

CEPE-Guidance for the Handling of engineered Nano-Objects in the Workplace

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Table of contents:

| 1. Introduction | 1 |
|---|----------------------------|
| 1.1. Nanotechnology | 4 |
| 2. Occupational Health and Safety | 7 |
| 2.1.Handling and use of nano-objects at the workplace Step 1) Make an inventory of the nano-objects used in your company and characterize the nano-objects Step 2) Classify the occupational health hazards of nano-objects | 9 1 1 1 1 3 |
| Step 8) Monitoring: Keeping track of workers possibly exposed16 Step 9) Investigate if Preventive Medical Surveillance is possible16 | |
| 2.2 Additional Information16 | 3 |
| 3. Conclusions and Outlook17 | 7 |
| 4. Annex – Important Definitions18 | 3 |
| 5. Sources, Studies and Bibliography20 |) |
| 6. List of tables | 1 |

This document provides guidance on how to organize a safe workplace when manufacturing paints, coatings, artist colours and printing inks containing nanomaterials.

The guidance has been developed by the Nanotechnology Working Group of CEPE, the European association for the paint, artist colours and printing ink industry.

A large part of this guidance was taken from the "Guidance working safely with nanomaterials and nanoproducts", as written in 2011 by IVAM UvA BV and Industox Consult, commissioned and published by FNV, CNV and VNO/NCW¹.

More info on the topics exposure to nano, fire and explosions, hazard banding, control measures and personal protective equipment and waste disposal can be found in the UK guidance document "Working Safely with Nanomaterials in Research & Development"².

This document is not all-inclusive but attempts to advise employers on how to protect their employees who work with nanomaterials. It is not developed to support the managing of occupational health risks arising as a consequence of any non-intentionally released nanomaterials (like diesel exhaust or welding fume), or cover materials which have been used safely for decades such as pigments or resins and are only now considered as nanomaterials.

The guidance does not cover the environmental issues relating to nanomaterials.

After completion of the various steps of the control strategy described here, an employer in the paint and printing ink industry should have a sound and solid basis for the risk management of nanomaterials.

Above all, it is important to emphasize that the existing legislation for working with hazardous substances always applies.

¹Guidance working safely with nanomaterials and nanoproducts, the guide for employers and employees, made by the Dutch organizations for employers and employees VNO-NCW, FNV and CNV - version 1.0 may 2011.

²Working Safely with Nanomaterials in Research & Development (by the UK NanoSafety Partnership Group).

1. Introduction

1.1. Nanotechnology

Nanotechnology is a key technology for the future. This technology relies on physical, chemical or biological effects of particles or material structures in a size range of less than 100 nanometres.

Particles in this size range have existed long before industrialization. Nature produces immense amounts of nanoparticles through the weathering of stones and rocks, in forest fires or on sea shores. By contrast, the technical production of nanoparticles and nanostructures for the purpose of achieving novel properties has started only recently.

Substances with nanoscale particles are nothing new to the paint and printing ink industry too: 2000 years ago the Roman architect Marcus Vitruvius Pollio used synthetically manufactured soot for wallpaints. As we know today, that soot came in the form of nanoparticles.

1.2. Definitions

For the term nanomaterial, various definitions exist:

- The EU Commission definition
- The OECD working definition
- The ISO definition.

We think the most appropriate is the ISO definition. All mentioned definitions are in the annex "Important definitions" of this guidance.

The EU Commission recommended a definition³ with a very broad approach. The recommendation says that 'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.

³EU Commission Recommendation http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF.

Relevant standardized definitions are mentioned in the international standard ISO/TS 27687:2008 ⁴ "Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate".

According to this standard, nano-objects are materials smaller than 100 nanometres in at least one dimension.

Nano-objects are subdivided into:

- Nanoplates with one dimension in the nanoscale.
- Nanofibres with two dimensions in the nanoscale.
- Nanoparticles with three dimensions in the nanoscale.

Nano-objects tend to cluster and form larger entities called agglomerates or aggregates. Such "nanostructured" entities are also nanomaterials.

When examining potential risks of "nanomaterials" to health and the environment, a clear distinction needs to be made between:

- Materials, which contain nano objects according to the above definition, and
- Paints, coatings and printing inks containing nanoscale structures but without discrete nano-objects in their films or on their surfaces.

The European standardisation committee CEN/TC 352⁵ WG2 aims at developing standards for the characterisation of nanomaterials in the manufactured form and for a voluntary labelling of nanomaterials in products.

1.3. Nano-objects in the coatings, artists colours and printing ink industry

When following the OECD working definition ^{6 (OECD)}, the number of types of nano-objects used in the paint, coating and ink industry is low. It is true that conventional pigments and extenders may be covered by definitions of nano-objects, due to their particle size distribution. However, these materials have been used safely by our industry for decades and their hazard properties are well-known.

http://www.cen.eu/cen/Sectors/Sectors/Nanotechnologies/Pages/default.aspx .

⁴ ISO/TS 27687:2008 "Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate.

⁵CEN TC 352

⁶OECD Working Party on Nanomaterials http://www.oecd.org/document/36/0,3343,en_2649_34269_38829732_1_1_1_1_1,00.html .

See the following examples of nano-objects used in the coatings industry:

- Nano titanium dioxide
- Nano silicon dioxide
- Nano carbon black
- Nano iron oxide
- Nano zinc oxide
- Nano silver

The anatase form of titanium dioxide has photocatalytic properties. For this reason, titanium dioxide in nanoscale form is found in certain wall paints for removing organic pollutants from ambient air. Nanostructured silicon dioxide mainly serves as a rheological additive; it is also used in self-cleaning wall paints. UV protection in transparent coatings is the most important application for iron oxide and nanoscale zinc oxide. Nano-soot protects against electromagnetic radiation. Silver in nanoform is a constituent of wall paints for hospitals and food processing operations, in order to prevent attack by bacteria and other micro-organisms.

Nanotechnology is of major significance in the development of new paints, inks and coatings. Over the next 30 years, the number of improvements to conventional paint products and new functions of paints is expected to increase very rapidly. For the next 10 years, it can be assumed that roughly 20 percent of the paint industry's sales will come from nanotechnology applications in the form of so-called "smart coatings".

Important properties have been achieved, for example, with the following products (nano-paints):

- Easy-to-clean paints
- Effect paints
- Antibacterial paints
- Scratch-resistant paints
- Photocatalytic paints
- Paints with UV protection
- Wall paints as screens against high-frequency electromagnetic radiation

Furthermore, the paint industry is actively engaged in research in the following fields:

- Electro-conductive paints
- Self-healing paints
- Nano-primers for anti-corrosive paints
- Heat-insulating paints

All of the above fields rely on the practical application of nanotechnology.

Nanomaterials used for these properties are embedded in a matrix, and recent studies demonstrated that they are not released from the dried coating, even under high stress conditions ^{7,8,9,10}.

2. Occupational Health and Safety

When nano-objects – and essentially nanoparticles - pose any risk to human health, such risk might occur through inhalation of these substances.

By contrast, the uptake of nanomaterials through the skin is of no practical importance. Toxicological studies show that nanoparticles cannot penetrate healthy human skin and thus do not enter the human body via this route¹¹. The risk of ingestion is negligible in intended use: in laboratories, technical facilities and production plants, eating or drinking should always be prohibited to comply with occupational health and safety rules.

For member companies of the paint and printing ink industry, the focus is on benefits for the respective product and for the substrate to be coated, whilst minimizing potential impacts on workers and environment. Where product benefits can be influenced by a nanoscale particle size, nano-objects are used in a targeted manner. Information about the technical characteristics and details about toxicological and eco-toxicological properties are or will be available in extended Safety Data Sheets (SDS) from raw materials manufacturers (some may not be received until after 2018). In SDSs, substance manufacturers need to describe exposure scenarios and recommend protective measures.

The paint, artist colours and printing ink industry itself does not manufacture any nanoobjects. Consequently, occupational health and safety in this industry starts with the **selection of nano-objects which are added,** based on available information.

Using such information, **risk assessments** should be made for the handling of input materials – irrespective of whether these are dangerous substances, and/or nanomaterials or other raw materials.

⁷Vorbau M, Hillemann L, Stintz M. (2009) Method for the characterization of the abrasion induced nanoparticles release into air from surface coatings. J Aerosol Sci; 40(3): 209–217.

⁸Koponen IK, Jensen KA, Schneider T. (2009) Sanding dust from nanoparticle-containing paints: physical characterisation. J Phys: ConfSer; 151 (012048).

⁹Koponen IK, Jensen KA, Schneider T. (2010) Comparison of dust released from sanding conventional and nanoparticle-doped wall and wood coatings. J Expo SciEnvEpid; 1-10.

¹⁰Göhler D, Stintz M, Vorbau M, Hillemann L. (2010) Characterization of nanoparticle release from surface coatings by the simulation of a sanding process. Ann OccupHyg; 54(6): 615-624.

¹¹Nanoderm Final report: http://www.uni-leipzig.de/~nanoderm/Downloads/Nanoderm Final Report.pdf.

CEPE-Guidance for the Handling of Nano-Objects at the Workplace

Risk assessments should comprise the following fields:

- Reception and warehousing of raw materials with nano-objects
- Laboratory
- Application/ Technical testing of product
- Production
- Filling*
- Finished goods storage*
- Distribution*

The work area and all equipment should be thoroughly cleaned after use or following a spillage by wet-wipe cleaning.

Do not brush.

Do not use compressed air for cleaning.

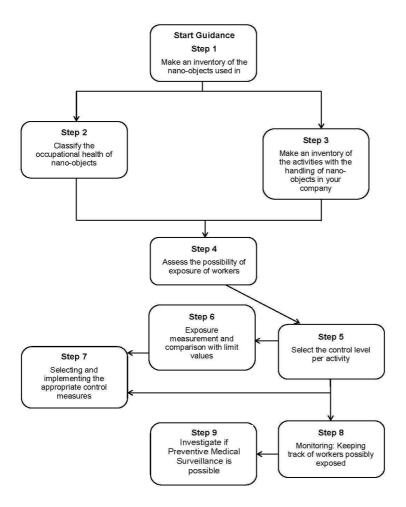
Do not use a standard vacuum cleaner.

Furthermore, sampling in the various steps of manufacture, cleaning of production plants, and maintenance of technical facilities and installations need to be taken into account.

*For these 3 steps the potential risk is negligible.

2.1. Handling and use of nano-objects at the workplace

Action plan for safe handling and use



Step 1) Make an inventory of the nano-objects used in your company and characterize the nano-objects

To obtain a better view on possible occupational health risks due to the exposure to nano-objects, one should have more detailed information on a number of substance and mixture characteristics which can be found in the SDS.

- Product name
- Chemical name
- CAS number
- Size distribution of primary particles

CEPE-Guidance for the Handling of Nano-Objects at the Workplace

- > Are there fibrous particles?
- ➤ Are there hazardous substances?(e.g. CMR)
- Water solubility
- Density
- Physical state of nanomaterial

Characterizing Nano-objects

To obtain a better understanding of the possible occupational health risks from exposure to nano-object compile detailed information as set out in Table 1. Sometimes more than one nano-object is contained in a nanoproduct. For every nanoproduct table 1 should be filled in separately.

The information needed to complete the Table should be available from the safety data sheet (SDS) for the chemical or technical data of the product. When this appears not to be the case, the supplier should be asked for this information.

Table1: Typical characteristics of nano-objects used or produced

| Table 1: Typical characteristics of nano-objects used or p | Nanoproductname: | | | | |
|---|------------------|------|------|------|--|
| INM= Manufactured Nano Materials | | | | | |
| | MNM1 | MNM2 | MNM3 | etc. | |
| Name(s) of Nano objects present in the material or nanoproduct | | | | | |
| Chemical name(s) of Nano objects present in the material or nanoproduct | | | | | |
| CAS Registration number(s) | | | | | |
| Size distribution of the Nano objects in the material or nanoproduct (nm) | | | | | |
| Distribution of the Nano objects in the nanoproduct (volume % and/or number %) | | | | | |
| Does the nanoproduct contain fibrous Nano objects(yes/no; if yes, specify its length and diameter) | | | | | |
| Have any of the Nano objects (or their parent material) been classified as hazardous substance? (Carcinogenic, Mutagenic, toxic to Reproduction) | | | | | |
| Is the solubility in water of all of the Nano objects greater than 100 mg/l (yes/no) | | | | | |
| Are any of the Nano objects bio persistent(yes/no) | | | | | |
| Density of the Nano objects (in kg/dm ³) | | | | | |
| Physical state of the Nano objects in the nanoproduct (liquid, solid [free particles, agglomerates, aggregates, in suspension, in solid matrix, large bodies etc.]) | | | | | |

Step 2) Classify the occupational health hazards of nano-objects

The nano-objects should be ranked according to their health hazards, which are shape related. In this guidance document three hazard categories, 1, 2, and 3, are identified according to Control Banding¹².

Hazard category 1: (water) soluble nanoparticles

Hazard category 2: Synthetic, nanomaterials (non-fibrous)

Hazard category 3: Fibrous, non-soluble nanomaterials for which asbestos-like

properties cannot be ruled out.

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 bulk material. Class 2 and 3 may also exhibit specific nano-related health effects.

Step 3) Make an inventory of the activities with the handling of nano-objects in your company

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 finished product or waste material.

Step 4) Assess the possibility of exposure of workers

Exposure Category 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.

Exposure Category 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.

Exposure Category III. Emission of primary nanoparticles (1 - 100 nm) during the activities is possible.

Step 5) Select the control level per activity

The control level follows the same format as the internationally used Control Banding. To date, the health risk of working with nano-objects can only be assessed qualitatively. Consequently, existing knowledge allows only for prioritizing provisional risk management measures.

¹²Control banding http://ioha.net/controlbanding.html.

Table 2:Description of the hazard category for nano-objects

| | Hazard category 1: (water) | Hazard category 2: Synthetic, persistent nano- objects (non-fibrous) | Hazard category 3: Fibrous, non-soluble nano-objects for which asbestos-like properties cannot be ruled out |
|--|----------------------------------|--|---|
| Exposure category I: Emission of free nano- objects minimized due to working in full containment | A | Α | В |
| Exposure category II: Emission of nano-objects embedded in a larger solid or liquid matrix (100 nm - 100 µm) is possible | A | В | С |
| Exposure category III: Emission of primary nano-objectsis possible | A | С | С |

Control Levels

Control Level A:

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 of appropriate 13 personal protective equipment.

Control Level B:

Medium

Investigate extra measures that can reasonably be applied.

Using the proposed Occupational Hygiene Strategy (see Step 6), the technical and organizational control measures should be evaluated on their economical feasibility. Control measures will be based on this evaluation.

¹³PPE:Personal protective equipment (PPE) refers to protective clothing, helmets, goggles, or other garment or equipment designed to protect the wearer's body from injury by physical hazards, electrical hazards, heat, chemicals, biohazards, particulate matter, and infection, for job-related occupational safety and health purposes: 89/656/EWG, 89/686/EWG.

Control Level C:

Highest

Apply the precautionary principle.

The Occupational Hygiene Strategy should be strictly applied and all protective measures that are both technically and organizationally feasible implemented. As this category covers fibrous materials, which could have long-term effects, special precautions will be needed to avoid exposure.

Step 6) Exposure measurement and comparison with limit values

If one of the following situations applies, you may decide to omit Step 7, and move directly to Step 8:

- The manufacturer or supplier of your nano-objects or products containing nanoobjects provides you with a validated exposure scenario; or
- Good practice guidance on the use of your MNMs (manufactured nanomaterials) or nanoproduct is available, showing that the exposure to MNMs during the intended use remains below the proposed OELs (occupational exposure limits) or
- Where you can demonstrate that appropriate exposure control can be assured by some other means.

For activities at the control level A and B (see Step 5) you are advised to measure the actual concentration of nano-objects in the breathing zone of exposed workers. Concentrations can be compared with OELs or DNELs (derived no-effect levels) as allocated by industries or research institutes.

Proposals for OELs/DNELs specifically for nano-objects are set out in Table 3.

Table 3: Proposals for OELs and DNELs for specific nanoparticles

| Substance | | OELorREL μg/m ³ | DNEL μg/m ³ | Reference |
|---------------------------|--------------------|-------------------------------|---------------------------|----------------|
| MWCNT (Baytubes)* | 8-hrTWA** | 50 | | Pauluhn, 2009 |
| MWCNT (Nanocyl) | 8-hrTWA | 2.5 | | Nanocyl 2009 |
| CNT (SWCNTand MWCNT) * | 8-hrTWA | 7 | | NIOSH 2010 |
| Fullerenes | Chronic inhalation | | 270 | Stoneetal 2009 |
| Ag (18-19nm) | DNEL | | 98 | Stoneetal 2009 |
| TiO2 (10 -100nm) (REL) ** | 10hr/day,40hr/week | 300 | | NIOSH 2011 |

^{*}CNT=Carbon Nanotube: SWCNT=single-wall CNT: MWCNT=multi-wall CNT

^{**} REL= Recommended exposure limit; TWA=Time-weighted average

Step 7) Selecting and implementing the appropriate control measures

The action plan is composed of all control measures that should be introduced to work safely with nano-objects. 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 Hygiene Strategy ¹⁴ should be used to select the measures. This implies the hierarchic control measures: source reduction first, personal protection measures last.

Further protection measures are usually not nano-specific and thus need to be identified in accordance with relevant general rules of occupational health and safety.

All protection measures taken in occupational health and safety need to be documented.

Occupational Hygiene Strategy

1. Source reduction: At all times, employers should prevent risks by removing the source of the emerging problem. For example, by substitution of a hazardous substance by a less hazardous alternative. Another example is source reduction by enclosing the system at hand.

Example

In order to prevent any potential risk to human health through inhalation of nanoobjects, supplies in dispersed – i.e. liquid or pasty – form should be preferred in the selection of nanoscale raw materials whenever possible. For this reason, manufacturers of mixtures need to find out from their suppliers whether raw materials can be supplied in non-dusting form prior to delivery.

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.

Example

When using nanoparticles in production, all necessary steps must be taken to minimize exposure of workers and emissions into the environment. For this reason, wherever feasible, production should take place in closed systems. For practical reasons, this is currently usually not possible throughout the entire process chain in the paint and printing ink industry. Therefore, reliable capture of dusts and aerosols – through local exhaust ventilation (LEV) – needs to be ensured wherever nanoparticles can be released. Additionally, well-performing technical ventilation systems¹⁵ must be in place.

¹⁵CEN TC 352 http://www.cen.eu/cen/Sectors/Sectors/Nanotechnologies/Pages/default.aspx .

¹⁴Occupational Hygiene Strategy: http://ioha.net/index.html.

Furthermore, LEV is necessary when filling and refilling, in order to prevent exposure in the event of dust formation.

3. Organizational measures: When technical measures cannot, or can no further be applied, the employer should apply control measures at 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); special training; or by reducing the number of workers that are being exposed.

Example

Where it cannot be reliably stated that exposure is only negligible, concentrations of nanoparticles at the workplace must be measured and documented regularly for control purposes. This applies, according to study results of the Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) and industry, irrespective of the fact that no risk to workers is likely in the production and spray application of paints containing nanoparticles.

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 is no longer needed.

Example

Where there is no alternative to deliveries in dusting form, suitable protective measures are to be taken. Intact packaging is essential for deliveries of goods in sacks. Dusty nano-objects released from packaging need to be damped by liquid (water), cleaned up and adequately disposed whilst ensuring respiratory protective equipment is worn.

Since most nanoparticles tend to agglomerate or aggregate, dusts which might form in the handling of such materials are usually composed of particles larger than 100 nanometres. Such agglomerations of nanoparticles are safely retained by high-quality respiratory protection dust masks¹⁶, the general standard in the paint and printing ink industry.

Commercial grade masks also provide respiratory protection against nano-objects with a low propensity to form agglomerates and aggregates. Where there are no data on rates of separation in given specific cases, filters of protection level FFP3 are advisable. They retain 99.98% of dust particles. Furthermore, nanoparticles absorb on the dust layers of filters.

Where personal protective equipment is necessary, such equipment must be provided by the employer e.g. respiratory protective equipment and protective gloves.

¹⁶PPE: Personal protective equipment (PPE) refers to protective clothing, helmets, goggles, or other garment or equipment designed to protect the wearer's body from injury by physical hazards, electrical hazards, heat, chemicals, biohazards, particulate matter, and infection, for job-related occupational safety and health purposes: 89/656/EWG, 89/686/EWG.

Step 8) Monitoring: Keeping track of workers possibly exposed

Monitoring can help identify at an early stage health effects occurring among specific groups of workers and allows quick action when new information on health hazards of specific substances becomes available.

Table 4: Example of a monitoring table

| Date or period of work activity | Name Employee | Name of Nanomaterial product | Characterisation of the activity | Duration of the activity |
|---------------------------------|------------------|------------------------------------|---|------------------------------|
| Date/time a | Employee A | Chemical name or product name | LocationWork placeProcessUsed amount | Total time Time per activity |
| Date/time b | Employee A | | | |
| Date/time c | Employee B | | | |
| Date/time d | Employee C | | | |

Step 9) Investigate if Preventive Medical Surveillance (PMS) is possible

At the moment there is no evidence for risks from nano-objects in paint, coatings and inks. There are no specific methods or medical tests available as well. Please investigate if preventive medical surveillance is available.

2.2. Additional Information

Abnormal and Emergency Situations

Special precautions may be needed for emergency or abnormal conditions:

Emergency procedures should be in place to deal with spillages and accidents. Spillages should preferably be cleaned up by wet-wiping. If not practicable, vacuuming may be used (only use a vacuum cleaner with a HEPA (high-efficiency) filter). Do not brush or use compressed air.

Existing emergency procedures may need to be adapted to ensure that emergency responders are aware of the hazards and take appropriate precautions

Information, instruction and training

Employees should be educated in the hazards and trained in the proper handling of nano-objects. They should have sufficient information to allow them to understand the risks to their health and the precautions needed to avoid or minimise exposure. Supervision may be required for new or inexperienced workers.

Where RPE (Respiratory Protective Equipment) is used, employees should be trained: to ensure that it fits properly, how to use it effectively, where to store it and when it should be serviced or thrown away.

Disposal

Deciding on the best method for disposal of nanomaterials will depend on its nature and character (e.g. whether it is 'raw' or bound in a matrix) The nanomaterial should be prepared so as to prevent exposure or release. This should include supplemental items such as wipers, used PPE.

Fire Risk

Nano-objects, like conventional dusts, may, if combustible, be an explosion risk. Residues should not be allowed to build up as they could be a potential source of a cloud of combustible dust that may form an explosive atmosphere.

3. Conclusions and Outlook

Nanotechnology enables the manufacture of coating, printing inks and artists colours materials with much improved or totally new properties. The same holds true for nanotechnology as for all other new technologies, which are still in their infancy: not all potential risks are known. Therefore, efforts need to be made to close these knowledge gaps.

The European paint and printing ink industry is actively and intensively engaged in the gathering of new findings on potential risk to human health. A number of studies were or are being conducted ^{17,18} to enable an estimation of potential risk in the handling of nano-objects.

Based on the results of existing studies on nano-paints, it is noted that nothing points to specific risks to the health of workers or to the environment, where general rules of occupational health and safety and good industrial hygiene are observed. Possibly, specific protection measures at the workplace – to take into account dusty input materials with nanoscale components – need to be identified based on risk assessment.

¹⁷Vorbau M, Hillemann L, Stintz M. (2009) Method for the characterization of the abrasion induced nanoparticles release into air from surface coatings. J Aerosol Sci; 40(3): 209–217.

¹⁸Göhler D, Stintz M, Vorbau M, Hillemann L. (2010) Characterization of nanoparticle release from surface coatings by the simulation of a sanding process. Ann OccupHyg; 54(6): 615-624.

4. Annex – Important Definitions

ISO

Definitions according to Technical Specification 27687 "Nanotechnologies – Terminology and definitions for nano-objects" of the International Organization for Standardization (ISO) ISO/TS 27687:2008

"Nanoscale": Size range from approximately 1 nm to 100 nm.

"Nano-object": Material with one, two or three external dimensions in the nanoscale.

"Nanoparticle": Nano-object with all three external dimensions in the nanoscale.

"Nanoplate": Nano-object with one external dimension in the nanoscale and the two other external dimensions significantly larger.

"Nanofibre": Nano-object with two similar external dimensions in the nanoscale and the third dimension significantly larger.

"Nanotube": Hollow nanofibre.

"Agglomerate": Collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components.

"Aggregate": Particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components.

Recommendation¹⁹ of the EU Commission the term nanomaterial

'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.

CEPE Proposal for a definition on the term nanomaterial A nanomaterial is a:

19EU Commission Recommendation http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF.

- 1. Solid, particulate substances which are not dispersed in a continuous medium
- 2. Particles intentionally manufactured at the nano-scale
- 3. Consisting of nano-objects with at least one dimension between 1 and 100 nm on the basis of ISO standards
- 4. And their aggregates and agglomerates
- 5. With a weight based cut-off of either
 - 10 wt.-% or more of nano-objects as defined by ISO or
 - 50 wt % or more of aggregates / agglomerates consisting of nano-objects
- 6. Where nano-objects are used to achieve specific properties

OECD

The OECD Working Party on Manufactured Nanomaterials (WPMN) has published a description of a nanomaterial on its website.

"A nanomaterial or a nanoparticle is usually considered to be a structure between 0.1 and 100nm (1/1,000,000 mm)". At the nanoscale, the physical, chemical, and biological properties of materials may differ in fundamental and often valuable ways from the properties of individual atoms and molecules or bulk matter.

OECD WPMN Guidance for the use of the OECD Database on Research into the Safety of Manufactured Nanomaterials. Ver.1 October 2008.

"Manufactured nanomaterials: Nanomaterials intentionally produced to have specific properties or specific composition, a size range typically between 1 nm and 100 nm and material which is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale)." This definition is based solely on size.

Control Banding

Control Banding schemes have been developed to allow users to quickly determine proper controls for worker protection (substitution with less hazardous agents; modification of work practices and engineering controls; and the selection and use of appropriate personal protective equipment) based on readily available information on agents' health hazards, exposure potential based on exposure determinants, and current controls. The schemes are primarily intended for use by small and medium sized enterprises that lack professional occupational hygiene or toxicological expertise, but are also used by skilled occupational hygiene professionals, primarily as a screening tool in the exposure assessment process. The intent of control banding schemes is to provide a level of worker protection consistent with the level of protection that would be identified by skilled occupational hygiene professionals using more robust scientific based techniques.

5. Sources, Studies and Bibliography

¹Guidance working safely with nanomaterials and nanoproducts, the guide for employers and employees, made by the Dutch organizations for employers and employees VNO-NCW, FNV and CNV - version 1.0 may 2011.

²Working Safely with Nanomaterials in Research & Development (by the UK NanoSafety Partnership Group).

³EU Commission Recommendation http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF.

⁴ISO/TS 27687:2008 "Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate.

⁵CEN TC 352

http://www.cen.eu/cen/Sectors/Sectors/Nanotechnologies/Pages/default.aspx.

⁶OECD Working Party on Nanomaterials http://www.oecd.org/document/36/0,3343,en_2649_34269_38829732_1_1_1_1_1,00.html .

⁷Vorbau M, Hillemann L, Stintz M. (2009) Method for the characterization of the abrasion induced nanoparticles release into air from surface coatings. J Aerosol Sci; 40(3): 209–217.

⁸Koponen IK, Jensen KA, Schneider T. (2009) Sanding dust from nanoparticle-containing paints: physical characterisation. J Phys: ConfSer; 151 (012048).

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¹¹Nanoderm Final report: http://www.uni-leipzig.de/~nanoderm/Downloads/Nanoderm Final Report.pdf.

¹²Control banding http://ioha.net/controlbanding.html.

¹³PPE: Personal protective equipment (PPE) refers to protective clothing, helmets, goggles, or other garment or equipment designed to protect the wearer's body from injury by physical hazards, electrical hazards, heat, chemicals, biohazards, particulate matter, and infection, for job-related occupational safety and health purposes: 89/656/EWG, 89/686/EWG.

¹⁴Occupational Hygiene Strategy: http://ioha.net/index.html.

¹⁵CEN TC 352 http://www.cen.eu/cen/Sectors/Sectors/Nanotechnologies/Pages/default.aspx.

¹⁶PPE: Personal protective equipment (PPE) refers to protective clothing, helmets, goggles, or other garment or equipment designed to protect the wearer's body from injury by physical hazards, electrical hazards, heat, chemicals, biohazards, particulate matter, and infection, for job-related occupational safety and health purposes: 89/656/EWG, 89/686/EWG.

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- A) 89/391/EWG Council Directive on the introduction of measures to encourage improvements in the safety and health of workers at work; 98/24/EG on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC
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- F) "Dispersion and Retention of Dusts Consisting of Ultrafine Primary Particles in Lungs", baua 2011 (http://www.baua.de/en/Publications/Expert-Papers/F2133.html):
- G) VdL-Guidance for the handling of nano-objects at the workplace http://www.lackindustrie.de/template_downloads/tmp_LackverbandInternet/127627Nano-leitfaden%20englisch%20komplett.pdf?DokNr=127627&p=16

6. List of tables:

Table 1: Typical characteristics of nano-objects used or produced

Table 2: Description of the hazard category for nano-objects

Table 3: Proposals for OELs and DNELs for specific nanoparticles

Table 4: Example of a monitoring table

¹⁷Vorbau M, Hillemann L, Stintz M. (2009) Method for the characterization of the abrasion induced nanoparticles release into air from surface coatings. J Aerosol Sci; 40(3): 209–217.

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¹⁹EU Commission Recommendation http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF.