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# Exposure Limits for Nanoparticles: Report of an International Workshop on Nano Reference Values

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**This article summarizes the outcome of the discussions at the international workshop on nano reference values (NRVs), which was organized by the Dutch trade unions and employers' organizations and hosted by the Social Economic Council in The Hague in September 2011. It reflects the discussions of 80 international participants representing small- and medium-size enterprises (SMEs), large companies, trade unions, governmental authorities, research institutions, and non-governmental organizations (NGOs) from many European countries, USA, India, and Brazil. Issues that were discussed concerned the usefulness and acceptability of precaution-based NRVs as a substitute for health-based occupational exposure limits (OELs) and derived no-effect levels (DNELs) for manufactured nanoparticles (NPs). Topics concerned the metrics for measuring NPs, the combined exposure to manufactured nanomaterials (MNMs) and process-generated NPs, the use of the precautionary principle, the lack of information about the presence of nanomaterials, and the appropriateness of soft regulation for exposure control. The workshop concluded that the NRV, as an 8-h time-weighted average, is a comprehensible and useful instrument for risk management of professional use of MNMs with a dispersible character. The question remains whether NRVs, as advised for risk management by the Dutch employers' organization and trade unions, should be under soft regulation or that a more binding regulation is preferable.**

*Keywords:* derived no-effect levels; nano reference values; occupational exposure limits; precautionary principle; risk management

## INTRODUCTION

The increasing production and use of manufactured nanomaterials (MNMs) has given rise to initiatives of governmental authorities, industrial organizations, and civil society organizations to advocate the application of the precautionary principle for risk management (EC, 2000). The tools chosen to make this principle operational for the workplace differ in approach, but they have in common that they all aim to minimize the occupational exposure as far as reasonably achievable. Control banding is an approach that is gaining growing acceptance among risk assessors. Several control-banding tools have been published, all making use of a two-dimensional matrix, generally combining a qualitative assessment of hazardous properties of the used nanomaterials with an estimate of the likeliness of inhalatory exposure (Paik *et al.*, 2008; Schulte *et al.*, 2008; ANSES, 2010; Höck *et al.*, 2011; Hansen *et al.*, 2011; van Duuren-Stuurman *et al.*, 2012). There are also guidances that combine control banding in a risk assessment tool (Cornelissen *et al.*, 2011). In the conventional quantitative approach to risk management of substances, health-based recommended occupational exposure limits (HBR-OELs) are accepted

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to determine maximum levels of exposure (SCOEL, 2009). In analogy the European legislation REACH requires that manufacturers derive a derived no-effect level (DNEL) for the substances they bring to the market (ECHA, 2010). DNELs may be used to establish acceptable exposure limits.

The 'new' properties of nanomaterials, incomplete information about the hazards of nanomaterials, their varying size distribution, and heterogeneous composition complicate application of the conventional approach for the derivation of limit values for nanomaterials (based on agreed toxicity test systems and safety factors). It has been suggested that a more generic approach might be more appropriate to generate acceptable exposure limits for groups of nanomaterials (Schulte *et al.*, 2010).

In line with this suggestion, and as a means to make the precautionary principle operational for the use of nanomaterials at the workplace, the Dutch employers' organization and trade unions advised developing the concept of nano reference values (NRVs) (SER, 2009). For this purpose, they further developed the benchmark level approach as suggested by the German Institut für Arbeitsschutz (IFA, 2009) and tested its comprehensibility and suitability for use at the workplace in a pilot project with companies applying MNMs.

The findings of the Dutch employers' organization and trade unions were presented and discussed in an international workshop at The Hague in September 2011 for an audience of experts and academia, workers' and employers' organizations, large industries and small- and medium-size enterprises (SMEs), non-governmental organizations (NGOs), and governmental authorities. A total of 80 participants from the Netherlands, Germany, Austria, France, UK, Ireland, Belgium, Luxembourg, Finland, Norway, USA, India, and Brazil took part in the discussions.

Chaired by Frank Barry from the Irish trade unions, introductory presentations were given by representatives from the Dutch trade union (FNV), W.v.V., and employers' organization (VNO/NCW), W.-H.S., explaining their positions towards safe working with nanomaterials. P.v.B. (IVAM UvA) and Bärbel Dorbeck-Jung (University of Twente) illustrated the findings of the pilot project on NRVs. Input from industries participating in the pilot project was given by Jolien Stevels (Holland Colours) and Robert Beckers (NanoCoatings) who clarified how in their company they make a precautionary approach operational. Markus Berges (IFA, DE) explained the basis for the derivation of the German guidance values for nanomaterials. P.S. [National Institute for Occupational Safety and Health (NIOSH), USA] elaborated on the NIOSH approach to standard setting for nanomaterials and illuminated the state of the art of OELs for nanomaterials. John Cherrie (Institute of Occupational Medicine, UK) finally explained how the UK manages potential risks from nanomaterials. A panel discussion chaired by L.R. (UvA, NL) with some of the speakers mentioned previously, Jorge Costa-David (European Commission, DG Employment) and Dirk van Well [Dutch Association of the Chemical Industries (VNCI)], focused on the definition of nanomaterials, the preferred metrics, and the appropriateness of applying limits to short-term peak exposures for nanoparticles (NPs). They also discussed the use of the precautionary principle for standard setting, the information about the presence of nanomaterials, the choice for voluntary initiatives (soft regulation) versus hard regulation, and the advisability to use NRVs. This article describes the results of this workshop.

## WORKSHOP ACHIEVEMENTS

### *Introductions*

*Health-based approach.* There are agreed protocols to identify a threshold above which an adverse health effect may occur (SCOEL, 2009; ECHA, 2010). For substances with such a threshold, health-based occupational Exposure Limits (OELs) or DNELs may be derived. For substances without an identifiable threshold level, as is the case for genotoxic carcinogenic substances and some allergenic substances, a risk-based approach defining a level that allows for a certain risk may be used. The Netherlands accepted, for example, a target level for one worker to develop a cancer in a population of $10^6$ (million) workers per year (incident $10^{-6}$) or one worker to get sensitized in a population of 100 workers per year, related to the exposure to the specific substance. For a few frequently used MNMs, exercises have been carried out to derive a health-based OEL or DNEL. Stone *et al*. (2010) derived provisional DNELs for some frequently used nanomaterials by using the methodology as described by REACH. P.S. illustrated the preference of NIOSH for health-based limit values by explaining the efforts to derive a recommended exposure limit (REL) for carbon nanotubes (CNTs) (NIOSH, 2010) and titanium dioxide ($TiO_2$) (NIOSH, 2011) (see Table 1). He stated that the NIOSH approach to $TiO_2$ is supported by the finding that the toxicity seems not to be significantly modified by the crystal structure (anatase or rutile) or the coating on the particle, which indicates that

Table 1. Proposals for OELs and DNELs for specific NPs

| Substance | | OEL or REL (mg $m^{-3}$) | DNEL (mg $m^{-3}$) | References |
|---|---|---|---|---|
| MWCNT (Baytubes) | 8-h TWA | 0.05 | | Pauluhn (2010) |
| MWCNT (10–20 nm/5–15 µm) Scenario NOAEC pulmonary effects | Short-term inhalation | | 201 | Stone *et al.* (2010) |
| | Chronic inhalation | | 33.5 | Stone *et al.* (2010) |
| MWCNT (10–20 nm/5–15 µm) Scenario LOAEC immune effects | Short-term inhalation | | 4 | Stone *et al.* (2010) |
| | Chronic inhalation | | 0.67 | Stone *et al.* (2010) |
| MWCNT (Nanocyl) | 8-h TWA | 0.0025 | | Nanocyl (2009) |
| CNT (SWCNT and MWCNT) | 8-h TWA | 0.007 | | NIOSH (2010) |
| Fullerenes | Short-term inhalation | | 44.4 | Stone *et al.* (2010) |
| | Chronic inhalation | | 0.27 | Stone *et al.* (2010) |
| Fullerene | | ~0.8 | | NEDO-2 (2009) |
| Ag (18–19 nm) | DNEL-lung scenario 1 | | 0.33 | Stone *et al.* (2010) |
| | DNEL-lung scenario 2 | | 0.098 | Stone *et al.* (2010) |
| | DNEL-liver | | 0.67 | Stone *et al.* (2010) |
| $TiO_2$ (21 nm) | Chronic inhalation | | 17 | Stone *et al.* (2010) |
| $TiO_2$ (10–100 nm; REL) | 10 h $day^{-1}$, 40 h $week^{-1}$ | 0.3 | | NIOSH (2011) |
| $TiO_2$ P25 (primary size 21 nm) | TWA 8 h $day^{-1}$, 5 day $week^{-1}$ | 1.2 | | NEDO-1 (2009) |

SWCNT, single-wall CNT; MWCNT, multi-wall CNT; NOAEC, no-observed adverse effect concentration; LOAEC, lowest observed adverse effect concentration.

the particle surface area of nano-$TiO_2$ seems to be the dominating factor in toxicity. This facilitates the use of the NIOSH REL for nano-$TiO_2$ since further characterization of the 'form' of the nano-$TiO_2$ for risk assessment could be limited. For CNTs, NIOSH found that a working lifetime exposure of 0.2–2 µg $m^{-3}$ [8-h time-weighted average (TWA)] would suffice to avoid health effects, but that the measurability, the relatively high upper limit of quantization, determined their proposal for the REL of 7 µg $m^{-3}$. Table 1 summarizes these attempts to derive a mass-based OEL or DNEL for MNMs. The table shows quite large differences for CNTs with 'similar' identity (but possibly differing in specific properties). The large amount of toxicity testing and data needed for deriving an OEL for single MNMs is recognized by P.S., and he suggests a more broadly useable approach to derive health standards for groups of nanomaterials that have a similar molecular identity (e.g. CNTs, metal oxides, and metals) or to group together nanomaterials that share a common mode of action (for example, the formation of reactive oxygen species) (Schulte *et al.*, 2010). A generic mass-based approach was published by Pauluhn (2011), suggesting to derive a DNEL for MNMs based on the 'overload hypothesis', stating that the particle displacement volume is the critical effect for lung toxicity.

*Pragmatic approach.* MNMs are often characterized by large deficiencies in hazard data, and thus safe exposure levels cannot be determined (Schulte *et al.*, 2010). There is growing evidence that the surface of the NPs seems an important trigger for the toxic effect (Abbott and Maynard 2010; Aschberger and Christensen, 2011, Ramachandran *et al.*, 2011), which indicates that the particles' number concentration seems to be a better metric for potential risks than the conventionally used mass-based approach. When there are large deficiencies in hazard data, NIOSH cites the use of qualitative control-banding methodologies for which several suggestions have been made (see Introduction) as an alternative for the OEL/REL approach for MNMs. This is also in line with the preferred approach in the UK as explained by Cherrie. He reflected on the approach of the British Standard Institute (BSI), who as a forerunner of the NRVs developed the idea of guidance values for nanomaterials, derived from existing OELs for coarse materials (BSI, 2007). This BSI approach was opposed by the HSE working group on action to control chemicals (WATCH) because in its opinion the meaning of benchmark exposure levels and their regulatory significance could be easily misinterpreted. WATCH prefers the gathering of exposure measurements for MNMs and focusing on principles of good control practices.

Table 2. NP number concentration for a mass concentration of 0.1 mg m$^{-3}$

| Name | Density (kg m$^{-3}$) | NP (cm$^{-3}$) | | | |
|---|---|---|---|---|---|
| | | *d* = 20 nm | *d* = 50 nm | *d* = 100 nm | *d* = 200 nm |
| CNT, commercial product | 110 | 217 029 468 | 13 889 886 | 1 736 236 | 217 029 |
| Polystyrene | 1050 | 22 736 420 | 1 455 131 | 181 891 | 22 736 |
| CNT | 1350 | 17 683 883 | 1 131 768 | 141 471 | 17 684 |
| Fullerene ($C_{60}$) | 1650 | 14 468 631 | 925 992 | 115 749 | 14 469 |
| Typical respirable dust | 2500 | 9 549 297 | 611 155 | 76 394 | 9549 |
| Titanium dioxide | 4240 | 5 630 481 | 360 351 | 45 044 | 5630 |
| Zinc oxide | 5610 | 4 255 480 | 272 351 | 34 044 | 4255 |
| Cerium oxide | 7300 | 3 270 307 | 209 300 | 26 162 | 3270 |
| Iron | 7874 | 3 031 908 | 194 042 | 24 255 | 3032 |
| Silver | 10 490 | 2 275 809 | 145 652 | 18 206 | 2276 |
| Gold | 19 320 | 1 235 400 | 79 083 | 9885 | 1236 |

Berges explained the pragmatic approach that was developed by IFA, the German Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA, 2009), to derive particle number–based benchmark levels for four groups of nanomaterials. IFA used size, form, biopersistence, and density as parameters to distinguish the groups. For the granular nanomaterials its aim was to establish a number-based benchmark with a mass concentration of maximum 0.1 mg m$^{-3}$. On the basis of the assumption that the granular particles have a sphere-like shape, for particles of different diameters, IFA calculated the number of particles per cubic centimetre that correspond to this mass concentration (see Table 2).

IFA divided the granular nanomaterials into two groups, one with a density >6000 kg m$^{-3}$ and the other with a density <6000 kg m$^{-3}$, and established benchmark levels for these groups as 20 000 and 40 000 particles cm$^{-3}$, respectively. From a mass-based point of view this means that for smaller nanomaterials the benchmark level for granular materials is stricter. For CNTs, IFA took the precautionary stand that for those CNTs that possibly exhibit asbestos-like effects, the use of the asbestos OEL as a benchmark level might be appropriate. At present, however, monitoring of the above value in plants is hampered by a lack of collection methods of verified suitability, corresponding analysis methods, and criteria for counting the fibres and determining the fibre count concentration. For soluble and non-biopersistent NPs a benchmark was assigned according to the applicable OEL for the coarse (or molecular) form because regarding hazard, these particles are supposed to behave like 'conventional' substances.

*Application of the precautionary principle in the Netherlands.* As explained by W.-H.S. and W.v.V., the Dutch employers' organization and trade unions have developed NRVs, building on the work of IFA. They acknowledge that when reliable data are missing and uncertainty prevails other tools are necessary to allow industry to use nanomaterials and to make acceptable risk assessment. W.-H.S. and W.v.V. advocate that alternative tools must be practical but transparent and trustworthy as well. This calls for close cooperation of workers' and employers' organizations on these matters, as was realized in the joint advice for safe working with nanomaterials at the workplace (SER, 2009). This cooperation has led to the derivation of NRVs, which provides the employer with a provisional limit value when airborne NPs may be generated at the workplace.

The IFA-benchmark levels were evaluated in the Netherlands by a group of experts (Dekkers and de Heer, 2010) and further developed by a coalition of trade unions and employers' organizations in the pilot NRV (van Broekhuizen *et al.*, 2011, 2012; P. van Broekhuizen and B. Dorbeck-Jung, in preparation). The NRVs were made part of the precautionary approach as developed in the advice of the Social Economic Council (SER, 2009). The following scheme for recommended NRVs (as 8-h TWA) was adopted (SER, 2012) (see Table 3).

NRVs are established as provisional limit values that are to be replaced by HBR-OELs or DNELs as soon as these become available for the specific NPs or for groups of NPs. NRVs are intended to be a warning level: when they are exceeded, exposure control measures should be taken. They are defined for MNMs as a background corrected 8-h TWA exposure level. With reference to the Dutch Labour Conditions Act, the Dutch Government states that they regard the provisional NRVs as the best available science and state-of-the art approach for risk

Table 3. NRVs for four classes of MNMs

| Class | Description | Density | NRV (8-h TWA) | Examples |
|---|---|---|---|---|
| 1 | Rigid, biopersistent nanofibres for which effects similar to those of asbestos are not excluded | — | 0.01 fibres $cm^{-3}$ | SWCNT or MWCNT or metal oxide fibres for which asbestos-like effects are not excluded |
| 2 | Biopersistent granular nanomaterials in the range of 1–100 nm | >6000 kg $m^{-3}$ | 20 000 particles $cm^{-3}$ | Ag, Au, $CeO_2$, CoO, Fe, Fe*x*O*y*, La, Pb, $Sb_2O_5$, $SnO_2$ |
| 3 | Biopersistent granular and fibre form nanomaterials in the range of 1–100 nm | <6000 kg $m^{-3}$ | 40 000 particles $cm^{-3}$ | $Al_2O_3$, $SiO_2$, TiN, $TiO_2$, ZnO, nanoclayCarbon black, $C_{60}$, dendrimers, polystyreneNanofibres with excluded asbestos-like effects |
| 4 | Non-biopersistent granular nanomaterials in the range of 1–100 nm | — | Applicable OEL | e.g. Fats, NaCl |

SWCNT, single-wall CNT; MWCNT, multi-wall CNT.

assessment of nanomaterials (Atsma, 2009; Donner, 2010).

## FORUM DISCUSSION

The introductory presentations were followed by a general discussion between the forum (with participation of van Well, P.v.B., P.S., Costa-David, and Cherrie chaired by L.R.) and the audience. The forum accepted the metric based on particles per cubic centimetre for the NRVs. With regard to the setting of a limit value for nanotubes in general, the forum welcomed the suggestion not to limit the first group of NRV scheme to CNTs only but to extend this group to all rigid biopersistent fibres in general. This choice reflects better the analogy of nanotubes with asbestos-like behaviour. P.S. indicated that this is a precautionary approach, but it may be difficult to count fibrous MNMs in 'bird-nest' agglomerates.

With regard to the definition of the size of nanomaterials in the NRV concept, there was agreement in the workshop that workplace risk assessment of NPs should take into account particles and agglomerates with a diameter >100 nm as well. Setting boundaries to the diameter of nanomaterials was argued to be preferentially practical, leading to a suggestion to take an upper limit of ~300 nm into account. This limit cannot be substantiated by scientific arguments favouring a cut-off point for 'nanohazard' [as was also discussed by Lidén (2011)], but practical arguments, e.g. existing upper detection limits of available measurement equipment were used. The physical transport behaviour in air was brought forward as an argument not to establish a limit >200 nm. The recommendation of the European Commission (EC, 2011), aiming to set a clear definition for nanomaterials for legislative purposes, sets the upper diameter limit for nanomaterials at 100 nm (for 50% of the particles in the material). The EC emphasizes that there is no scientific evidence to support the appropriateness of this value in view of hazard and that the use of a single upper limit value might be too limiting for the classification of nanomaterials and a differentiated approach might be more appropriate. The choice to bring the concept of NRV scheme (see Table 3) in line with the European definition for nanomaterials must be seen against this background. In practical situations, 'larger' structures (agglomerates and aggregates) of primary particles of <100 nm may have to be taken into account for risk assessment.

With regard to the idea to set, in addition to the 8-h TWA, a standard for short-term peak exposures to nanomaterials, the forum almost unanimously took a critical stand. P.S. pointed at spikes that may occur while opening a reactor vessel and stated that these incidents should not be ignored in risk assessment. But he emphasized that this does not legitimize the development of a separate standard for these short-term peaks. Berges also criticized the idea, based on the fact that effects of short-term peaks for particulate exposure cannot be substantiated by toxicological knowledge. A toxicologist from the audience reflected at the slow processes in the lung so as to argue not to take peaks into account in the assessment of risks by NPs. L.R., in contrast, reflected on the evidence that short-term peaks of ultrafine particles in ambient air could be associated with cardiovascular effects. The panel agreed to dismiss the approach as proposed for momentary peaks (lasting only a few seconds): $NRV_{peak}=10 \times NRV_{8\text{-h TWA}}$. On the other hand, the proposal to use the 'rule of thumb' as used in chemical risk assessment for exposure to NPs over a 15-min TWA period, $NRV_{15\text{-min TWA}} = 2 \times NRV_{8\text{-h TWA}}$, found considerable support in the forum. For risk management a NRV over a 15-min period seems a useful tool as argued by Berges and van Well.

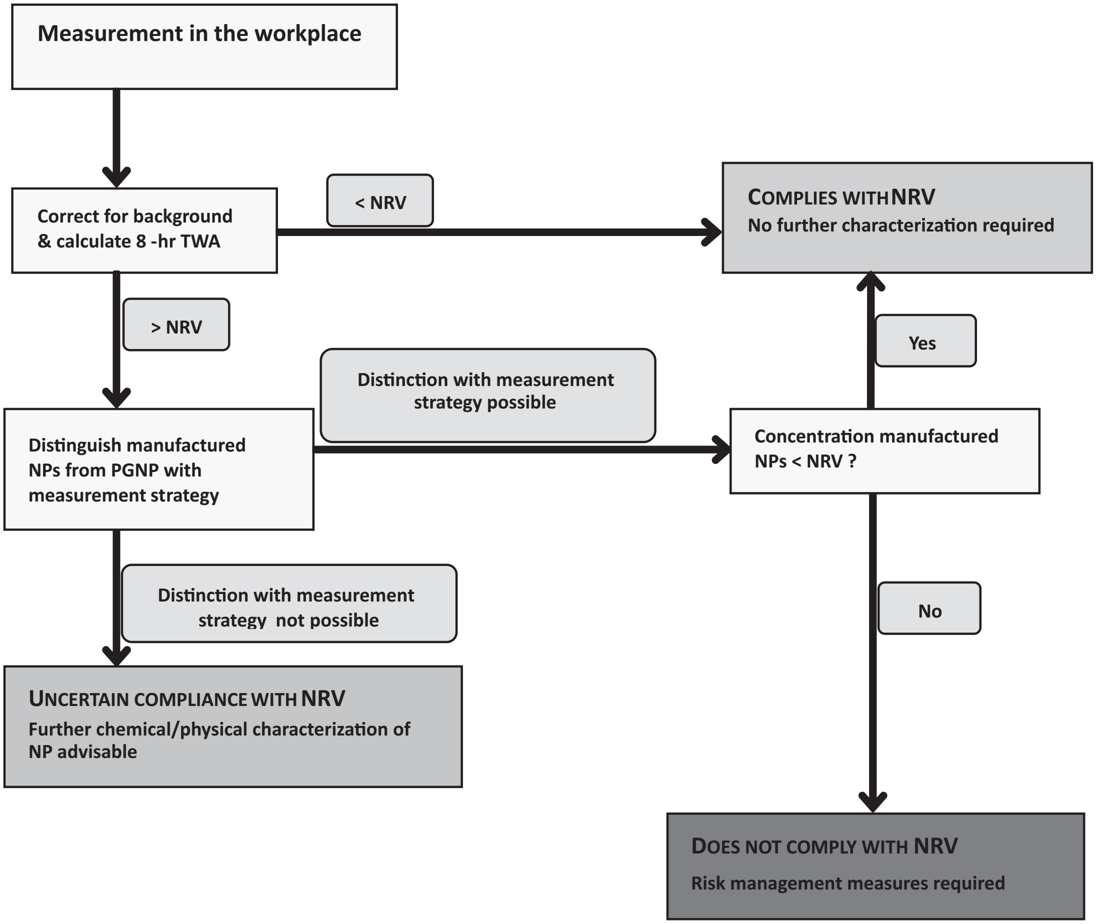


**Fig. 1.** Traffic light scheme for characterizing NPs and use of NRVs (in colour in the online edition).

*Process-generated NPs*

A complication for measurement of NPs at workplaces is that electrical machines and heating and combustion processes may generate process-generated NPs (PGNPs) that may contribute substantially to the nanoparticulate pollution in the workplace air. Additionally, certain conventional compounds used at some workplaces may contain as well a nanoparticulate fraction that may contribute to the total concentration of NPs in the workplace air (van Broekhuizen *et al.*, 2012). PGNP adds to the total exposure to NPs (Donaldson *et al.*, 2005; BéruBé *et al.*, 2007; Evans *et al.*, 2008; van Broekhuizen *et al.*, 2012). It is likely that PGNPs will agglomerate with airborne MNMs, making the 'simple' use of NP-specific OELs (when available) questionable. A strategic scheme for comparing measured workplace NP concentrations with the NRVs is presented in Fig. 1.

The need to prevent the formation and emission of PGNPs was recognized as an issue of high importance by the forum. Although the formation of PGNPs is well known from welding and from diesel exhaust particulates, formation by other common sources (such as electromotors) has so far often escaped the attention of risk assessors. Costa-David from the EC and Berges from IFA stated that PGNP preferably needs a separate policy approach and emphasized that they should not be mixed up in handling MNMs. They emphasized that the choice to consider both sources in a combined approach is a political one. Cherrie and P.v.B. argued that the choice to take both sources, PGNPs and MNMs, into consideration is a correct one in dealing with potential hazards. This approach would also simplify a practical assessment.

It was emphasized that harmonization of measurement strategies for exposure to MNMs is a topic of high priority. Initiatives were discussed earlier in the workshop on harmonization strategies to measure and analyse exposure to (manufactured) nano-objects in the workplace air (Brouwer *et al.*, 2012).

*Precautionary principle*

The importance of using the precautionary principle within the frame of MNMs, with limited hazard and exposure data and uncertain risks, was emphasized by all speakers. Speakers for the employers' organizations explained their leading policy principle: a minimization of all exposures to airborne MNMs and as such for the industry to adopt a proactive attitude and also to take care of a transparent communication on the use of MNMs. Both the Dutch trade unions and employers' organizations emphasized the need for pragmatism in risk management and recognized the fact that precaution means that policy measures must be comprehensible and easy to use for the users of MNMs and nano-functionalized products. It is their opinion that where possible the exposure control measures must be scientifically underpinned, preferably health based. But they acknowledge that waiting for OELs or DNELs until enough evidence is available is not the appropriate way and that they themselves have the responsibility to bring the precautionary approach into practice. However, the ideas on how to make the precautionary principle operational for the workplace vary widely. Trade union groups from France and the UK, for example, take the stand that uncertainty concerning hazard of nanomaterials unambiguously leads to a policy focused on zero exposure. According to these trade unions exposure higher than zero is unacceptable, and so is the NRV approach because a low exposure is accepted. Substitution should be leading, which in case of the use of nanomaterials could be, for example, the selection of materials with a coating of low toxicity, functionalized to avoid the dustiness, or applied in a non-dispersive matrix. P.S. made a critical note by stating that although we know little about the actual toxicity of nanomaterials, we know quite well how to control exposure. And knowing this we must question ourselves what risks we are willing to take, given the benefits the materials may bring. What we clearly do not want according to P.S. is to lay the burden on the shoulders of the workers. And as Costa-David added, precaution is not identical to prevention. Precautionary action is indicated where risks are unknown but likely, whereas prevention is indicated where risks can be qualified and quantified and as a consequence focused measures can be designed.

*Attitudes towards NRVs*

As pointed out by P.v.B. and Dorbeck-Jung, one of the findings of the pilot NRV (van Broekhuizen *et al.*, 2012; P. van Broekhuizen and B. Dorbeck-Jung, in preparation) is that Dutch professional users of MNMs involved in the pilot NRV take a proactive stance and accept to use NRVs based on the perception of usefulness, motivated by the idea that these provide certainty, create trust among workers, and may forestall overregulation. Some doubts and disengagement were ventilated by one of the companies as well about the necessity to use NRVs, especially when exposures to MNMs are shown to be very low. With regard to the ability to use NRVs in practice, it was shown in the pilot NRV that the NRV concept is comprehensible, but it is questionable whether companies always have the right understanding of how to relate NRVs to the MNMs, the background concentrations, and the PGNPs at the workplace. The need to carry out (or to commission) workplace measurements is experienced as a burden, especially regarding the costs to be made. The results of workplace measurements of concentrations of airborne NPs, as carried out in the pilot NRV and presented in the workshop, did show that the concentration of MNMs is generally low, and that conventional fine dust control measures taken at the workplace are generally efficient to control MNMs compared with the advised NRVs (van Broekhuizen *et al.*, 2012). The pilot NRV showed as well that use of NRVs in risk assessment was not restrictive for most of the assessed workplaces. But, as stated by the social partners as well as by the company representatives, recognition of the NRVs by governmental institutions, especially by the labour inspectorate, will stimulate their use in practice.

*Lack of information*

The lack of information on the presence of MNMs in products and their possible release during use at the workplace was brought up by the audience as an important issue relating to risk management. The first step in risk assessment is to get information about the type of nanomaterials to which exposure is possible. In spite of some good intentions from the manufacturing industry to supply required information, much of the information is lost along the production chain, resulting in largely uninformed end users. According to P.S., this limits the usability of NRVs (because some users may be simply unaware whether they actually use or are exposed to MNMs). P.S. argued in favour of a broad activity to develop 'good practices' in which exposure measurements show acceptable working situations. Comprehensible guidance documents, to guide the safe working with nanomaterials, are thought to be useful tools as well to support SMEs and workers in risk management. Quite a number of guidance documents on safe working with nanomaterials have been published (Paik *et al.*, 2008; Schulte *et al.*, 2008; Höck *et al.*, 2011; ANSES, 2010; Cornelissen *et al.*, 2011; van Duuren-Stuurman *et al*. 2012). Reference was also made to the SDS (safety data sheet) of products along which line more information on nanomaterials in products might come available. It is foreseen that a new adaptation of the SDS format, with respect to the reporting of some NP-specific data, will provide more information about nanomaterials used in the product (ECHA, 2011).

### *Soft or hard regulation?*

A critical remark from the audience pointed at the experience of trade unions that guidance documents may be readily available in practice, but that these are generally poorly used. For 'nano' their expectance is not much better. This view has been confirmed by Engeman *et al.* (2012) in a study of company practices in 14 countries worldwide. Engeman *et al.* (2012) identified a lack of information as an impediment to implement nano-specific health and safety practices and found that companies were not taking advantage of widely available government guidance documents. The neglect of guidance documents was argued to call for more awareness of users of nanomaterials and an enhanced activity of enforcement authorities (like the labour inspectorate) to enforce the use of legal instruments. Dorbeck-Jung stated that there is a legal obligation for manufacturers and suppliers to provide proper health and safety tools but that the development of precautionary guidance tools, like the NRV, so far is considered to fall within the domain of soft law. It is, therefore, questionable whether their use can be enforced within existing legislation that does not recognize the notion of precaution as a basis of risk management. This shifts the initiative to the social partners, trade unions, and employers' organizations to take the responsibility to put this issue on the political agenda. Here, however, the trade unions' preference for binding legislation meets the preference of employers' organizations for a soft law approach. Costa-David suggested that the NRV could be referred to in the ongoing initiative of DG Employment that studies the extent to which OHS legislation gives, and should give explicit, attention to nanomaterials, and also in the European guidance for safe working with nanomaterials.

## CONCLUSIONS

The precautionary NRV is thought to be a comprehensible and useful risk management tool as long as health-based OELs for MNMs are not available. Other sources at the workplace may generate (non-manufactured) NPs as well, and these may complicate exposure control measurement. An appropriate measurement protocol should be used to distinguish the MNMs from the PGNPs. It is advisable to develop a policy approach for these PGNPs as well.

A strong political support to actively use the NRV is essential. The deliberative setting of the Dutch SER where employers' organizations discuss occupational health issues with trade unions proofed to be a successful structure to provisionally repair the gap in the standard setting for MNMs. A broader awareness-raising campaign to explain the benefits of this tool for risk management may help further acceptance. Governmental acknowledgement should especially be reflected in the recognition of the labour inspectorate of NRVs as a provisional risk management tool.

## EPILOGUE

Motivated by the positive outcome of this international workshop, the Dutch SER formulated its advice to the Dutch Minister of Social Affairs in March 2012 to accept the NRV as a provisional risk management tool for MNMs at the workplace. It advised to set up an active awareness campaign to draw attention to this tool and to actively stimulate the use of NRVs by companies. The SER also advised the minister to examine whether it is possible to develop a generic health-based OEL for PGNPs (SER, 2012).

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