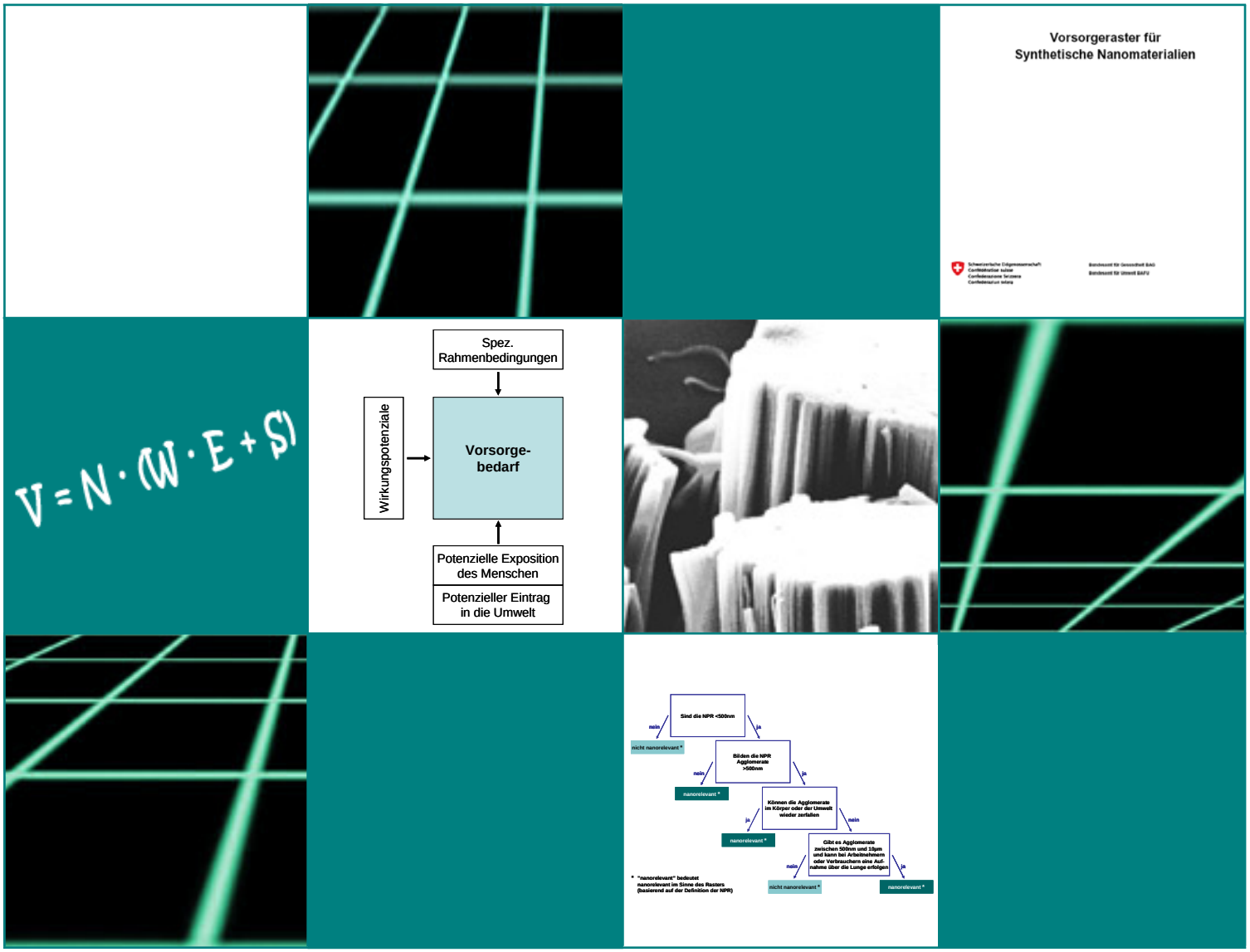
FAQs and Responses on the Precautionary Matrix for Synthetic Nanomaterials



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Federal Office of Public Health FOPH

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FAQs	Responses
What support is available for using the precautionary matrix, and where and how can I comment on the precautionary matrix and provide my own opinion?	For all questions or comments concerning the precautionary matrix and its use, the following persons are at your disposal: • Ch. Studer (FOPH), christoph.studer@bag.admin.ch • A. Weber (FOEN), andreas.weber@bafu.admin.ch • Ch. Rüegg (SECO) christoph.rueegg@seco.admin.ch • M. Tellenbach (Terraconsult) mtellenbach@bluewin.ch • J. Höck (TEMAS AG), juergen.hoeck@temas.ch. Additional information can be found on the BAG website: http://www.bag.admin.ch/, under Topics/Chemicals/Chemicals from A-Z/Nanotechnology. Industry and trade associations are also willing to receive your questions and comments on the precautionary matrix.
Are nanoparticles dangerous?	In no way and with no conceivable tool can this question be flatly answered. Different answers result here from case to case; the same nanoparticle can have different effects in another environment or under other conditions.
What is the legal status of the precautionary matrix?	The matrix is non-binding and is used on a voluntary basis; no one has to justify the results. However, it can serve as a confirmation that planned processes or products have been examined in the context of prevention and existing scientific knowledge, and applicable measures were introduced.
Is a digital version of the precautionary matrix available?	In order to considerably facilitate the process and save time, a digital version is now available to the wider public on the FOPH website. This digital version has already been used in user training courses.
How much effort is required to complete a precautionary matrix?	Experience has shown that once the relevant data are available and have been prepared, it takes between 1 and 2 hours to complete the matrix for the first time with the help of the PC-based version. In order to modify the various scenarios, each of the other process or application steps take only minutes to assess.

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Can the precautionary matrix also be completed by non-specialists?	Non-specialists can only use the precautionary matrix with the assistance of specialists, as a certain basic knowledge is required in order to correctly assess the parameters Likewise, under certain circumstances, a network of connections to experts is necessary in order to answer specific questions. The precautionary matrix has to have this scientific level, as in the absence of a scientific background it would be unable to produce any exploitable assertions. The same applies in principle to the interpretation of competed precautionary matrices.
Is the matrix based on scientific fundamentals?	The parameters from the precautionary matrix are based on scientific considerations and intensive collaboration with pertinent experts. Should the state of scientific knowledge change then the parameters will also be adjusted accordingly.
Is the precautionary matrix self-explanatory?	With an adequate background, the precautionary matrix can be filled out following the guidelines; however, experience has shown that training is particularly advantageous. Contact: Ch. Studer (FOPH), christoph.studer@bag.admin.ch
Can examples of completed precautionary matrices be obtained?	Such examples are not available, as in the absence of the relevant context and the required introduction, they could be misunderstood and consequently have little value. However, practical examples were presented and discussed in the user training courses that were offered.
In the context of the precautionary matrix, what are “synthetic nanomaterials”?	In the context of the precautionary matrix, synthetic nanomaterials are those that comprise nanoparticles or nanorods (abbreviated to NPR in the precautionary matrix) that were specially manufactured for a defined purpose. As a general rule, it is recommended that the precautionary matrix be used for all NPR with at least two dimensions smaller than 500nm. Nanostructured materials, coatings (in so far as they do not contain any of the cited particles) or fine particulate matter for example, are excluded.
What does nano-relevance mean?	Nano-relevance in the context of the precautionary matrix refers to the presence of NPRs (see above) in a free, matrix-bound, aggregated or agglomerated form. The precautionary matrix does not record any materials that are not covered by this definition.

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What is the significance of the "specific framework conditions"?	The specific framework conditions relate to the knowledge of the material systems used. Any knowledge gaps are associated with greater precautionary need since they involve additional uncertainty.
What exactly do "known" and "assessable" mean in the context of the specific framework conditions?	Each user must decide this themselves. If there is uncertainty about whether something is known and can be evaluated, it is recommended to answer the questions as if there were no available knowledge.
What do the following two questions mean for primary manufacturers of NPRs? • Is the origin of the (nanoscale) starting materials known? (S1) • Is sufficient information available to complete the precautionary matrix for nanoscale starting materials? (S2)	These questions should be answered by the primary manufacturers of NPRs as follows: • S1: Answer the question for non-nanoscale starting materials • S2: If no nanoscale starting materials are present, the answer for this parameter should be 'yes'
What does "precautionary need" mean and why is "risk" or "risk potential" not used?	The precautionary matrix does not determine risk in terms of a risk assessment, but rather only provides indications of where a need for action exists in order to clarify possible risk potentials, i.e. the need for precautionary work to identify any sources of risk at an early stage and review and implement appropriate measures.
What does “nanospecific” mean?	This term relates to properties of nanomaterials which result solely from their nanometric size, and which cannot be predicted from the properties of the bulk material.
What do the point counts mean and what is their purpose?	The point counts used to classify the results of the matrix are based on a mathematical formula. They represent an arbitrary classification on a scale in order to facilitate the analysis of risk potentials and the comparison of different scenarios.
What does "potential exposure of humans" mean"?	This does not mean the actual exposure, but the maximum possible exposure (in the worst case) of a human, taking into account the quantity and availability of the NPRs being handled.
What does the question on coatings / functionalisation mean?	It is important to decide whether functionalised NPRs of this type continue to exist in a different form and must therefore be treated in a further precautionary matrix. This question establishes this reference.

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A molecule is not a synthetically manufactured NPR, but what about 10 or 100 molecules?	With this and other borderline cases, it should be noted that when using the precautionary matrix one is not concerned with the exact definition of “nano”, but rather much more about determining whether a possible nanospecific need for action exists independently of such a definition. With this in mind, in case of doubt the use of the precautionary matrix for a giant molecule or agglomerate of single molecules is not wrong.
Is this also true for fine particulate matter?	The precautionary matrix was not designed for use with fine particulate matter. However, here as well, the use of the matrix is not absurd as long as all required data are available.
How should e.g. a colour pigment mixture be treated, which consists of several nanorelevant species?	The precautionary matrix can be used as long as these individual pigments have homogeneous properties in the context of the parameters of the precautionary matrix. Otherwise one should work on the basis of the most reactive species (when known).
How should mixtures of various NPRs be treated when the properties of the mixtures do not correspond to the sum of the individual properties of the NPRs, i.e. in the presence of synergistic effects?	These “cocktail effects” are not taken into account by the precautionary matrix. One should work on the basis of the most reactive species (when known).
Why is the ISO definition of the nanoscale (<100 nm) not used?	Recent results have demonstrated that not only the change in physical and chemical properties in the range between 1 and 100 nm (quantum effects) are relevant to a nanospecific effect on health and the environment. Size effects alone (proven for up to around 300nm) also determine the interactions with the biological environment: Consequently these particles also function differently (nanospecifically) than the corresponding bulk materials.
Is the use of the precautionary matrix binding to anything?	The precautionary matrix is voluntary and is conceived only as a tool to provide support.
Is there a list of possible measures for the precautionary matrix?	The precautionary matrix is not used as a catalogue for possible measures, but rather for early assessments, namely when identifying handling requirements. The choice of measures is on a case-by-case basis and may not appear in the context of the precautionary matrix.
Is there a labelling obligation that depends on the classification given by the precautionary matrix, or is one planned?	Such a labelling obligation based on two classes is not meaningful, as the information content is insufficient as a basis for taking a purchasing decision.

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Does a poor classification mean proscription?	Absolutely not! Moreover, the classification means neither a danger nor a defined risk. It simply indicates the level of need for clarification. The classification is particularly suitable for comparing two or more scenarios; the point counts do not have any absolute meaning *per se*.
Am I allowed to publish my results?	Every user is free to publish his results. However, the use of the results to lead someone to believe in a possibly non-existent product safety (e.g. with a label “precautionary matrix class A”) is not welcomed. This does not correspond to the sense and the spirit of the precautionary matrix that, with its results, triggers deeper evaluations and should not itself be misunderstood as a risk-assessment tool.
How can the potential effect be evaluated in the absence of more detailed data?	From the scientific point of view, a statement of limiting values for assessing the potential effect is not possible today. The assessment should be made intuitively (in case of doubt, preferably overestimate), optionally in comparison with known nanomaterials (e.g. 3 nm nano-gold: high potential effect). A list of comparative materials is integrated in the Guidelines on the Precautionary Matrix.
If someone only relies on the achieved point score, then this can result in ambiguous information that can be highly counter productive when published. How is this tackled?	This difficulty will always arise, no matter how a tool of the precautionary matrix type is designed. This cannot be avoided even by adapting the precautionary matrix. Consequently, specific measures will be taken in order to prevent misinterpretations (information brochures, training courses, dialogues…)
Can the precautionary matrix be meaningfully used as a supplement to the safety data sheet?	Can the precautionary matrix be meaningfully used as a supplement to the safety data sheet?
Will the precautionary matrix take into consideration any misuse of products by workers or consumers?	Will the precautionary matrix take into consideration any misuse of products by workers or consumers?

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Can consumers also use the precautionary matrix?	In principle, anyone with sufficient data and understanding can use it. Indeed, the precautionary matrix has been designed for use by industry, trade and commerce. Following the evaluation, these users should assess the precautionary need and communicate appropriate protective measures.
Is it foreseen that the precautionary matrix will also be used outside Switzerland?	Use of the precautionary matrix is not limited to Switzerland; a cross-border exchange of information and experience is, on the contrary, even explicitly welcomed.
I obtain my nanomaterials from foreign suppliers; in spite of this can I still use the precautionary matrix?	The precautionary matrix is not explicitly limited to Switzerland, rather it can be used everywhere, where a precautionary need should be evaluated. The parameters in the precautionary matrix are set up such that no in-house secrets are requested. Therefore, it is also possible to request a foreign supplier to supply the required material parameters.
Isn't the precautionary matrix a Swiss solo initiative?	The initiative for the precautionary matrix comes from Switzerland; a similarly pragmatic tool does not yet exist in other countries. A solo effort, however, is not envisaged; international cooperation is under way and is intended to be further intensified. In particular, coordination has been initiated with the German federal authorities.
Has the practical suitability of the precautionary matrix been tested?	The precautionary matrix has been tested for its practical suitability and revised accordingly in a trial phase in which about 80 predominantly industrial users participated.
Will the precautionary matrix be updated on a regular basis?	The matrix will be reviewed and adjusted as needed and after feedback has been received.
What does the question about nanospecific disposal mean?	Nanospecific disposal or recycling of industrial and commercial waste is currently managed by a special FOEN working group. This question highlights the link to these activities.

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What does environmental assessment by the precautionary matrix actually involve?	The assessment of precautionary environmental need is much more generic than the health assessment. No new matrix parameters that would improve this situation can currently be defined. For the ongoing support of users, a fact sheet has therefore been produced to explain the interpretation of results and the need for considering compartments and material flows. It also includes links to information materials and experts.
Is standard literature available to evaluate the precautionary matrix and select appropriate measures?	No. The precautionary matrix and its evaluation must be examined on a case-by-case basis, i.e. based on specific issues. A list of standard literature sources for all these different cases is not available.
A high score in the classification can arise both as a result of a lack of knowledge or poor actual scores. Is a distinction made here in the precautionary matrix?	No. Users evaluate this point in the precautionary matrix themselves. Analysing inadequate knowledge is part of the process suggested by the precautionary matrix.
Why is material toxicity not used as an evaluation criterion?	Evaluation with the precautionary matrix is designed in such a way that it does not rely on data that are difficult to obtain or unavailable (e.g. data on nanospecific toxicity) and which moreover must be considered for each specific case.
How can deliberately incorrect completion of the precautionary matrix be prevented?	It cannot be prevented at all. Each user is responsible for completing this tool correctly. Since its use is voluntary, users will not gain any advantage by completing it incorrectly.
In what languages is the precautionary matrix available?	The precautionary matrix is available in German, French, Italian and English.
What are the target groups of the precautionary matrix?	The target groups are all stakeholders who are responsible for the safety of employees, consumers or the environment (industry, trade, commerce, government authorities, insurers, etc.)

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What are the key messages of the precautionary matrix?	The precautionary matrix delivers the following key messages: • The precautionary principle must and can be applied to synthetic nanomaterials • Differentiation is necessary when considering the safety and risks (for employees, consumers and the environment): restricted to NPRs • Not all NPRs are the same: Case-by-case differentiation of scenarios depending on the conditions of use or the surrounding conditions in each case • Voluntary measures by the responsible parties ("causers") are needed, but should be supported by unbureaucratic assistance • The precautionary matrix provides such support, but is incorporated in a greater whole (the action plan) • The precautionary matrix produces a rough preliminary decision and uniform basis for discussions of the need for more extensive investigations

Contacts

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