

Café Europe II: Regulation & Dialogue

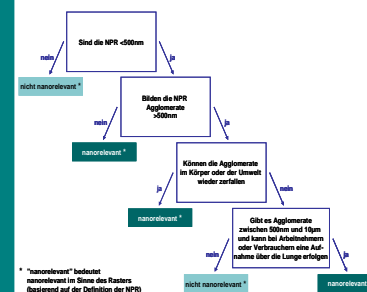
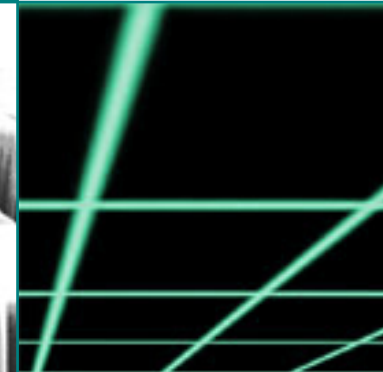
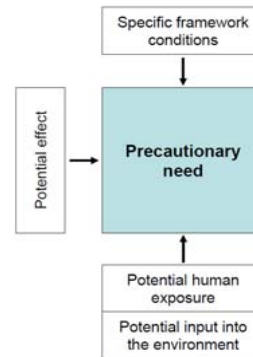
Nanosafety: regulatory tools for industry

Precautionary Matrix for
Synthetic Nanomaterials

 Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Rechtsamt für Umwelt RUA
Rechtsamt für Umwelt RUF

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



Dr. Jürgen Höck
TEMAS AG

May 24, 2013



Swiss Action Plan Synthetic Nanomaterials and InfoNano Portal

The Swiss Federal Council adopted the **Swiss Action Plan Synthetic Nanomaterials** in 2008.

Since 2012, a dedicated web portal called InfoNano is available:

www.infonano.ch



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Basel, May 23 - 24, 2013

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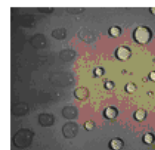
Glossary

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InfoNano

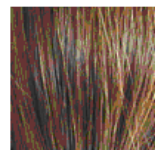
InfoNano is the central federal information platform for nanotechnology. The Federal Offices of Public Health, for the Environment and for Agriculture, the Commission for Technology and Innovation, Swissmedic and the State Secretariats for Economic Affairs as well as for Education and Research are involved in the website.

InfoNano provides information about the **opportunities** and **risks** associated with nanotechnology and synthetic nanomaterials. It is aimed at promoting the dialogue among administrative, economic, research and societal stakeholders.



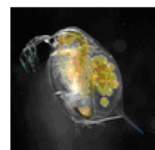
Products

The possibilities of nanotechnology for consumers are promising and range from scratch-resistant lenses and anti-graffiti paint to ultra-light bicycles or more powerful batteries and solar cells. However, the concerns about possible risks are growing along with the rising prevalence of nanoproducts and media reports about seemingly fantastical visions for the future.



Health

In the field of medicine, nanotechnology offers new opportunities in the development of drugs and diagnostics and for the improvement of implants. But nanomaterials may be harmful if they are released during the manufacture, use or disposal of a product and are inadvertently taken up through airways, gastrointestinal tract or skin.



Environment

Nanotechnology promises increased resource and energy efficiency and may in some cases be used to replace harmful substances. However, adverse effects have been observed in laboratory experiments with fish and other organisms in connection with certain synthetic nanomaterials.



Occupational safety

Nanomaterials are used in a growing number of production and processing processes. The availability of information along the entire production and trade chain is essential in order to define the respective required protective measures.



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Action plan for synthetic nanomaterials

The "Action plan for synthetic nanomaterials" illustrates the work required in Switzerland for the safe handling of nanomaterials. It was adopted by the Federal Council in April 2008. On 25 April 2012 the Federal Council decided to continue the action plan until 2015.

The action plan was developed by the Federal Office of Public Health (FOPH), the Federal Office for the Environment (FOEN) and the State Secretariat for Economic Affairs (SECO) in cooperation with an **inter-departmental task force** and the involvement of a **panel of scientific and economic experts**.

The **objectives** of the action plan include:

1. development of regulatory framework conditions for the responsible handling of synthetic nanomaterials;
2. creation of scientific and methodical conditions aimed at identifying and preventing potential harmful effects of synthetic nanomaterials on health and the environment;
3. promotion of the public dialogue about opportunities and risks of nanotechnology;
4. better utilisation of existing tools for the development and rollout of sustainable nanotechnology applications.

The creation of regulatory framework conditions is divided into two phases:

- **Phase 1** (short and medium term): Strengthening of corporate responsibility through different tools (precautionary matrix, guide to self-regulation, support of private-sector codes of conduct, guidelines for nano-specific safety data sheets, improved consumer information, disposal guide)
- **Phase 2** (medium and long term): Development of legal framework conditions for the safe handling of synthetic nanomaterials (review of measures exceeding existing provisions and coordination with developments abroad)

For further information, see pages:

[List of implemented projects](#)

[Legislative process and enforcement](#)

The action plan for synthetic nanomaterials is based on a **basic report** compiled in 2007 and follows a similar **action plan of the EU** from June 2005.

The increasing scientific, economic and societal significance of nanotechnology was the **impulse** for developing the action plan for synthetic nanomaterials. It is aimed at staking out new opportunities and utilising sustainable applications. At the same time, it will help assess possible risks extensively and promptly and, if necessary, implement measures to protect the environment and public health.



Further information

- [Report of the Federal Council dated 25 April 2012, Action plan for synthetic nanomaterials](#)
only available in german or french
25.04.2012 | 324 kb | PDF
- [Action plan Synthetic Nanomaterials](#)
- Report of the Federal Council dated 9 April 2008
- [Synthetic Nanomaterials \(Summary\)](#)
- Risk Assessment and Risk Management. Basic report for the Swiss Action Plan 2007
- [EU action plan \(pdf\)](#)
- from 2005



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List of implemented projects

The following projects have been implemented within the scope of the “action plan for synthetic nanomaterials” as of March 2012:

[Precautionary matrix for synthetic nanomaterials](#)

The precautionary matrix for synthetic nanomaterials is geared toward industry and trade. It was first published in 2008. A precautionary matrix is a method for assessing the nano-specific health and environmental risks of nanoproducts. The matrix is regularly revised based on experiences and new scientific knowledge.

[Safety data sheet: Guide for synthetic nanomaterials](#)

The guide is designed to help manufacturers correctly complete the safety data sheet for nanomaterials, thus improving the flow of information along the supply chain.

[Disposal of industrial nanowaste](#)

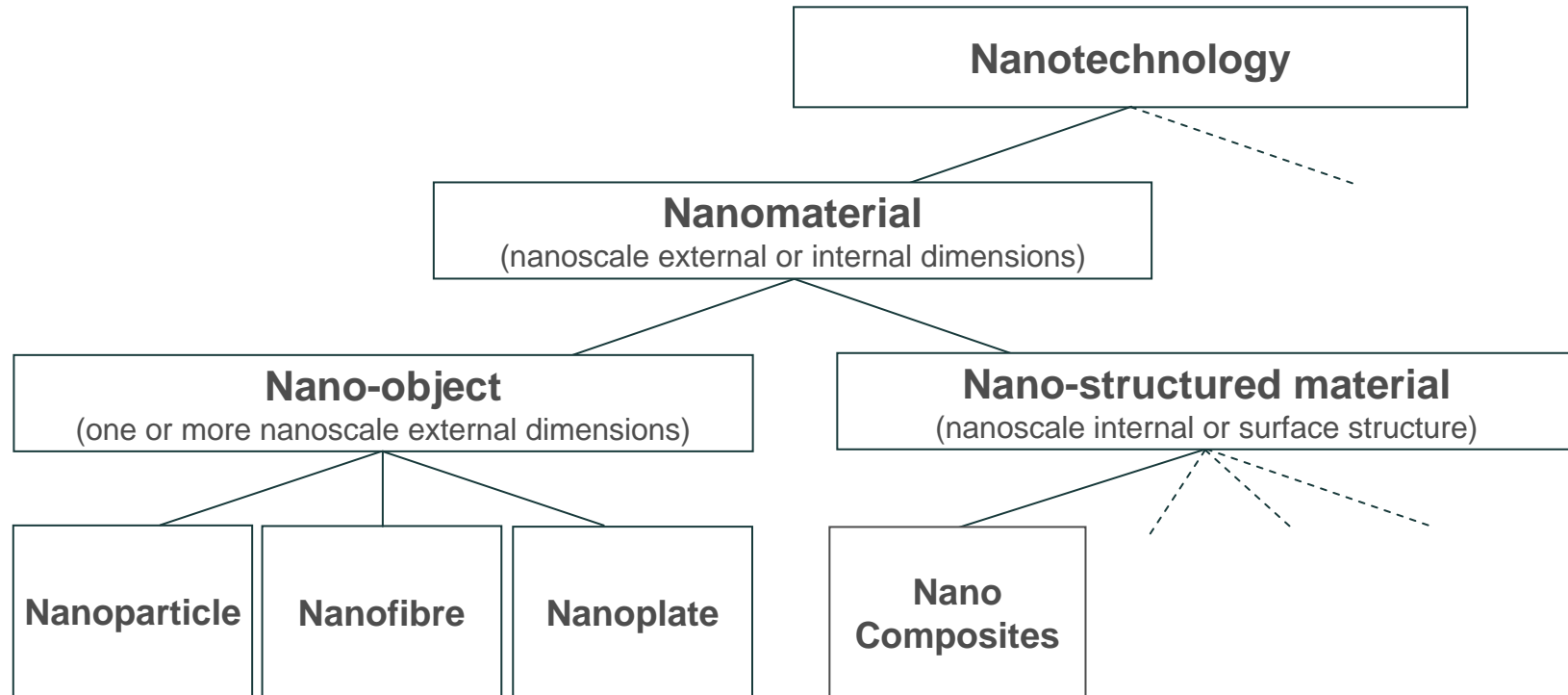
Industrial nanowaste containing releasable nanomaterials can arise from production, industrial and commercial processing of nanomaterials and in connection with research and development activities. A task force appointed by the Federal Office for the Environment (FOEN) has developed basic principles of an implementation aid for the environmentally compatible and safe disposal of this type of waste.

[NANO dialogue platform of the FOPH](#)

In 2009, the Federal Office of Public Health (FOPH) extended an invitation to initiate a dialogue with representatives of the authorities, consumer organisations, industry and retail. The purpose was to find ways of informing the public about nanotechnology and its applications in a transparent and easy-to-understand fashion.



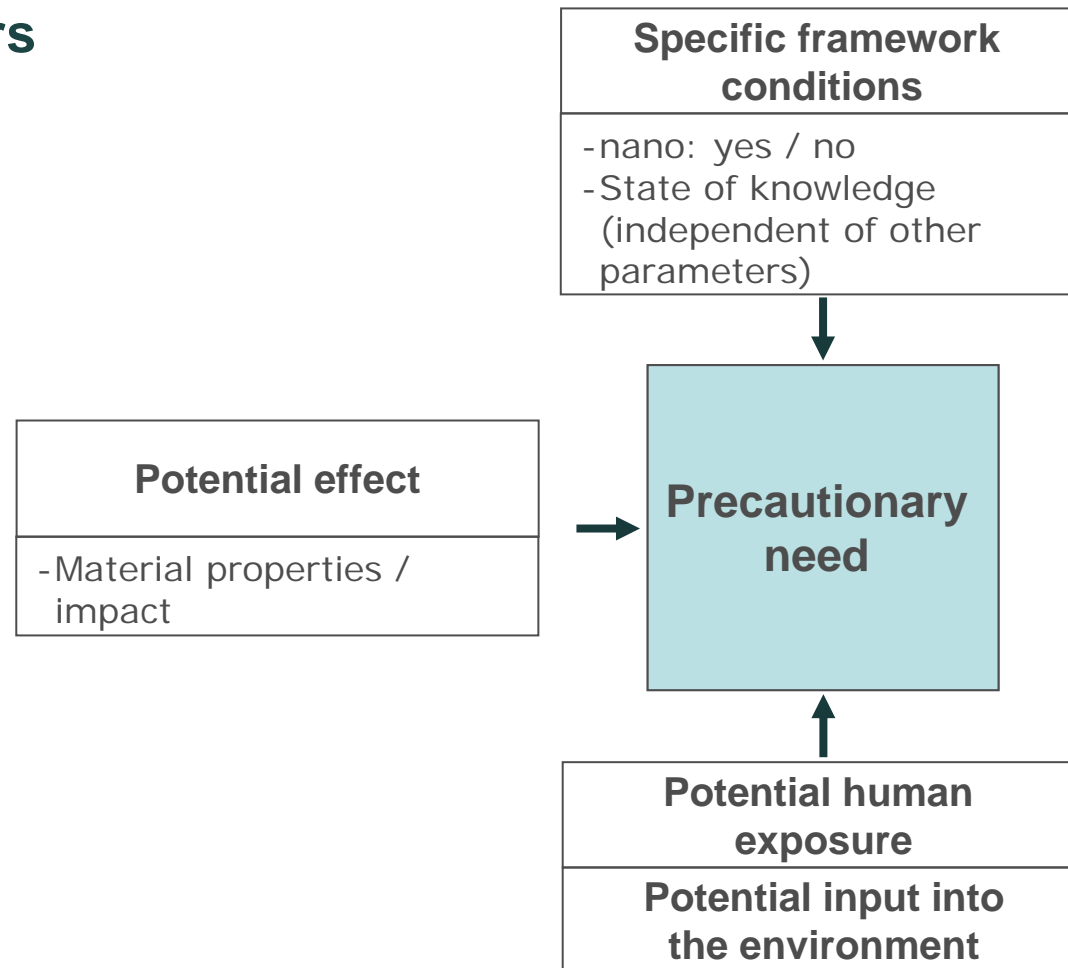
Precautionary Matrix: focus



Adapted from ISO TS 27687



Parameters





Electronic version

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Precautionary matrix

Web application precautionary matrix

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Disposal of industrial nanowaste

Prevention of major accidents

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Web application

Precautionary Matrix for Synthetic Nanomaterials

Complete precautionary matrix

- Use the "More" button if you'd like to be guided through the precautionary matrix step by step. Each form has to be completed in its entirety.
- Use the navigation bar if you'd like to complete the precautionary matrix in random order. The forms do not need to be completed in their entirety, but the precautionary needs cannot be calculated until all the necessary information has been provided.
- **Caution:** All data expires 20 minutes after the last page view. Please save your data when you interrupt work.

Save/load data

On this page you can download the entered information as an XML file to your computer and re-import it at a later time. **The data will not be saved on the federal web server.** You may also reset all data on this page.

Print preview

Use this feature to view the entire precautionary matrix on a single page. If needed, activate "Print background colours and images" in the "Page setup" pop-up window.

[Web application precautionary matrix](#)

Federal Office of Public Health (FOPH)

[Contact](#) | [Legal framework](#)



Boundaries

- The current Precautionary Matrix is focussing on materials or applications containing synthetic nanomaterials
- surface structures and coatings with thicknesses in the range of nanometers are not considered by the Precautionary Matrix
- particles in the nanometer range of size can also be produced by abrasion or combustion, and by the release of fragments from coatings. This topic is dealt with in connection with fine /very fine particulate matter and is not covered by the Precautionary Matrix
- Issues of health and environment which are not nanospecific, e.g. resulting from the toxicity of the chemical composition of a nanomaterial (classical “chemical toxicity”), are not covered by the Precautionary Matrix. These risks can be assessed by conventional standard procedures.



Added value

- Facilitated decision, if a given material or product is nanorelevant or not
- guidelines for the structured approach towards the topic „safe nanoproducts“ in the frame of existing regulation
- revealing of knowledge gaps and focal points for actions and measures
- triggering of measures
- cross-linking along the value chain.



Planned next steps

- Publication of a new and improved version of the Precautionary Matrix and all linked documents until autumn 2013
- Continuous further development of the Precautionary Matrix based on actual progress or latest findings in the field

Contact person for guidance with the application of the Matrix:
Dr. Christoph Studer, BAG
(christoph.studer@bag.admin.ch)



Safety data sheet: Guide for synthetic nanomaterials

- The guide for synthetic nanomaterials supplements the existing general guide for “The safety data sheet in Switzerland”. It is designed to help identify the particularly relevant additional information and to correctly fill in the safety data sheets for nanomaterials.
- The guide explicitly deals with manufactured and hence “synthetic” nanomaterials; naturally occurring nanomaterials are not considered.
- For feedback and further information:

Dr. Kaspar Schmid, SECO Chemicals and Occupational Health, Kaspar.Schmid@seco.admin.ch



Second version of the guidelines

The available second version (April 2012) has improved wording and is based on the nanomaterial definition recommended by the EU commission, which also considers the particle size distribution.

Furthermore this version has taken into consideration the latest standard and threshold values for maximal occupational workplace concentrations - the values have been integrated in the two SDS examples (SUVA standard values 2012).

The two SDS examples have been separated from the main text and the accompanying leaflet summarizes the most important content of the guidelines on three pages.



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Discussion

There is time for table discussions now. Questions and suggestions are highly welcome!

Thank you for your attention!