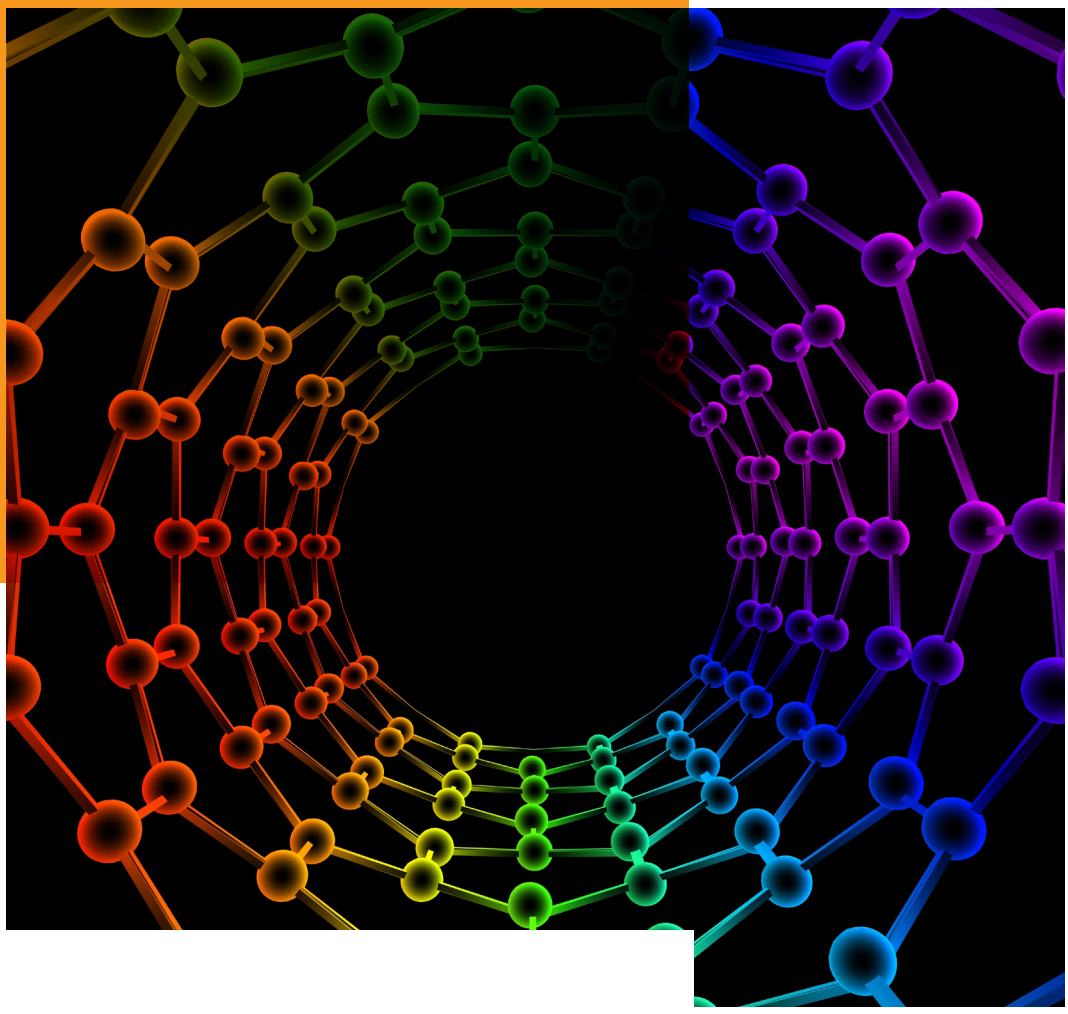
ADVISORY REPORT 12/01 | March 2012

SER

Provisional nano reference values for engineered nanomaterials



SOCIAL AND ECONOMIC COUNCIL

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SOCIAL AND ECONOMIC COUNCIL

The Social and Economic Council and its mission

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This is a translation of the SER-report:

Voorlopige nanoreferentiewaarden voor synthetische nanomaterialen
2011, 258 pp., ISBN 978-94-6134-035-1

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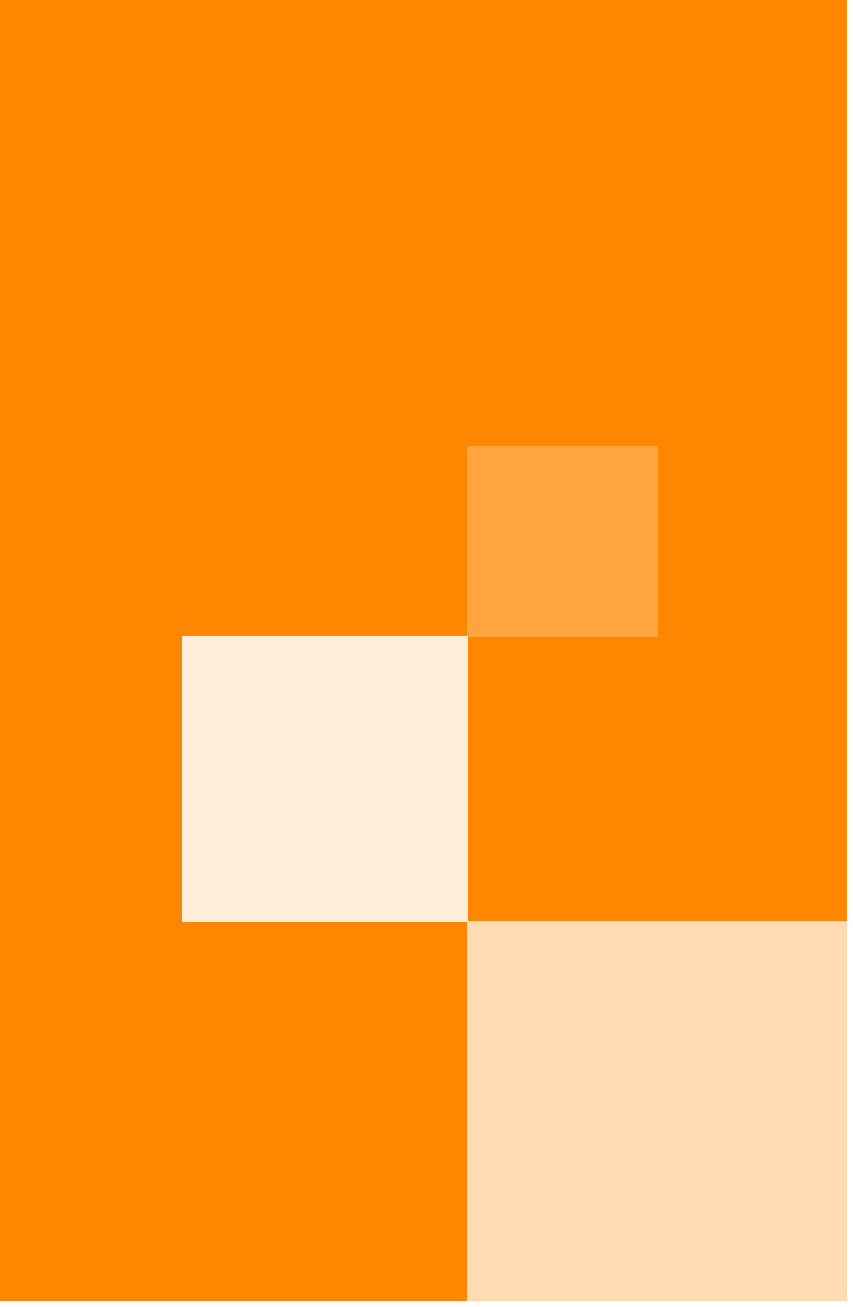


Advisory report

1. Engineered nanomaterials

In the spring of 2009, the Working Conditions Committee of the Social and Economic Council of the Netherlands presented its advisory report entitled *Nanoparticles in the Workplace: Health and Safety Precautions*[1] to the Dutch Minister of Social Affairs and Employment (SZW). In its report, the Committee asked the Minister to urge the Health Council of the Netherlands to prioritise the setting of health-based occupational exposure limits (OELs) for a number of frequently used nanoparticles. In its response, the Health Council stated that there was too little scientific evidence available to determine such health-based OELs. The Committee also urged the setting up of an "early warning system" so as to monitor the health of employees who work with engineered nanoparticles (ENPs). There is still much uncertainty concerning the potential impact that exposure to such particles may have on health. That is why health-based OELs have not been set so far. These uncertainties are also influencing the design and use of an early warning system.

In addition, the Minister of SZW wishes to link the early warning system to a system of exposure registration. The Health Council is preparing an advisory report on this subject at the Minister's request. Publication is expected in 2012.

In the meantime, the social partners have continued to study this issue. With the increasing use of ENPs in products and the associated potential danger to health, health risks must be avoided. Normally, occupational exposure is assessed by comparing the level of exposure to an acceptable occupational exposure limit, which is also a desirable procedure for airborne nanoparticles. As indicated however, the current state of scientific knowledge is too limited to derive health-based occupational exposure limits for nanoparticles. Given this limitation and taking into account the basic principle "no data, no exposure", it is up to companies to take steps to prevent employees' exposure to nanoparticles. A provisional nano reference value[2] based on the precautionary principle offers an alternative solution to this problem.

Regarding these *provisional* nano reference values (NRVs), the Committee has included several recommendations for the social partners' consideration and several recommendations for government in this advisory report (see Section 3).

1 Original Dutch-language document: SER (2009) Advies *Veilig omgaan met nanodeeltjes op de werkplek,* publ.no. 2009/01.
2 In Dutch: *nanoreferentiewaarden.*

2. Provisional nano reference values

2.1 Background

Following on from the Council's advisory report *Nanoparticles in the Workplace: Health and Safety Precautions*, the then Minister of SZW asked RIVM-KIRnano[3] to advise on the usefulness of nano reference values and the related concept. The Minister requested that RIVM-KIRnano involves the Expert Platform on Working Conditions (DAKIR)[4] in its investigation. In 2010, RIVM-KIRnano published its report *Tijdelijke nano-referentiewaarden. Bruikbaarheid van het concept en van de gepubliceerde methoden* [Provisional nano reference values. Usefulness of the concept and of the methods published][5]. It considers the guidance values as developed by the IFA[6] an interesting and acceptable approach that can provide a basis for determining nano reference values. The IFA's method was then used to set provisional nano reference values for nanomaterials. The report states that NRVs are meant as practical guidelines only, and do guarantee that exposure below the nano reference value is safe.

The social partners[7] then carried out the *pilot nano reference values* intended to test the feasibility of the provisional NRVs in practice and to propose any necessary improvements in the NRV concept. The social partners commissioned the research organisations IVAM University of Amsterdam, the University of Twente and IndusTox Consult to carry out the pilot study. The study was carried out between April 2010 and December 2011.

The findings of the pilot study have been incorporated into the Final Report on Pilot Nano Reference Values.[8]

The following sections review the provisional NRVs for four classes of ENPs, along with an explanation. These provisional NRVs differ in a limited extent from the provisional NRVs as described in the RIVM-KIRnano report.

3 The Expertise and Information Centre for Risks of Nanotechnology [Kennis- en informatiepunt risico's (KIR) nanotechnologie], part of the National Institute for Public Health and the Environment [Rijksinstituut voor Volksgezondheid en Milieu, RIVM].
4 DAKIR's members are: RIVM, the Netherlands Institute for Applied Scientific Research (TNO), Delft University of Technology (TU Delft), the Institute for Risk Assessment Sciences (IRAS) at Utrecht University, Zuyd University, and IVAM Research and Consultancy on Sustainability at the University of Amsterdam.
5 RIVM; S. Dekkers and C. de Heer (2010), *Tijdelijke nano-referentiewaarden. Bruikbaarheid van het concept en van de gepubliceerde methoden,* Utrecht; Rijksinstituut voor Volksgezondheid en Milieu.
6 Institut für Arbeidsschutz der Deutschen Gesetzlichen Unfallversicherung (=IFA).
7 VNO-NCW, FNV and CNV.
8 FNV, VNO-NCW, CNV (2001); *Pilot Nanoreferentiewaarden – Nanodeeltjes en de nanoreferentiewaarde in Nederlandse bedrijven; Eindverslag,* carried out by IVAM UvA, IndusTox Consult and the University of Twente (Report no. NRV070 – 1126-o).

2.2 Proposed provisional reference values with explanation

On 10 November 2011, the ad hoc nano working party set up by the Subcommittee on Limit Values for Substances in the Workplace (GSW Subcommittee)[9] met to discuss and arrive at agreements between the social partners concerning the future use of provisional NRVs for four classes of ENPs.

A distinction is made in NRVs between "reasonable measures" and "all possible technical measures". "Reasonable measures" are identified according to the occupational hygiene strategy and are assessed on their technical, organisational and economic feasibility. Based on this assessment, a decision is made as to the risk management measures that will be introduced.[10]
"All possible technical measures" refer to applying the precautionary principle. It involves a serious consideration of the hierarchical steps in the occupational hygiene strategy and introduction of all technically and organisationally feasible solutions. The *reasonableness principle* is not used in the latter case.

Considerations when utilising NRVs

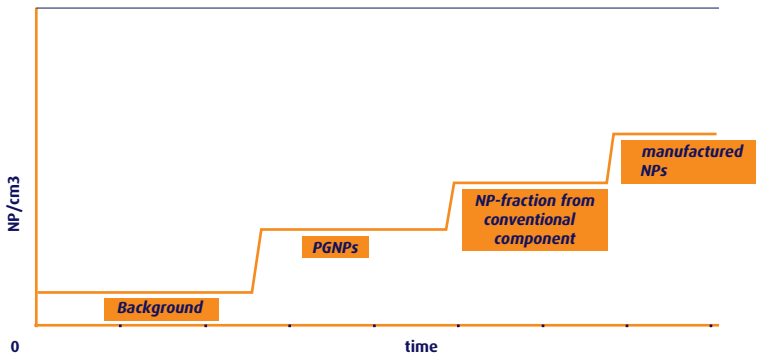
A point to consider when making agreements on the use of nano reference values is the background concentration of outdoor airborne nanoparticles of natural and anthropogenic origin. There may also be process-generated nanoparticles (PGNPs) present in the workplace. PGNPs can be generated by electrical equipment (engine-generated) or by combustion or heating processes (combustion-derived); they can also be generated when using some "conventional" components of products that contain a substantial fraction of nanoparticles. The toxicity of PGNPs is comparable to that of engineered nanoparticles (and there is also still much confusion about PGNP toxicity) and it is likely that they agglomerate or aggregate with engineered nanoparticles.[11] With (simple) measuring equipment it is difficult to distinguish background nanoparticles and PGNPs from engineered nanoparticles, and they are often measured as a single total concentration. In many cases, application

9 This is a subcommittee of the Council's Working Conditions Committee.
10 See also: FNV, VNO-NCW, CNV (2010), *Handleiding veilig werken met nanomaterialen en nanoproducten.* Also published in English: FNV, VNO-NCW, CNV (2011), *Guidance for working safely with nanomaterials and nanoproducts.*
11 Donaldson, K., Tran, L., Jimenez, L.A., Duffin, R., Newby, D.E., Mills, N., MacNee, W., Stone, V. (2005) "Combustion-derived nanoparticles: a review of their toxicology following inhalation exposure". Part Fibre Toxicol 2:10.

of a intelligent measurement strategy makes it possible to distinguish between the two to a certain extent, but to make a clear-cut distinction requires in-depth and expensive laboratory analyses. The concentration pattern for ENPs in the workplace atmosphere often consists of high peak concentrations of short duration.

See Figure 1 for a diagram showing how airborne nanoparticles become concentrated in the workplace.

Figure 1 **Diagram showing potential concentration of airborne nanoparticles in the workplace.**



Agreements with social partners concerning NRVs

Table 1 **Provisional nano reference values for the four classes of ENPs.**

Class	Description	Density	NRV (8-hr TWA)	Examples
1	Rigid, biopersistent nanofibres for which effects similar to those of asbestos are not excluded	–	0.01 fibres/cm3 (= 10,000 fibres/m^3)	SWCNT or MWCNT or metal oxide fibres for which asbestos?like effects are not excluded by manufacturer.
2	Biopersistent granular nanomaterial in the range of 1 and 100 nm	> 6000 kg/m^3	20,000 particles/cm^3	Ag, Au, CeO_2, CoO, Fe, Fe_xO_y, La, Pb, Sb_2O_5, SnO_2
3	Biopersistent granular and fibre form nanomaterials in the range of 1 and 100 nm	< 6000 kg/m^3	40,000 particles/cm^3	Al_2O_3, SiO_2, TiN, TiO_2, ZnO, nanoclay Carbon Black, C60, dendrimers, polystyrene Nanofibres for which asbestos-like effects are excluded
4	Non-biopersistent granular nanomaterials in the range of 1 and 100 nm	–	Applicable OEL	e.g. fats, common salt (NaCl)

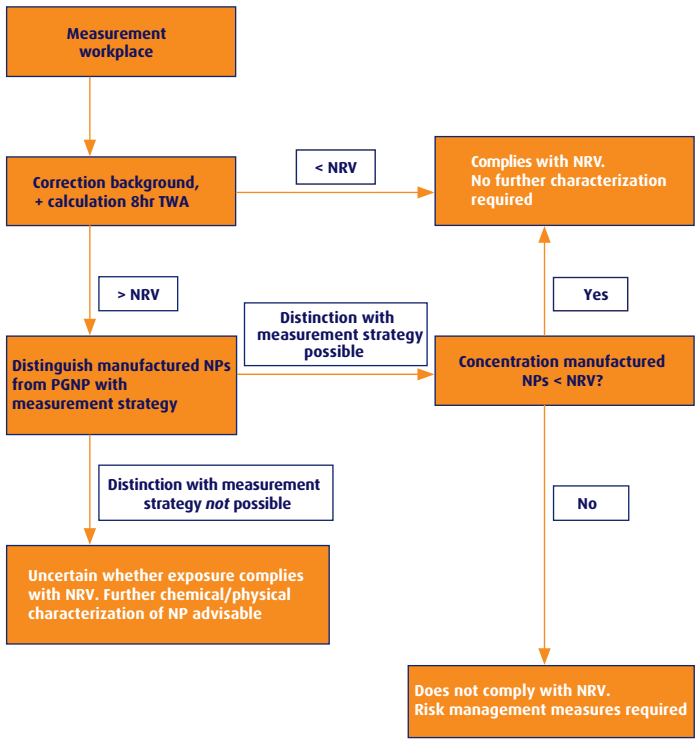
The concentration of engineered nanoparticles in the workplace breathing zone may exceed or fall below the NRV, with different actions then applying. This is explained in Table 2.

Table 2 Actions after applying the NRV

	Action
Concentration < NRV	1. Measurements indicate that the 8-hour time weighted average (TWA) concentration of ENPs in the breathing zone (nanoparticles/cm^3), corrected for the background concentration, is *lower* than the NRV for the ENP. 2. There may be nanoparticles in the breathing zone generated by process-based ENPs, by the processing equipment used, or by the use of heating or combustion processes. In addition, conventional products may sometimes also contain a substantial fraction of nanoparticles that are dispersed into the breathing zone when used. 3. There is no need to further characterize (chemical/physical analysis) the nanoparticles in the breathing zone. 4. The recommendation is that reasonable measures must be taken (the aim being to reduce the length and intensity of exposure to nanoparticles as much as possible). 5. Repeated exposure measurements are recommended whenever the process is altered.
Concentration >NRV	1. Measurements indicate that the 8-hour time weighted average (TWA) concentration of ENPs in the breathing zone (nanoparticles/cm^3), corrected for the background concentration, is *higher* than the NRV for the ENP. 2. There may be nanoparticles in the breathing zone generated by process-based ENPs, by the processing equipment used, or by the use of heating or combustion processes. In addition, conventional products may sometimes also contain a substantial fraction of nanoparticles that are dispersed into the breathing zone when used. 3. All possible technical measures are necessary in order to reduce exposure to below the NRV *.....or.....* 4. The nanoparticles in the breathing zone must be distinguished into ENPs and process-generated nanoparticles (PGNPs). It may be possible to make this distinction by using a special measurement strategy. If this is not possible, then the two categories must be distinguished by means of an elaborate physical/chemical analysis. 5. If the elaborate analysis shows that the concentration of engineered nanoparticles in the breathing zone is *lower* than the NRV, the recommendation is that reasonable measures must be taken (the aim being to reduce the length and intensity of exposure to small particles as much as possible). 6. If detailed analysis shows that the concentration of engineered nanoparticles in the breathing zone is *higher* than the NRV, the recommendation is that all possible technical measures must be taken to reduce exposure to below the NRV.
PGNP > NRV	It is possible that the elaborate physical/chemical analysis shows that the production process is generating PGNPs in a concentration higher than the NRVs. This means that many other nanoparticles are being generated in the workplace, even if engineered nanomaterials are not being used. In many cases, an OEL has not (as yet) been set for such particles, and Table 1 for NRVs does not apply to them. The recommendation, however, is to take reasonable measures to reduce the concentration of particles in the workplace (after all, it is better for health to reduce the length and intensity of exposure to small particles as much as possible). An exception concerns particles for which a health-based occupational exposure limit has already been set (for example welding fumes). The applicable OEL should be enforced for those particles.

The various actions outlined in Table 2 are shown in diagram in Figure 2.
The following measurement strategy can be applied to determine whether the concentration of nanoparticles in the workplace exceeds the NRV (see Figure 2).

Figure 2 Applying the NRV and the relevant actions



Explanation of Figure 2:

- The workplace concentration can be measured in accordance with the strategy defined in NEN-689. This states that the effective risk management criterion has been met if the threshold is not exceeded in 95% of the time (95th percentile of the frequency distribution is < NRV). In the case of a single measurement, 10% of the threshold is often accepted as satisfying the criterion owing to the huge variability in exposure.
- A measurement strategy that distinguishes between ENPs and PGNPs is to take a measurement when the machinery is running but nanomaterials are not being used in the process, and then to repeat the measurement when nanomaterials are being used. The difference between the two concentration levels may indicate emissions of engineered nanoparticles (once again, a meticulous analysis of the local situation is necessary).

Agreements governing use

The social partners arrived at the following agreements concerning the provisional nano reference values.

a. The nano reference values (NRVs) are *provisional* NRVs for assessing workplace concentrations of engineered nanoparticles. The NRVs are based on the *precautionary principle*, with the values being temporary ones. They will be replaced as soon as HBR-OELs (Health-Based Recommended Occupational Exposure Limits) or DNELs (Derived No-Effect Levels) defined within the context of REACH become available for the specific nanoparticles or for a group of similar nanoparticles.

b. The provisional NRV provides an alarm level that signals a need for risk management in the workplace. If the provisional nano reference value is exceeded, this is an instruction to reduce employees' exposure.

c. The provisional NRVs are defined as an 8-hour time weighted average concentration (8hr-TWA). The provisional NRV defines a maximum, generic level for the concentration of nanoparticles in the workplace atmosphere. The level is adjusted for the background concentration and PGNPs.

d. The PGNPs are *not* included in background concentration; they should be considered separately. As long as the 8hr-TWA remains below the NRV, the ENPs can be assessed together with the PGNPs, without subjecting the particles to further (physical/chemical) analysis. If the NRV is exceeded, then further analysis is desirable so that tailor-made measures can be taken.

e. In dealing with nanomaterials for which insufficient data are available, the principle to be upheld is "no data, no exposure", with the emphasis being on preventing exposure, in other words on applying the precautionary principle. The precautionary principle implies that the employer must make an effort to prevent exposing employees to nanoparticles and – in cases where exposure is unavoidable – to reduce the length and intensity of exposure as much as possible; in other words, to minimise exposure.[12]

12 See Council (SER) advisory report *Nanoparticles in the Workplace: Health and Safety Precautions* , publ.no. 2009/01, p. 35.

f. Existing legislation governing hazardous substances in the workplace also applies to ENPs. For example, if employees work with nanomaterials whose parent material has CMR[13] properties, or if the nanomaterial itself has CMR properties, then the legislation governing CMR must also be enforced. The most stringent risk management measure must be applied.

Other comments concerning the NRVs, their application and use.

Definition

With respect to the size of the nanoparticles this document uses the same definition for NRVs as that laid down by the European Commission. The Commission defines 100 nm as the upper limit for the diameter of nanomaterial.[14] This definition is intended to clarify matters for legislation and registration purposes. However, it does not rule out any potential risks associated with nanoparticles. It should be noted that larger agglomerations in excess of 100 nm may have a similarly harmful effect on health, and as a consequence should *not* be excluded from risk assessment.

Applicable OEL

There are already OELs for some particle-like concentrations in the workplace atmosphere. One example is welding fumes. For the record, it should be noted that the applicable OEL must be enforced for such "substances".

Availability of measuring equipment

Portable measuring equipment has recently become available for measuring airborne concentrations of nanoparticles. Such equipment can simultaneously measure the concentration of nanoparticles and their average particle diameter. This makes it possible for companies to apply the provisional nano reference value.

PCR and MOP

Precaution Characterization Ratio (PCR) or the Margin of Precaution (MOP) can be used as a reference for communicating measurement data.

$$PCR = \frac{concentration\ nanoparticles}{NRV} \quad \text{and} \quad PCR = {}^{1}\!/_{MOP}$$

13 CMR = carcinogenic, mutagenic, reprotoxic.

14 COMMISSION RECOMMENDATION of 18 October 2011 on the definition of nanomaterial (2011/696/EU): '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. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.'

The PCR applies the terminology used in *occupational health and safety policy*, whereas the MOP uses the customary terminology of *environmental policy*. If the PCR > 1, then further characterization of the nanoparticles and risk reduction measures are desirable (see Table 2).

2.3 Initiatives based on the Council's advisory report in 2009

In addition to the social partners' joint efforts to identify the provisional NRVs indicated in Table 1 for the four classes of engineered nanomaterials, they have undertaken numerous other activities – ranging from the setting of NRVs to information campaigns for employees – since the Committee published its advisory report *Nanoparticles in the Workplace: Health and Safety Precautions* in 2009.

3. Recommendations

Based on the foregoing, the Working Conditions Committee advises social partners to do the following:

- Draw the attention of their members to the availability of provisional nano reference values as an alternative to occupational exposure limits when assessing risks in the workplace, and encourage members to make use of those values.

- Include the NRV system in the phased plan set out in the manual *Guidance for safe working with nanomaterials and nanoproducts* issued by the trade union confederations CNV and FNV and the employers' confederation VNO-NCW.

- Develop industry-specific good practices. They should describe how to work safely and acceptably with nanomaterials. To guarantee the provisional nano reference values and good practices, it would also be advisable to include both in the health and safety catalogue.

The Working Conditions Committee recommends that government do the following:

- Investigate whether an occupational exposure limit can be set for the PGNPs in accordance with the appropriate procedure. OELs have either a public or a private status in the Netherlands. ENPs may have an identified owner and many of them will therefore be categorised in the private domain (company-derived OELs). However, if a specific engineered nanoparticle has been classified as a genotoxic carcinogen or allergen for which there is no applicable threshold

value, then a public OEL must be set for it. PGNPs also appear to belong in the public domain, as they are nanoparticles “without an owner”.

- In industrial inspections, recognise provisional nano reference values as an alternative to OELs where these do not exist.

- Actively advise companies to use NRVs.

Colophon

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