Webinar Precautionary Matrix for Nanomaterials

Guidelines on the Precautionary Matrix for Synthetic Nanomaterials

Sabine Frey & Christoph Studer
Federal Office of Public Health

calIBRAte, March 8, 2018
Agenda

• Welcome
• Andrea Porcari, introduction to caLIBRAte and the webinar
• Christoph Studer, The Precautionary Matrix
• Sabine Frey, Precautionary Matrix demo, based on a case study
• General discussion
• Concluding remarks

Moderator: Claire Skentelbery
The Precautionary Matrix:

- Is a control banding tool based on a limited number of parameters
- Can be applied early in the safe-by-design process
- Is generally applicable
- Gives an indication of where a need for precautionary measures exist
- Helps to detect knowledge gaps and risk potentials for workers, consumers and the environment

The Precautionary Matrix does not replace risk assessment
Field of application

Value-chain

- Disposal
- Research and Development
- Primary Production
- Further Stages of Processing
- Final Processing
- Transport
- Trade
- Consumption / Use
- caLIBRAte: Webinar PCM, March 8, 2018
Set-up of the Precautionary Matrix:

Context (N,I)
- Nano-relevance; yes / no (N)
- Current state of knowledge (I)

Potential Effects (W)
Reactivity and Stability

Potential for Human Exposure (E)

Potential Emission into the Environment (E)

\[ P = N(W \cdot E + I) \]

\( P \) = Need for precautionary action

Result is a number, the higher the number the higher the need for a closer look
Nano-relevance

Entry according to EU-proposed definition

Material containing primary particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the primary particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm

or (if the number size distribution is unknown)
Material where the specific surface area by volume is greater than 60 m²/cm³

or
Material consists of fullerenes, graphene flakes or single wall nanotubes.

No

Entry according to precautionary approach

Material containing primary particles with one or more external dimensions is in the size range 1 nm - 500 nm

or
Material consists of fullerenes, graphene flakes or single wall nanotubes.

Yes

Not nano-relevant*

No

Does the nanomaterial form agglomerates >500nm?

Yes

Not nano-relevant*

No

Could the agglomerates disintegrate again in the body or environment?

Yes

Nano-relevant*

No

Relevant for human health only („Not nano-relevant“ for the environment):
Do agglomerates between 500nm and 10μm exist and could they be inhaled by employees or consumers?

Yes

Nano-relevant*

No

Not nano-relevant*

*Nano-relevant* means nano-relevant according to the matrix
### Potential effect and exposure of human beings / input into the environment

<table>
<thead>
<tr>
<th>Potential effect (W)</th>
<th>Potential exposure of human beings / input into the environment (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>▪ <strong>Reactivity</strong>: redox activity, catalytic activity, oxidative stress, induction of proinflammatory cytokines</td>
</tr>
<tr>
<td></td>
<td>▪ <strong>Stability</strong> of the nanomaterial in different media (Halflife)</td>
</tr>
<tr>
<td>▪ <strong>Physical Matrix</strong> in which the nanomaterial is embedded</td>
<td></td>
</tr>
<tr>
<td>▪ <strong>Total amount</strong> handled / used by workers or consumers per day</td>
<td></td>
</tr>
<tr>
<td>▪ <strong>Frequency</strong> of potential exposure</td>
<td></td>
</tr>
<tr>
<td>▪ <strong>Emissions</strong> into the environment from production</td>
<td></td>
</tr>
<tr>
<td>▪ <strong>Annual amount</strong> of nanomaterials marketed in consumer products</td>
<td></td>
</tr>
</tbody>
</table>
Examples: reactivities of some nanomaterials

<table>
<thead>
<tr>
<th>Nanomaterial Reactivity (data refer to uncoated and non-functionalised nanomaterials)</th>
<th>Redox activity (pH7) Estimated, based on the standard redox potential or the position of the conduction band(^{19})</th>
<th>ROS-formation behaviour or induction of inflammation reactions</th>
<th>(Photo)catalytic activity (at environmental temperatures)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>low (1)</td>
<td>medium (5)</td>
<td>high (9)</td>
</tr>
<tr>
<td>Ag[0]</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ag(_2)O</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CeO(_2)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CuO</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fe[0]</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FeO</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fe(_3)O(_4)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fe(_2)O(_3)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SiO(_2) (amorph)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TiO(_2) (anatase)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TiO(_2) (rutile)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZnO</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

caLIBRAt: Webinar PCM, March 8, 2018
<table>
<thead>
<tr>
<th>Nanomaterial (uncoated and unfunctionalized)</th>
<th>Redox-activity (Band Gap)</th>
<th>Fotocatalytic activity</th>
<th>Biological oxidative damage, BOD</th>
<th>Induction of IL-8, IL-1β or TNFa</th>
<th>ROS induction</th>
<th>GSH depletion</th>
<th>Protein carbonylation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ag (0)</td>
<td>c (Ø: 35-60 nm)</td>
<td></td>
<td>d, NM300</td>
<td>d, NM300</td>
<td></td>
<td></td>
<td>d, NM300</td>
</tr>
<tr>
<td>CeO₂</td>
<td>a (Ø: 18.3 nm)</td>
<td>c (Ø: 7-2.5 nm)</td>
<td>f, h (Ø: 9.7 nm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co₃O₄</td>
<td>a (Ø: 10.0 nm)</td>
<td>c (Ø: 20 nm)</td>
<td>f (Ø: 18.4 nm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CuO</td>
<td>a (Ø: 12.8 nm)</td>
<td>c (Ø: 18-34 nm)</td>
<td>f (Ø: 23.1 nm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fe₂O₃</td>
<td>a (Ø: 12.3 nm)</td>
<td>c (Ø: 30 nm)</td>
<td>h (Ø: 15 nm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fe₃O₄</td>
<td>a (Ø: 12.0 nm)</td>
<td>c (Ø: 25 nm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mn₂O₃</td>
<td>a (Ø: 51.5 nm)</td>
<td>c (Ø: 45 nm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SiO₂ (amorph)</td>
<td>a (Ø: 13.5 nm)</td>
<td>c (Ø: 15 nm)</td>
<td>h, l (Ø: 14 nm)</td>
<td>i, NM200, NM203 (Ø: ~15 nm)</td>
<td>g, i, NM101</td>
<td>g, NM105</td>
<td>g (Ø: 15 nm)</td>
</tr>
<tr>
<td>TiO₂ (anatase)</td>
<td>a (Ø: 12.4 nm)</td>
<td>b (Ø: 10-100 nm)</td>
<td>h, l, P25 (Ø: 20-80 nm)</td>
<td>i, P25</td>
<td>d, NM101</td>
<td>g, NM105</td>
<td>g (Ø: 21 nm)</td>
</tr>
<tr>
<td>TiO₂ (rutile)</td>
<td>b (Ø: 100 nm)</td>
<td>c (Ø: 5000 nm)</td>
<td>f (Ø: 30 nm)</td>
<td></td>
<td>d, (Ø: 80-400 nm)</td>
<td></td>
<td>d (Ø: 80-400 nm)</td>
</tr>
<tr>
<td>BaSO₄</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>g, NM220 (Ø: 32 nm)</td>
</tr>
<tr>
<td>MWCNT</td>
<td>c (Ø: 8 nm, L: 20 μm)</td>
<td></td>
<td>d, NM400 (Ø: ~14 nm, L: ~850 nm)</td>
<td></td>
<td>d, NM400</td>
<td>g, NM400</td>
<td>g, NM400</td>
</tr>
<tr>
<td>MWCNT</td>
<td>c (Ø: 15 nm, L: 1-40 μm)</td>
<td></td>
<td>d, NM402 (Ø: ~12 nm, L: ~1370 nm)</td>
<td></td>
<td>d, NM402</td>
<td>g, NM402</td>
<td>g, NM402</td>
</tr>
</tbody>
</table>

Reactivities of nanomaterials

Draft revised version (March 2018)
Predictive power of the calculated, acellular and the cellular assays for lung toxicity

<table>
<thead>
<tr>
<th></th>
<th>Correct prediction</th>
<th>False positive prediction</th>
<th>False negative prediction</th>
<th>Evaluated datasets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculated and acellular (in vitro) reactivities ⇒ acute lung toxicity (in vivo)</td>
<td>8</td>
<td>1</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Calculated and acellular (in vitro) reactivities ⇒ Subchronic inhalation toxicity (in vivo)</td>
<td>3</td>
<td>0</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Cellular reactivities (in vitro) ⇒ acute lung toxicity (in vivo)</td>
<td>9</td>
<td>2</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>Cellular reactivities (in vitro) ⇒ Subchronic inhalation toxicity (in vivo)</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Calculated and acellular (in vitro) or Cellular reactivities (in vitro) ⇒ acute lung toxicity (in vivo)</td>
<td>10</td>
<td>2</td>
<td>0</td>
<td>12</td>
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<tr>
<td>Calculated and acellular (in vitro) or Cellular reactivities (in vitro) ⇒ Subchronic inhalation toxicity (in vivo)</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>8</td>
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</tbody>
</table>
## Classification

<table>
<thead>
<tr>
<th>Number of points</th>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 20</td>
<td>A</td>
<td>The nanospecific risks can be classified as low. No further clarification is necessary.</td>
</tr>
<tr>
<td>&gt; 20</td>
<td>B</td>
<td>Possible nanospecific risks cannot be excluded. Further clarification of the risks is needed or measures for risk reduction have to be taken as regards manufacture, use and disposal, with a view to a precautionary approach.</td>
</tr>
</tbody>
</table>
Available documents:

- Guidance on the Precautionary Matrix for Synthetic Nanomaterials
- FAQs and Responses on the Precautionary Matrix for Synthetic Nanomaterials
Checklist for users

1. Draw up an inventory of materials/products/applications
2. Check the nano-relevance of each material
3. Find and separate steps in the value chain to be evaluated
4. Decide for which steps a matrix has to be completed
5. Complete the matrixes as far as possible
6. Obtain lacking information using the relevant questions from the matrix
7. Finish the matrix and localise the relevant precautionary need
8. Clarify any need for action (commence further clarifications, protection measures and measures to provide information)
Recommendation

It is recommended to completed and evaluated the precautionary matrix in two iterative steps:

1. A first rapid evaluation demonstrates knowledge gaps and uncertainties and leads to a preliminary precautionary matrix.

2. An additional data-gathering step and clarifications regarding knowledge gaps will lead to the final evaluation.
Case Study

Scratch-resistant varnish for parquet flooring containing nano SiO$_2$
Collecting information

General information

- Product name: Nano Anti-Scratch
- Product contains amorphous SiO2 (primary particle size 10-20 nm)

- Value-cain processes to be evaluated:
  a) Varnishing the floor with Nano Anti-Scratch
  b) Consumer living in a room with a varnished floor
Information for process a) Varnishing the floor with Nano Anti-Scratch

Informaiton on the product and its application
- Varnish is a aqeous formulation
- Product contains 5% amorphous nano SiO₂
- Required amount of varnish: 5 kg/10 m²
- Worker can treat 50 m²/day

Informaiton on amorphous SiO₂
- Particle size 10-20 nm; no coating, no surface treatment
- Potential effect of amorphous nano SiO₂:
  - Redox-activity: low
  - ROS induction: low
  - Induction of proinflammatory cytokines: medium
  - Stability (halflife in the body): unknown
  
Data from literature
Precautionary Matrix: Web application

Precautionary matrix for synthetic nanomaterials

General information

Precautionary matrix completed by / responsible contact person

The wooden floor company; Contact person: John Rain

Brief description of the considered nanospecific field (type of nanomaterials, which surrounding, in which application)

Varnishing the floor with the product "Nano Anti Scratch" by professional worker

Brief description of the considered (process) step (production, packaging, transport, further stages of processing, disposal, use...), brief description

Size of varnished floor: 50m²; Amount of varnish required: 25 kg; Amount of amorphous SiO₂ nanolarticles (diameter 10-20 nm) in required varnish: 1.25 kg (5%); Wast.: Waste disposed in specialised facilitie
Choose scenario

Scenario: Calculation of the precautionary need...

☑ for employees
☐ for consumers
☑ for a specific disposal step (see footer 35 in the guidelines)

Attention: when inputs are changed, the worksheet "Exposure" will be reset

Are coated / functionalised nanomaterials involved?

☐ if yes, see statements in the guidelines, section 4.5
☑ no

› Insert note

next
Nano-relevance

The precautionary matrix includes two approaches for the clarification of nano-relevance. The first approach is based on the EU proposed definition 2011/696/EU. The second precautionary approach includes primary particles with external dimensions from 1 to 500 nm, as nano-specific effects on biological systems can also be caused by particle sizes of 100-500 nm.

- Entry according to EU-proposed definition (2011/696/EU)
- Entry according to precautionary approach (external dimensions of primary particle from 1 to 500 nm)
Nano-relevance according to the precautionary matrix

N-EU   EU recommendation on the definition of nanomaterial
Material containing primary particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the primary particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm
or (if the number size distribution is unknown)
Material where the specific surface area by volume is greater than 60m²/cm³
or
Material consists of fullerenes, graphene flakes or single wall nanotubes.

☐ true (→ go to N1a)
☐ untrue (→ go to N-EUa)
☐ unknown (→ go to N1)

N-EUa  Do you want to include primary particles from 1 to 500 nm in your evaluation?

☐ no (→ evaluation terminated)
☒ yes (→ go to N1)

Remark: According to the EU-proposed definition, primary particles larger than 100 nm are not nano-relevant.
N1  Order of size of the primary particles in the materials (free, bound, aggregated or agglomerated)

☐ over 500 nm (→ evaluation terminated)

☒ 1-500 nm (→ go to N1a)

Note: primary particles larger than 500nm are not nano-relevant. If applicable, evaluation can be concluded.

N1a  Do the primary particles form agglomerates >500 nm?

☐ no

☐ yes (→ go to N2AV and N2U)

< Insert note

N1a: Agglomeration status unknown. Worst case assumption: No agglomeration
Information on the life cycle

<table>
<thead>
<tr>
<th>I1</th>
<th>Information on the life cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>I2</td>
<td>Is the origin of the (nanoscale) starting materials known?</td>
</tr>
<tr>
<td>I3</td>
<td>Are the subsequent users of the considered nanomaterials known?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I1</th>
<th>yes</th>
<th>partly</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td>I2</td>
<td>yes</td>
<td>partly</td>
<td>no</td>
</tr>
<tr>
<td>I3</td>
<td>yes</td>
<td>partly</td>
<td>no</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>A</th>
<th>V</th>
<th>U</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
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<td>6</td>
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<tr>
<td>3</td>
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<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
I4 How accurately is the material system known, or can disturbing factors (e.g. impurities) be estimated?

- accurately
- not accurately
- unknown

Insert note
## Potential effect

<table>
<thead>
<tr>
<th>W Potential effect</th>
<th>guidelines section 4.5</th>
<th>A</th>
<th>V</th>
<th>U</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>45</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td>W1 Reactivity</td>
<td></td>
<td>5</td>
<td>5</td>
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</tr>
<tr>
<td></td>
<td>Redox activity of the nanomaterial</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>low</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td></td>
<td>medium</td>
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<td></td>
<td>high</td>
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</tr>
<tr>
<td></td>
<td>not known</td>
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<tr>
<td></td>
<td>Catalytic activity of the nanomaterial</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>low</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td></td>
<td>medium</td>
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<td>high</td>
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<tr>
<td></td>
<td>not known</td>
<td></td>
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<tr>
<td>W1</td>
<td>Oxygen radical formation potential of the nanomaterial</td>
<td></td>
<td></td>
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<tr>
<td>----</td>
<td>-------------------------------------------------------</td>
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<tr>
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<td>low</td>
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<td>high</td>
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<tr>
<td></td>
<td>not known</td>
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</tr>
</tbody>
</table>

| 1 | 1 | 1 |

<table>
<thead>
<tr>
<th>W1</th>
<th>Induction potential for inflammatory reactions of the nanomaterial</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>low</td>
</tr>
<tr>
<td></td>
<td>medium</td>
</tr>
<tr>
<td></td>
<td>high</td>
</tr>
<tr>
<td></td>
<td>not known</td>
</tr>
</tbody>
</table>

| 5 | 5 | 5 |
W2 Stability

W2AV Stability (half-life) of the primary particles present in the nanomaterial in the body
- hours
- days-weeks
- months
- not known

W2U Stability (half-life) of the primary particles present in the nanomaterial under environmental conditions
- hours
- days-weeks
- months
- not known

> Insert note

next
Potential exposure

guidelines section 04.06.01

E1 Carrier material

- Air, Aerosols <10 µm
- Air, Aerosols >10 µm
- Liquid media
  - Solid matrix, not stable under relevant process conditions or conditions of use
  - Solid matrix, stable under relevant process conditions or conditions of use, nanomaterial mobile
  - Solid matrix, stable under relevant process conditions or conditions of use, nanomaterial not mobile

> Insert note
### E2 Maximum possible exposure of humans

#### E2.1 Amount of nanomaterials which a worker handles per day

- [ ] up to 1.2 mg
- [ ] 1.2 - 12 mg
- [x] over 12 mg
- [ ] not known

#### E2.2 Amount of nanomaterials with which a worker comes into contact in the "worst case"

- [ ] up to 12 mg
- [ ] 12 - 120 mg
- [x] over 120 mg
- [ ] not known

#### E2.3 Frequency with which a worker handles the nanomaterial

- [x] monthly
- [ ] weekly
- [ ] daily
- [ ] not known

> Insert note
### E3  Maximum possible input into the environment

#### E3.1  Amount of nanomaterials reaching the environment from wastewater, exhaust gases, solid waste per year

- [ ] up to 5 kg
- [ ] 5 - 500 kg
- [x] over 500 kg
- [ ] not known

#### E3.3  Amount of disposed nanomaterials per year

- [ ] up to 5 kg
- [ ] 5 - 500 kg
- [x] over 500 kg
- [ ] not known

**Insert note**

E3.1 All waste is collected at the building site and disposed off in a specialized facility; E3.3: Wast from treated wood during deconstruction
Evaluation precautionary needs

The precautionary matrix calculates a total score for workers, consumers and the environment. A precautionary need is given for **scores over 20** (see statements in the guidelines, section 5.3)

**Please note:** The precautionary matrix does not produce a definitive evaluation in terms of a risk assessment!

**for workers**

| Precautionary need for employees | $V_A$ 47 |
| Precautionary need for employees (Worst Case) | $V_A^{WC}$ 87 |

**for environment**

| Precautionary need environment production | $V_U^P$ 51 |
| Precautionary need environment (disposal step production waste) | $V_U^{PSE}$ 411 |
| Precautionary need environment (disposal step utility product) | $V_U^{GSE}$ 411 |
**Calculated data**

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>W</th>
<th>E</th>
<th>I</th>
</tr>
</thead>
<tbody>
<tr>
<td>$V_A$</td>
<td>46.5</td>
<td>1</td>
<td>45</td>
<td>0.9</td>
</tr>
<tr>
<td>$V_A^{WC}$</td>
<td>87</td>
<td>1</td>
<td>45</td>
<td>1.8</td>
</tr>
<tr>
<td>$V_U^P$</td>
<td>51</td>
<td>1</td>
<td>45</td>
<td>1</td>
</tr>
<tr>
<td>$V_U^{PSE}$</td>
<td>411</td>
<td>1</td>
<td>45</td>
<td>9</td>
</tr>
<tr>
<td>$V_U^{GSE}$</td>
<td>411</td>
<td>1</td>
<td>45</td>
<td>9</td>
</tr>
</tbody>
</table>

"Unknown" fraction

This diagram shows the unknown part of the result (red bar). If the unknown part is consequential, a few clarifications can lead to a significantly more favourable result.

* Further clarification can possibly allow these values to fall into the green zone.
Preliminary conclusion for the process «Varnishing the floor with Nano Anti-Scratch»

There is a precautionary need and therefore measures are necessary

• Unknowns could be responsible for the precautionary need for employees

  Second data gathering round, risk assessment and/or personal protection of employees necessary

• Regarding environmental safety additional data will not reduce the the precautionary needs in all cases

  Collect wast and make sure, that it is disposed off in a safe manner or conduct risk assessment for the environment
W2 Stability

W2AV Stability (half-life) of the primary particles present in the nanomaterial in the body

- hours
- days-weeks
- months
- not known

W2U Stability (half-life) of the primary particles present in the nanomaterial under environmental conditions

- hours
- days-weeks
- months
- not known

> Insert note
### Calculated data

\[ V = N \times (W \times E + I) \]

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>N</th>
<th>W</th>
<th>E</th>
<th>I</th>
</tr>
</thead>
<tbody>
<tr>
<td>(V_A)</td>
<td>28.5</td>
<td>1</td>
<td>25</td>
<td>0.9</td>
<td>6</td>
</tr>
<tr>
<td>(V_A^{wc})</td>
<td>51</td>
<td>1</td>
<td>25</td>
<td>1.8</td>
<td>6</td>
</tr>
<tr>
<td>(V_U^P)</td>
<td>31</td>
<td>1</td>
<td>25</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>(V_U^{PSE})</td>
<td>231</td>
<td>1</td>
<td>25</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>(V_U^{GSE})</td>
<td>231</td>
<td>1</td>
<td>25</td>
<td>9</td>
<td>6</td>
</tr>
</tbody>
</table>

### "Unknown" fraction

This diagram shows the unknown part of the result (red bar). If the unknown part is consequential, a few clarifications can lead to a significantly more favourable result.
Final conclusion for the process «Varnishing the floor with Nano Anti-Scratch»

There is a precautionary need and therefore measures are necessary

• Unknowns are only partly responsible for the precautionary need for employees

  Risk assessment and/or personal protection of employees is necessary

•

• Regarding environmental safety additional data will not reduce the precautionary needs in all cases

  Collect waste and make sure, that it is disposed off in a safe manner or conduct risk assessment for the environment
Information for process b) Consumer living in a room with a varnished floor

Information in relation to consumer exposure

- Varnish forms a solid coating on the floor
- Room size: 50 m²
- Amorphous nano SiO₂ content in the floor coating of the room: 1.25 kg
General information

Precautionary matrix completed by / responsible contact person

The wooden floor company; Contact person: John Rain

Brief description of the considered nanospecific field (type of nanomaterials, which surrounding, in which application)

Consumer living in a room with a varnished (name of product: Nano Anti Scratch) floor

Brief description of the considered (process) step (production, packaging, transport, further stages of processing, disposal, use...), brief description

Varnish forms a solid coating on the floor; Room size: 50m²; Amount of amorphous SiO2 nanolarticles (diameter 10-20 nm) in coating: 1.25 kg
Choose scenario

Scenario: Calculation of the precautionary need...

☐ for employees
☑ for consumers
☐ for a specific disposal step (see footer 35 in the guidelines)

Information: when inputs are changed, the worksheet "Exposure" will be reset.
### Potential exposure

#### guidelines section 04.06.01

<table>
<thead>
<tr>
<th>Carrier material</th>
<th>$E_{1A,V}$</th>
<th>$E_{1U}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air, Aerosols $&lt;$10 μm</td>
<td>0.0001</td>
<td>0.0001</td>
</tr>
<tr>
<td>Air, Aerosols $&gt;$10 μm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liquid media</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid matrix, not stable under relevant process conditions or conditions of use</td>
<td>0.0001</td>
<td>0.0001</td>
</tr>
<tr>
<td>Solid matrix, stable under relevant process conditions or conditions of use, nanomaterial mobile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid matrix, stable under relevant process conditions or conditions of use, nanomaterial not mobile</td>
<td>0.0001</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Insert note
### E2 Maximum possible exposure of humans

#### E2.4 Amount of nanomaterials which a consumer handles daily through the utility product

- up to 1.2 mg
- 1.2 - 12 mg
- **over 12 mg**
- not known

#### E2.5 Frequency with which a consumer uses the utility product

- monthly
- weekly
- **daily**
- not known

> Insert note
### E3 Maximum possible input into the environment

#### E3.2 Amount of nanomaterials in utility products per year

- **up to 5 kg**
- **5 - 500 kg**
- **over 500 kg**
- **not known**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>( U^p )</th>
<th>( U^G )</th>
<th>( U^{G. sp} )</th>
<th>( U^{PSE} )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>up to 5 kg</strong></td>
<td>0</td>
<td>9</td>
<td>0.0009</td>
<td>0</td>
</tr>
<tr>
<td><strong>5 - 500 kg</strong></td>
<td>9</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>over 500 kg</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>not known</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Insert note**

E3.2: It is unknown how waste from treated wood will be disposed of after deconstruction of the floor
Evaluation precautionary needs

The precautionary matrix calculates a total score for workers, consumers and the environment. A precautionary need is given for scores over 20 (see statements in the guidelines, section 5.3).

Please note: The precautionary matrix does not produce a definitive evaluation in terms of a risk assessment!

for consumers

Precautionary need for consumers \( V_y \) 11

for environment

Precautionary need environment (during use with specific waste disposal) \( V_{U^{G,spz}} \) 11

Precautionary need environment (during use without specific waste disposal) \( V_{U^G} \) 416
Final conclusion for the process «Consumer living in a room with a varnished floor»

There is no need for precautionary measures to protect consumers

There is a need for precautionary measures regarding environmental safety (wast disposal)

Additional data will not reduce the precautionary needs in all cases

Collect wast and make sure, that it is disposed off in a safe manner or conduct risk assessment for the environment
Q&A of the participants