GUIDANCE WORKING SAFELY WITH NANOMATERIALS AND NANOPRODUCTS

THE GUIDE FOR EMPLOYERS AND EMPLOYEES

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This guide is based on the latest (scientific) knowledge and views that were available in October 2010. The knowledge on health and safety issues and the appropriate ways to deal with both knowns and unknowns in the field of nanotechnology is rapidly growing. Companies that work in this field are therefore recommended to stay informed about the latest developments. Growing insights may lead to the need to adjust the currently leading ideas about working safely with nanomaterials and –products, including the appropriate measures to reduce exposure. The manufacturer or supplier of the nanomaterial or –product should generally be the one to inform you on these issues.

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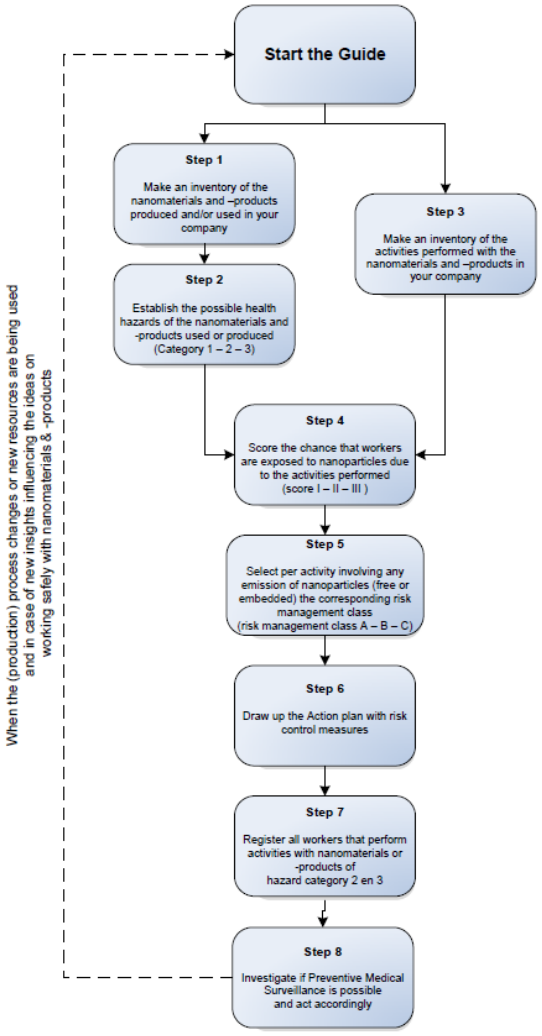
Guidance on working safely with nanomaterials and nanoproducts

Action plan for a safe work practice

This document provides guidance on how to organize a safe workplace when working with nanomaterials and nanoproducts (NMP)[1]. This guidance has been developed by employers and employees with combined forces. This guidance is not all-inclusive but attempts to support employers and employees who work with nanomaterials in their design of suitable control measures to organize a safe workplace according to the current state of knowledge on health and safety issues of nanomaterials. A more general awareness raising on 'nano-risks' is a secondary aim.



This guidance aims to support working safely with engineered nanomaterials and is <u>not</u> developed to support the managing of occupational health risks arising as a consequence of any non intentionally released nanomaterials such as e.g. diesel exhaust or welding fume.

Above all, it is important to emphasize that the existing legislation for working with hazardous substances does apply always. In those cases in which the parent material of the nanomaterial in its bulk-form has been classified as CMR[2] substance, or the nanomaterial itself does show CMR characteristics, the appropriate legislation for working with this type of substance should always be met. The most stringent measures prescribed in those cases should be leading.

After completion of the various steps of the control strategy described here, you, as an employer, have a sound and solid basis for the development of the risk management of NMP as required for working with hazardous substances in national and EU legislation. Communication with employees can proceed i.e. via regular toolbox meetings or work instructions or by developing information brochures or flyers. When (new) NMP are introduced in the company, possibly substituting bulk substances, this is a good moment for instructing employees about good work practices, possible risks and risk management measures they should take.

[1] A nanoproduct is a product to which one or more engineered nanomaterials are added as an ingredient.

[2] CMR = carcinogenic, mutagenic, reproduction toxic

Step 1 Make an inventory of the NMP produced and/or used in your company

To obtain a better view on possible occupational health risks due to the exposure to nanoparticles[3] from NMP one should have more detailed information on a number of material- and product characteristics. These are summarized in Table 1. Each characteristic identified in Table 1 can be found on the material safety data sheet (MSDS) or technical data sheet of the product. When this appears not to be the case, the supplier should be asked for this information.

Table 1. Typical characteristics of NMP that are used or produced by the company

	NMP 1	NMP 2	NMP 3	NMP 4	etc.
Product name	…….	…….	…….	…….	……
Chemical name	…….	…….	…….	…….	……
CAS Registration number	…….	…….	…….	…….	……
Size distribution of the primary particles in the material or product (in nm)	…….	…….	…….	…….	……
Does the material or product involve fibrous particles (yes/no; if yes, specify its length and diameter)	…….	…….	…….	…….	……
Has the nanomaterial (or its mother material) been classified as CMR substance? (Carcinogenic, Mutagenic, Reproduction toxic)**	…….	…….	…….	…….	……
Water solubility (yes/no; the substance is soluble in water when its solubility is higher than 100 mg/l)	…….	…….	…….	…….	……
Density (in kg/dm^3)	…….	…….	…….	…….	……
Physical state of the nanomaterial (liquid or solid)	…….	…….	…….	…….	……

** This information will be used to assess whether or not additional to the control measures described in this guidance document additional measures should be taken to meet the legal requirements for working with CMR substances.

[3] A nanoparticle is a particle with three dimensions in the range of 1 – 100 nm. A fibrous particle does have two dimensions in the nano range of 1 – 100 nm

Step 2 Classify the occupational health hazards of the NMPs

The nanoparticles should be ranked according to their health hazards. In this guidance document three hazard categories, 1, 2, and 3, are identified. The higher the category number, the higher the anticipated health risk. Nanoparticles of category 1 are relatively harmless. These are expected to exhibit "only" the health hazards similar to the chemical mother material. Class 2 and 3 are expected to exhibit also specific nano related health effects. Use Table 2 to determine the category the NMPs used or produced in your company belong to.

Table 2. Classification of NMP used in your company based on their possible occupational health hazards

Hazard category	**Definition of the NMP**	**NMP** 1 = ……..	**NMP** 2 = ……..	**NMP** 3 = ……..	**NMP**4 = ……..	etc.
1	(Water) soluble nanoparticles. Solubility > 100 mg/l. ***Example: lipid-, sucrose- or siloxane particles with a diameter in de range of 1 – 100 nm.***	☐	☐	☐	☐	☐
2	Synthetic, persistent nanomaterials (non-fibrous). ***Example: metals (i.e. Ag, Au, Pb, La), metal oxides (i.e. TiO_2, ZnO, CeO_2, CoO), carbon black, fullerenes, nano-clay, polymers, dendrimers with a diameter between 1 – 100 nm.***	☐	☐	☐	☐	☐
3	Fibrous, nonsoluble nanomaterials for which asbestos-like effects cannot be rules out. ***Example: SWCNT (= Single Wall Carbon Nanotubes) and MWCNT (= Multi Wall Carbon Nanotubes)***	☐	☐	☐	☐	☐

Step 3 Make an inventory of the activities with handling the NMP in your company

Investigate for each NMP in your company during which activities nanoparticles could be released. Assess the whole "life cycle" starting at the moment the materials or products enter the company and ending when those materials or products leave the company again as "ready-for-use product" or waste material. Table 3 lists ten generic activities and identifies its relevance for the life phase of the NMP: the primary production of the nanomaterial (= the nano raw material production), the secondary production of the nanoproduct (e.g. the production of a nano-paint) and the professional use of nanoproducts (e.g. the application of a nano-coating by a painter). Complete this table.

Table 3. Characteristics of activities performed with NMP in your company

	Place of activity in the production chain			**Activity**	**Name NMP:** …….				
	Primary production nano-material	*Secondary production nano-product*	*Professional use nano-product*		*Used amount (in kg, liter)*	*Emission of dust/mist/haze possible (yes/no)*	*Duration of the activity (in minutes)*	*Frequency of the activity (times per day, week or month)*	*Amount of workers exposed (N)*
1		X	X	Reception and storage of nanomaterials/-products	…….	…….	…….	…….	…….
2		X	X	Opening of the packaging	…….	…….	…….	…….	…….
3		X	X	Addition of the nanomaterial	…….	…….	…….	…….	…….
4	X			Production of the nanomaterial	…….	…….	…….	…….	…….
5			X	Working with NMP	…….	…….	…….	…….	…….
6	X	X		Sampling (quality control)	…….	…….	…….	…….	…….
7	X	X		Filling / packaging of end product	…….	…….	…….	…….	…….
8	X	X	X	Cleaning and maintenance	…….	…….	…….	…….	…….
9	X	X		Transfer and transportation	…….	…….	…….	…….	…….
10	X	X	X	Waste treatment and removal of waste	…….	…….	…….	…….	…….
11				Other	…….	…….	…….	…….	…….

Step 4 Classify the possibility of exposure of workers to nanoparticles during the activities with handling of the NMP

The possibility that workers will be exposed to 'free' nanoparticles is determined by the way one works with these NMPs. In this guidance three exposure categories are used:

I. Emission of nanoparticles (1 - 100 nm) is not possible due to use of a 100% closed system. I.e. using glove-boxes or working with a fully contained production process.

II. Emission of larger particles (100 nm - 100 µm) composed of nanoparticles embedded in a solid or liquid matrix is possible. i.e. during weighing or adding nanomaterials or polishing, spraying or sanding nanoproducts.

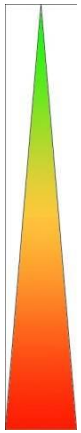
III. Emission of primary nanoparticles (1 - 100 nm) during the activities is possible. For example during the production of nanoparticles or during research activities.

Based on the information tabulated in Step 3, to each activity with each NMP an exposure class (I to III) can be assigned. For this, use Table 4.

Table 4. Possibility of exposure to nanoparticles during activities with NMP in your company

Name nanomaterial/nanoproduct : …….

Exposure-category	Description	Activity 1 = ……..	Activity 2 =……..	Activity 3 = ……..	Activity 4 = ……..	Activity 5 = ……..	Activity 6 =…….
I	No emission of free nanoparticles due to working in full containment.	☐	☐	☐	☐	☐	☐
II	Emission of nanoparticles <u>embedded</u> in a matrix is possible	☐	☐	☐	☐	☐	☐
III	Emission of free nanoparticles is possible	☐	☐	☐	☐	☐	☐

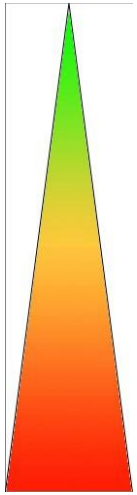


Explanation: For each NMP, this Table should be completed by scoring the exposure categories that apply to the different activities performed with that material or product

Step 5 Select the control approach band per activity

The control level follows the same format as the internationally used Control Banding. To date the health risk of working with NMP can only be assessed qualitatively. Consequently, existing knowledge allows only for prioritizing provisional risk management measures. A distinction has been made for three different control levels A, B and C as shown in table 5. For each level a control approach is recommended

Table 5. Three risk management classes with the risk management strategy advised by the Dutch Social Partners

Control level	*Risk level*		*Priority to take control measures*	*Recommended approach*
	Description	*Colour*		
A	Low		Lowest	**Use the commonly used measures to control the exposure risks at the workplace that comply with legislation.** This implies: apply sufficient (room) ventilation, if needed local exhaust ventilation and/or containment of the emission source and use appropriate personal protective equipment.
B	Uncertain		Medium	**Investigate extra measures that can reasonably be applied.** According to the Occupational Hygienic Strategy, the technical and organizational control measures are evaluated on their economical feasibility. Control measures will be based on this evaluation.
C	High		Highest	**Apply the precautionary principle.** The Occupational Hygienic Strategy will be strictly applied and all protective measures that are both technically and organizationally feasible will be implemented.

The control level is selected, based on the decision matrix as shown in Table 6. The control level is obtained by combining the health hazard category established in Table 2 with the category for the risk of exposure as established in Table 4.

Table 6. Decision matrix to determine the control level for activities with NMP.

Possibility of exposure to nanaoparticles during a certain activity with NMP	Description of the hazard category for NMP		
	Hazard category 1: (water) soluble nanoparticles	***Hazard category 2:*** Synthetic, persistent nanomaterials (non-fibrous)	***Hazard category 3:*** Fibrous, non soluble nanomaterials for which asbestos like properties can not be ruled out
Exposure category I: Emission of free nanoparticles minimized due to working in full containment	**A**	**A**	**B**
Exposure category II: Emission of nanoparticles (1-100 nm) embedded in a larger solid or liquid matrix (100 nm - 100 µm) is possible	**A**	**B**	**C**
Exposure category III: Emission of primary nanoparticles (1-100 nm) is possible	**A**	**C**	**C**

This assessment should be carried out for each NMP. Write down the control level of all NMP per activity in Table 7.

Table 7. Control level for all activities with NMPs.

No.	NMP	Activity	Control level		
			A	B	C
1	……	……	☐	☐	☐
2	……	……	☐	☐	☐
3	……	……	☐	☐	☐
4	……	……	☐	☐	☐
5	……	……	☐	☐	☐
6	……	……	☐	☐	☐
7	……	……	☐	☐	☐
8	*etc.*				

Step 6 Selecting and implementing the appropriate control measures

The action plan is composed of all control measures that should be introduced to comply with safely working with NMP. The workers (-representatives) involved, the safety representative, the occupational health and safety expert and the company management together decide which concrete control measures fit best for each specific situation. The tiered Occupational Hygienic Strategy will be used to select the measures. This implies the hierarchic control measures: source reduction first, personal protection measures last (see also Table 9).

Table 8. Advice for control measures for the different control levels

Control level	Advised control measures
A	Apply sufficient (room) ventilation, if needed local exhaust ventilation and/or containment of the emission source and use appropriate personal protective equipment.
B	According to the hierarchic Occupational Hygienic Strategy, the technical and organizational feasible protective measures are evaluated on their economical feasibility. Control measures will be based on this evaluation
C	The hierarchic Occupational Hygienic Strategy will be strictly applied and all protective measures that are both technically and organizationally feasible will be implemented.

Table 9. The tiered Occupational Hygienic Strategy

1. Source reduction:
   At all times, employers should prevent risks to occur by removing the source of emerging problem.. For example, by substitution of a hazardous substance by a less hazardous alternative or by source reduction by enclosing the system at hand.
2. Technical measures:
   When source reduction measures are not possible, the employer should take collective measures to reduce the apparent risks. For example, by physically shielding the source or installing a ventilation system.
3. Organizational measures:
   When technical measures cannot, or no further be applied, the employer should take control measures on the level of the individual worker. For example, by implementing job rotation, shifts that aim to spread exposure over more workers (and as such reducing the individual exposure level) or by reducing the number of workers that are being exposed.
4. Personal protective equipment:
   When nothing else is possible, the employer can prescribe the use of personal protective equipment to mitigate the risks. In principle these measures are intended as provisional measures only, until the work situation has been improved in such a way that personal protective equipment are no longer needed.

When selecting appropriate control measures a creative ‘brainstorm’ meeting with all stakeholders in the company is important. In order to assist this process an extensive, but not all-inclusive, list of possible control measures is presented in table 11. The measures listed in this table are ranked according to the hierarchic structure of the Occupational Hygienic Strategy and can be useful to provide a starting point for the formation of idea’s for actions during i.e. brainstorm sessions. The Action plan is established in mutual agreement with the involved actors in the company. The responsible health and safety specialist or the person with similar responsibility in the company drafts the final plan, including a concrete working strategy. The format of Table 10 can be used. If needed, one can additionally chose to consult an (external) expert in the exercise of drafting the Action plan. The final Nano Action Plan will become part of the company’s Risk Inventory and Risk Evaluation. Both the company Management and the Works Council or worker-representative will have to agree with this Nano Action Plan.

Table 10. Action plan, for working safely with NMP

No.	NMP	Activity	Control level (A, B or C)	Proposed control measures	Officer responsible for the implementation	Planned date for the measure being in operation
1.	……..	……	……..	……..	……	….-….-…..
2.	……..	……	……..	……..	……	….-….-…..
3.	……..	……	……..	……..	……	….-….-…..
4.	……..	……	……..	……..	……	….-….-…..
5.	……..	……	……..	……..	……	….-….-…..
6.	……..	……	……..	……..	……	….-….-…..
7.	……..	……	……..	……..	……	….-….-…..
8.	……..	……	……..	……..	……	….-….-…..
Etc.	……..	……	……..	……..	……	….-….-…..

Table 11. Suggestions for risk management measures to improve the safety of working with NMP

Source reduction measures:

- Check if the NMP can be replaced by a non-NMP or by one that is classified in a lower hazard category;
- Powdery or gaseous NMP should be handled in an enclosed system as much as possible;
- NMP should be transported in a closed packaging;
- Use not more than the material you need;
- Try to use ready-for-use materials/-products to avoid further preparation prior to use at the work place;
- Preferably use nanoparticles in a matrix (i.e. dispersion, suspension, paste, palletized or encapsulated);
- Choose those work methods that generate as little aerosols as possible: i.e. cutting instead of sawing and brushing/rolling instead of spraying.

Technical measures:

- Nanoparticles disperse like a gas. Where possible, try to work in containment;
- If possible, use a fume hood or glove-box to prevent dispersion of aerosols at the workplace;
- Use local exhaust ventilation. The efficiency of the equipment is optimum when the distance to the source is smaller than the diameter of the vent hole;
- Prevent recirculation of air that might be polluted with NMP and make sure that the exhaust air is not circulated into another room;
- Equip the ventilation system with HEPA-filters to filter-out the nanoparticles;
- Nanoparticles can escape through leaks in the ventilation system. Repair leaks and maladjusted joints immediately;
- In the case of a construction site: make optimum use of natural ventilation by opening doors and windows and minimize any shielding of the work place, etc.;
- In case of working in open air: position nanoparticle generating activities (including diesel engines) downwind. The wind will mitigate the concentration of nanoparticles in the air;
- Prevent unintentional dispersion of nanoparticles after use by fixing them in a resin, liquid, etc. Dispose nanoparticles as Chemical Waste;
- Regularly clean the workplace where NMP are handled. Always use wet-cleaning methods or an industrial vacuum cleaner equipped with HEPA-filter.

Organizational measures

- Appoint an employee within the company to specialize in risks of nanomaterials and train this person accordingly. This person will function as contact point for colleagues within the company.
- Consult your supplier about the possibility of custom-made packaging to minimize exposure (i.e. a water soluble packaging that makes unwrapping no longer necessary);
- Ask your supplier to add a warning sign to the outside of the package like: to be opened only by the recipient/user in a controlled environment;
- Limit the number of different handlings per material/product (weighing, pouring, mixing, etc.);
- Physically shield those work places where one works with NMP;
- Limit access to places where NMP are used;
- Use disposable instrumentation and dispose of them as chemical waste. Also production waste and leftovers should be disposed of as chemical waste. A best practice would be to fix these product waste and leftovers in i.e. a resin or liquid prior to disposal.
- Provide workers with adequate instruction and information on working safely with NMP. These should be focussed on:
  - the possible risks of their work activities with NMP;
  - how to recognize these materials/products;
  - safe use, storage and waste treatment;
  - (in house) occupational exposure limits for nanomaterials (if available);
  - the correct use, service and maintenance of personal protective equipment;
  - the correct use, service and maintenance of the technical safety measures;
  - what to do in case of spills or calamities;
- Take care of adequate periodic service and maintenance of the exhaust ventilation system.

Personal protective measures

- Provide workers with transparent and tangible user instructions on safe and proper use of the personal protective equipment prescribed.
- Use disposable gloves (preferably non-woven). According to the current knowledge, appropriate materials are i.e. nitril, latex and neoprene.
- Use safety goggles during activities where dispersion of nanoparticles is possible;
- Use protective clothing, preferably non-woven i.e. made of Tyvek;
- Use at least FFP3-respiratory protection (with a NPF of 30 or higher).

Step 7 Registration: Keeping track of workers possibly exposed

Because of the current level of uncertainty with respect to the occupational health hazards of nanomaterials, the Social Partners in the Social and Economical Council in the Netherlands (the SER[4]) advised to keep record of all workers that might be exposed to nanoparticles during their work. This registration should help any early stage identifying of health effects occurring among specific groups of workers and should allow to act quickly when new information on health hazards of specific substances becomes available. The Social Partners advice to only keep record of those workers that might be exposed to NMP that are classified in Hazard category 2 or 3 in *Step 2* of this Guidance. Table 12 presents a possible format for registration.

Table 12. Example of a possible format to keep track of workers possibly exposed to NMP in Hazard category 2 or 3.

Date or period of work activity	Name Employee	Name of NMP	Characterisation of the activity	Duration of the activity
Date/time a	Employee A	Chemical name or product name	- Location - Work place - Process - Used amount	Total time Time per activity
Date/time b	Employee A			
Date/time c	Employee B			
Date/time d	Employee C			

[4] Social and Economic Council Advisory Report. Nanoparticles in the Workplace: health and Safety Precautions. Publication number 1, March 2009. ISBN 90-6587-984-0/ CIP

Step 8 Investigate if Preventive Medical Surveillance (PMS) is possible

At the moment, no medical tests have been established to investigate any possible adverse effects of exposure to nanoparticles. Only non-specific methods are available such as ECG, Röntgen images or lung function tests.

Based on the advice by NIOSH[5], companies that do intent to perform PMS to monitor any health effect as a consequence of exposure to nanoparticles are being advised to use the usual biomonitoring programs for that same chemical substance in its micro/macro form (if present).

[5] National Institute for Occupational Safety and Health (2009) Current Intelligence Bulletin 60. Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles. Publication No. 2009–116

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