum and maximum values

For cases where the specific framework conditions do not make any additional contribution (S=0) and the physical surroundings permit maximum NPR availability (E1=1), the minimum and maximum values are as follows:

For employees and consumers:

- Low reactivity (W1=1) and stability ($W2_{A,V}$ =1), low maximum possible exposure (E2=1): 1 point
- High reactivity (W1=9) and stability ($W2_{A,V}$ =9), high maximum possible exposure (E2=81): 6561 points

For the environment:

- Low reactivity (W1=1) and stability ($W2_U$ =1), low input into the environment (E3=1): 1 point
- High reactivity (W1=9) and stability ($W2_U$ =9), high input into the environment (E3=9): 729 points

Conclusion: Significance of a high score

- The precautionary matrix is based on the assumption that no protective measures of any kind are in place for employees, consumers or the environment. Consequently, the score represents a measure of the need to **review existing measures** or **evaluate new measures**. A statement about the specific precautionary need can be made only by analysing the individual parameters
- High scores can also result from a lack of knowledge and the consequent precautionary high scores for individual parameters. This possibility should also be taken into account when analysing the results
- High scores do not necessarily mean that the reviewed NPRs represent a hazard or involve definitive risks, rather only that there is a great need for knowledge procurement, additional explanations and testing as well as possible specific measures.

6 Appendix

6.1 Differentiating between various nano-objects

The following graphic is designed as a decision-making aid to help users differentiate between nanoparticles, nanorods and – not relevant for the precautionary matrix – nanoplates. It is based both on size and aspect ratio (according to ISO/TS27687).

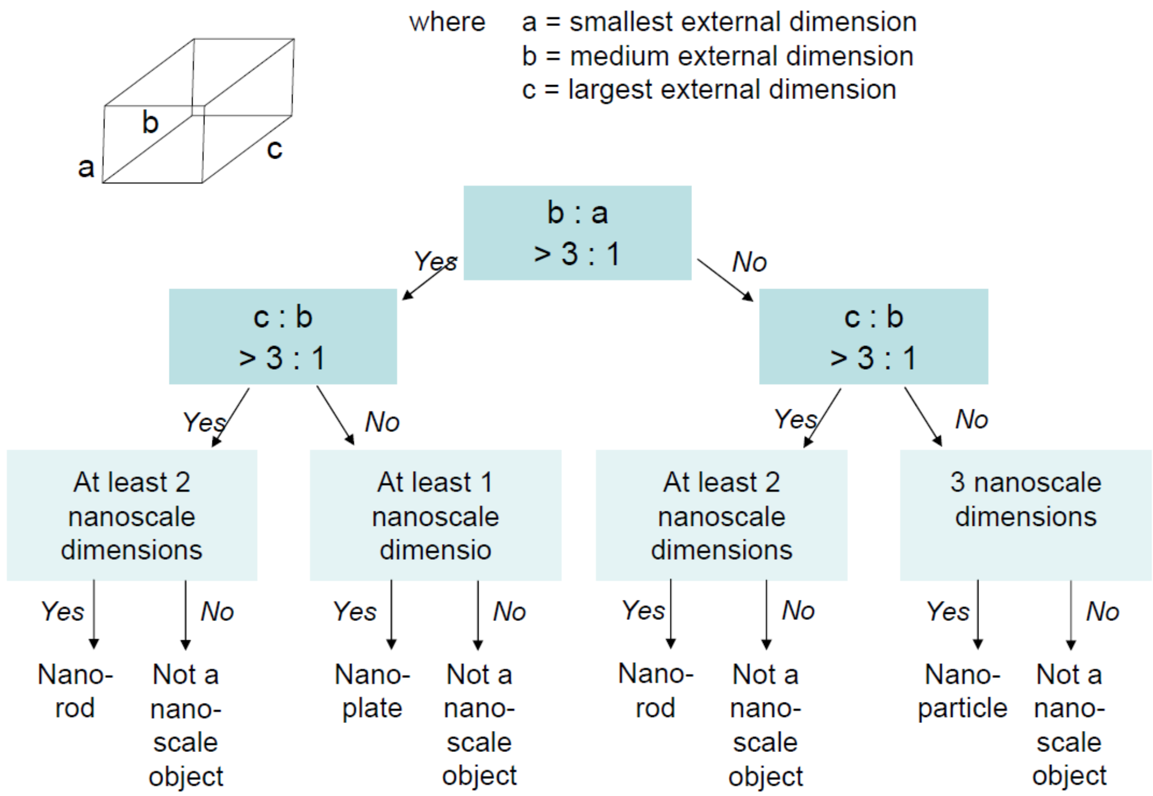

Figure 8: Differentiating between nanoparticles, nanorods and nanoplates (according to ISO/TS 27687[5])

6.2 Assessment of agglomerates in the precautionary matrix

When assessing the nano-relevance of a system in the context of the precautionary matrix, the size of the primary particles, the ability of the system to create agglomerates and the stability of those agglomerates are all important. It is important to note that, even for stable agglomerates >500nm (up to approx. 10µm) with nanoscale side branches, nano-specific toxicity can occur in the lung when in contact with pulmonary tissue. Employees and consumers must take this aspect into account.

Accordingly, there are three possible scenarios:

1. The primary particles create agglomerates that are not stable in the body or the environment and which disintegrate into NPRs <500nm. This scenario is treated as

nano-relevant in the precautionary matrix and it applies generally to humans and the environment.

2. The primary particles create agglomerates which are stable and which do not disintegrate into NPRs <500nm. The NPRs are not produced or integrated into a utility product in a manner that could entail exposure via the lungs. This case applies only to employees and consumers and is not treated as nano-relevant in the precautionary matrix.
3. In contrast with 2, however, the NPRs are produced or integrated into a utility product in a manner that could entail exposure via the lungs (agglomerates in the range between 500 nm and 10µm). In this case the NPRs are assessed as nano-relevant, and a precautionary matrix should be completed with E1 (physical surroundings = air). This case applies only to employees and consumers and is not relevant for the assessment of the environment.

6.3 Basis for estimating E2.1 and E2.3

For the determination of the threshold values for assessing parameters E2.1 and E2.3, the Suva threshold values in the workplace 2007 (MAK value) for diesel soot pollution has been used[32] (Suva, December 2006). This is 100 µg /m^3 for 8 hours' exposure in the workplace, related to the elemental carbon (EC) core of the particle, which is able to penetrate the alveoli. Since the density of these particles is very low, the amount of particles provides a very effective threshold value for daily pollution exposure: the same amount of denser particles (i.e. most of all particles) means fewer particles in the same volume, and so an overestimate of exposure. This is done deliberately to ensure that the risk of exposure to NPRs will never be underestimated.

According to Freijer et al., 1997, the average volume of air breathed by a person during normal physical exertion can be calculated by:

$$Q_{inh} = 2.3 \cdot B_w^{0.65}\ m^3/day$$

where B_w is body weight in kg. To convert this to a value for 8 hours, the volume obtained must be divided by 3, since the equation gives the value for an entire day (24 hours).

Using an assumed average weight of 70 kg, the volume of air breathed during 8 hours is about 12 m^3. Multiplying this by 100 µg/m^3 gives an acceptable maximum quantity of 1200 µg of NPR. In other words: If all NPRs enter the air and are then breathed in by an employee or consumer, these are still within the range of the MAK value. Since this is very likely to be a massive overestimate of the possible exposure, the value of 1200 µg can legitimately be termed a "low" material quantity.

[32] Diesel particles provide a good model system for NPRs and their agglomerates and aggregates: these are primary particles measuring a few nanometres across with aggregates of a few dozen nanometres and agglomerates up to 1 micrometre

This approach represents a rough approximation for estimating E2.1 and E2.3, whose values will have to be further refined and adapted during practical use of the precautionary matrix.

Strictly speaking, the amount of particles given for E2 only applies in air; however, it can be taken as an initial approximation of NPRs in all surroundings (air, liquid and solid matrices). E1 can be used to differentiate potential exposure according to these parameters. This may result in overestimations of exposure in liquid and solid surroundings.

6.4 Basis for estimating E3.1, E3.2 and E3.3

The derivation of the estimation limit of 500 kg for the amount of NPR disposed per year which reaches the environment in wastewater, exhaust air or solid waste, the amount of NPR in utility products and the amount of disposed NPR per year (E3.1 and E3.2) is based on the following model: based on ecotoxicity data of nano TiO_2, a PNEC of 1 µg/l is assumed. For an estimated use of 200 l per day for each inhabitant of Switzerland (ca. 8 million), the considered annual volume is 580×10^9 l. Together with the assumed PNEC, this results in 550 kg per year as the limit, below which no effect occurs. Taking into account a precautionary approach 500 kg per year was taken as the relevant limit.

This projection is very general and set at a high level for Switzerland as a whole. It should be pointed out that locally strongly different quantitative scenarios are possible. This is not however considered in the scope of the precautionary matrix.

Notes: