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Exposure Limit Values for Nanomaterials – Capacity and Willingness of Users to Apply a Precautionary Approach

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Exposure Limit Values for Nanomaterials – Capacity and Willingness of Users to Apply a Precautionary Approach

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ABSTRACT
In the European Union, the legal obligation for employers to provide a safe workplace for processing manufactured nanomaterials is a challenge when there is a lack of hazard information. The attitude of key stakeholders in industry, trade unions, branch and employers’ organizations and governmental policy advisors towards nano reference values (NRVs) has been investigated in a pilot study, which was initiated by a coalition of Dutch employers’ organizations and Dutch trade unions. NRVs are developed as provisional substitutes for health-based occupational exposure limits (OELs) or derived no-effect levels (DNELs) and are based on a precautionary approach. NRVs have been introduced as a voluntary risk management instrument for airborne nanomaterials at the workplace. A measurement strategy to deal with simultaneously emitting process-generated nanoparticles (PGNP) was developed, allowing employers to use the NRVs for risk assessment. The motivational posture of most companies involved in the pilot study appears to be pro-active regarding worker protection and acquiescent to NRVs. An important driver to use NRVs seems to be a temporary certainty employers experience with regard to their legal obligation to take preventive action. Many interviewees welcome the voluntary character of NRVs, though trade unions and a few companies advocate a more binding status.

KEY-WORDS: Nanomaterials, precautionary approach, Nano Reference Values, Occupational Exposure Limits, Soft Regulation

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INTRODUCTION
The Chemical Agents Directive \(^1\) lays down the minimum requirements for protecting workers from the adverse effects of chemical agents that are present at the workplace, or as a result of any work activity involving chemical agents. In principle these minimum requirements regard nanomaterials as well. Dutch employers are required to assess the risks and control them \(^2\). In the case of nanomaterials for which toxicology information is lacking \(^3\), producers and users of nanomaterials are required to proactively obtain state of the art knowledge about managing exposure and health risk. Considerable gaps exist regarding hazard data and occupational exposure limits (OELs) for nanomaterials. To date attempts have been made to derive health-based limit values for only several frequently used manufactured nanomaterials (MNMs): for carbon nanotubes (MWCNT) \(^4,5,6,7\), for fullerenes (C60) \(^8\), for TiO\(_2\) \(^9,10\) and for nano-Ag \(^5\). However, a derivation of an OEL requires large amounts of toxicity data. It is complicated and expensive. Note that the term MNM is synonymous with the term engineered nanoparticle (ENP) as used by other hygienists. The composition of MNMs may be complex, being for example a multi-component material (e.g. with a surface coating of another composition or a material with specific active sites at the surface) and having a large particle size distribution with a possibly different hazard for different sizes \(^11,12,13\). The workplace air may also contain incidental nanoparticles that are generated by electrical equipment, or heating or combustion processes. In risk assessment these process-generated nanoparticles (PGNPs) and agglomerates thereof with MNMs have to be taken into account as well. In view of a lack of data a precautionary approach has been advocated \(^14,15\).

As a provisional alternative to OELs the German Institute for Occupational safety and Health (IFA) has developed benchmark levels for evaluating exposure to MNMs \(^16\). The benchmarks draw on the finding that the surface of the nanoparticles is an important determinant of hazard \(^17,18,19\), and use size, form, biopersistence and density as parameters to distinguish four groups. For low density (<6,000kg/m\(^3\)) and high density (>6,000kg/m\(^3\)) granular nanomaterials, with a supposed sphere-like shape (diameter <100nm) number-based benchmarks were established corresponding to a mass concentration of 0.1 mg/m\(^3\). For carbon nanotubes (CNTs) which possibly exhibit asbestos-like effects the asbestos OEL is used as a benchmark level. The fourth group regards non-biopersistent nanomaterials. These benchmarks were further developed as nano reference values (NRVs) by social partners in the Netherlands \(^20,21,22,23\). The four classes of NRVs (8-hours time-weighted average; 8-hr TWA), as adopted by the Dutch Social Economic Council in 2012 \(^24\), are shown in Table 1.
NRVs are intended to be precautionary warning levels: when they are exceeded, exposure control measures should be taken. As such, they support compliance with the legal duty to control the health risks of MNMs. Use of NRVs requires measurement of the particle concentration and diameter and requires limited information about the identity of the processed (and measured) MNMs. For identification information is required regarding the shape of the MNMs (fiber or sphere-like shape), its biopersistency and information on the density of the nanomaterial.

NRVs presently are not legally binding. By regarding NRVs as part of the current state of science the Dutch Minister of Social Affairs and Employment has recommended to use NRVs as provisional limit values that should be accompanied by additional measures to minimize exposure \(^{(25,26)}\). The Minister’s recommendation can be regarded as a ‘soft’ regulation \(^{(27,28)}\). Although not legally binding, this regulatory measure involves certain commitments either to employ the NRVs or to search for alternatives.

In 2010 the Dutch social partners initiated a pilot study to investigate whether NRVs are accepted in practice and how relevant actors perceive their usefulness. One of the goals was to explore whether producers and users of nanomaterials are capable and willing to use NRVs. Such information can inform further regulatory action.
METHODS

The potential of compliance with the NRVs in the Netherlands was studied in a pilot in whom the nanomaterials using industry was involved. Workplace concentrations of nanoparticles (NPs) (and simultaneously their diameter) were measured and compared with NRVs. The results thereof are published elsewhere (21). The measurements were followed by in-depth interviews with representatives of the involved companies (who were previously informed about the results of the measurements) and with representatives of trade unions, branch organizations, and governmental authorities to get insight into perceived feasibility and advisability of the use of NRVs, as well as into activities and ideas to stimulate compliance. The topics of the interviews covered the issues of the requirements of rule compliance, according to the analytical framework that has been developed in regulatory governance studies to get insight into effectiveness issues of soft-regulation that is established to comply with legal obligations (29,30,31,32,33, 34,35). Governance studies suggest that the successful use of soft regulation in the case of the NRVs first depends on the preconditions of appropriate and easily available measurement strategies at low cost, as well as on adequate information supply about nanomaterials used in products and their possible release during intended use. Second, the potential users of NRVs must know the rules, have a correct understanding of them and have financial resources to employ NRVs. Third, the value of NRVs in practice depends on the willingness of companies to employ them. Willingness builds on ideas on the usefulness of the NRVs, the interests of the companies to use the NRVs, and the compliance culture of the company and the social responsibility within the industrial sector. It builds also on, the available sanctions, pressures/binding force and incentives and pro-active and knowledgeable oversight and enforcement.

Candidate companies were selected based on the MNMs they used. The MNMs had to be biopersistent and insoluble, and present on the OECD list of manufactured nanomaterials (36). The companies included manufacturers and users of products containing MNMs, and small to large companies. Low priority was given to the involvement of raw nanomaterial producers, because these appear not to be a key industry in the Netherlands. Involvement of R&D institutes had also a low priority, because these institutes were subject to an earlier study indicating a generally use of small amounts of MNMs and a potentially low exposure (37). Sixty candidate companies were identified, of which 26 were approached and 12 agreed to participate. Some companies refused cooperation without giving a reason or based on their own assessment of low MNMs’ exposure risk (23%). Two companies not using MNMs were included to provide some information on nanoparticulate emissions generated by during conventional activities. Measurements were carried out in 12 companies (Table 2).

In-depth interviews were carried out with representatives from the companies involved (see Table 2), with representatives of R&D institutions involved in health & safety management, with key persons from branch organizations and with governmental authorities. The companies’ interviewees generally were experts involved in health & safety management. In a few cases they were part of the companies’ management board. For the branch organizations and trade unions health & safety policy advisors were interviewed. Interviewed governmental authorities were involved in regulating chemical substances (and
nanotechnologies). In total 25 interviews were carried out. Table 3 gives an overview of the interviewees.

**Table 2**
**Selected companies for measurement of airborne NPs**

<table>
<thead>
<tr>
<th>Type of Industry</th>
<th>Nr</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D, Innovation support</td>
<td>1</td>
</tr>
<tr>
<td>Paint, coating manufacturer</td>
<td>4</td>
</tr>
<tr>
<td>Glass industry</td>
<td>1</td>
</tr>
<tr>
<td>Electronic industry</td>
<td>1</td>
</tr>
<tr>
<td>Transport industry</td>
<td>1</td>
</tr>
<tr>
<td>Construction industry</td>
<td>1</td>
</tr>
<tr>
<td>Metal/machine industry</td>
<td>2</td>
</tr>
<tr>
<td>Service industry</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>12</td>
</tr>
</tbody>
</table>

**Table 3**
**Characterization interviews**

<table>
<thead>
<tr>
<th>Background interviewee</th>
<th>Nr</th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D organization</td>
<td>3</td>
</tr>
<tr>
<td>Company large</td>
<td>5</td>
</tr>
<tr>
<td>Company SME</td>
<td>7</td>
</tr>
<tr>
<td>Branch organization</td>
<td>2</td>
</tr>
<tr>
<td>Employers’ organization</td>
<td>1</td>
</tr>
<tr>
<td>Trade union</td>
<td>3</td>
</tr>
<tr>
<td>Governmental authority</td>
<td>3</td>
</tr>
<tr>
<td>Labour Inspectorate</td>
<td>1</td>
</tr>
<tr>
<td><strong>total</strong></td>
<td>25</td>
</tr>
</tbody>
</table>

All participating companies and interviewees were informed about the concept of NRVs through an informative flyer, an introductory presentation by the study team, their involvement in measurements, the consequential reporting of the results and a discussion on the consequences with the research team.

**RESULTS**

Interviewees emphasize that NRVs are useful only if there is appropriate measuring equipment available. Workplace monitoring of nanoparticles’ concentrations and diameter was provided to the participating companies. For most interviewed companies the actual measurements in the pilot were their first structured activity to assess airborne nanoparticles at the workplace. Some interviewees believed that using a particles/m³ metric for airborne MNMs was not as informative for risk assessment as a mg/m³ metric.

Two interviewees stated it was difficult to distinguish airborne MNMs from nanoparticles in ambient air and nanoparticles generated by processes like combustion (or PGNPs). They conclude that NRVs are useful for workplaces that process pure MNMs. Two interviewees from a trade union and a branch organization suggest that extending the scope of the NRVs, to cover both MNMs and PGNPs, is an excellent idea. Their argument is that with the existing uncertainties on the toxicity of both MNMs and PGNPs, the use of a generic NRV covering both sources is appropriate. And, as one of the interviewees put it: “Adopting NRVs, to control both MNMs and PGNPs, is in line with a precautionary approach.”

Hazard identification is one of the key-issues for downstream users of products containing MNMs. In general, the end-user is not informed about a possible release of MNMs during intended use of the product. The interviewed Labour Inspectorate stated that 70% of
the upstream manufacturers do not inform the users of their products about the contained MNMs, because there is no requirement to do so [38]. The interviewees from the car repair industry state that downstream users, confronted with this lack of information, are forced to use a precautionary approach for all activities where airborne MNMs might be generated.

All of the company appeared to be well informed about existing chemicals legislation and workplace health and safety regulations [1,39]. They are acquainted with the concept of OELs. The company interviewees agreed that the legal duty means minimizing exposure to MNMs. They know as well that NRVs are considered to be measures of best practice. Some interviewees conclude that this implies that NRVs are binding, while others are not sure about the binding character.

One interviewee emphasizes the warning function of NRVs: “Their value lies in signaling the importance to handle nanoproducts with care”. Another company representative adds that NRVs helps risk management provided that exposure measurements can be carried out reliably. Most interviewees see a direct link between the legal obligation to provide a safe workplace and the use of NRVs. One interviewee summarizes: “NRVs are a good instrument to fulfill the duty of care responsibility, provided there is an efficient way to apply them in practice.” A representative of a trade union stated: “It is clear that the company has to substantiate their activities to control exposures. They have to prove that they take the new risks into account. The NRVs are perceived to be an excellent tool for this. According to another interviewee “NRVs are the latest state of the art of risk management and therefore it is the responsibility of the employer to act accordingly.” Some interviewees hold that additional measures to reduce exposure to nanomaterials at the workplace have to be taken when exposure measurement shows that the NRVs are exceeded. An interviewee from a branch organization notes that a role of the NRVs is to raise the awareness. He thinks that the usefulness of NRVs lies in anticipating coming legislation and mandatory information supply, and a stimulus to become active in relation to the REACH legislation and the safety data sheets (SDS).

All interviewees prefer to use OELs based on specific toxicological information for specific MNMs, but they are aware that it will take time before such OELs become available. They recognize that the use of NRVs is a provisional solution and that it is useful to “forestall/reduce fear of employees, industry and consumers.” The NRVs gives reassurance to the company that measures are adequate in view of the current state of science. One of the interviewees remarks that the OELs are limited just as the NRVs are limited because they also involve information gaps and uncertainty.

The impression of the research group during workplace visits [21] was, that source oriented exposure control measures in place, were often designed to control the emission of conventional substances. None of the companies involved had installed extra equipment to control NP emissions. One of interviewees stated that his company does not need additional control measures for working with MNMs, because their control measures for conventional hazardous substances (like abrasion dust, welding fumes, isocyanates and organic solvents) are thought to sufficient. On the other hand, one of the companies applies a precautionary
exposure control protocol for working with nanomaterials, including separate storage of nanomaterials, the use of additional personal protective equipment for the operations, the registration of personnel involved in working with MNMs, and indirectly as well the personnel involved in transport of MNMs and waste management.

Interviewees emphasize that the NRVs motivate a company to consider uncertainty in the degree of health risk posed by MNMs and stimulate a continuous efforts to reduce exposure. Yet, undesirable overprotection is also a concern. An end-user states that they may lead to unnecessary fears among the employees rather than reassurance. A plant manager remarked that overprotection (irrespective of the use of NRVs) may lead to eliminating the production process using MNMs.

In sum. The motivational posture of most of the interviewees (particularly producers) toward using the NRVs can be characterized as pro-active and acquiescent. Most of them see the usefulness of the NRVs in providing ‘temporary’ certainty, supporting the employer’s legal obligation to care and to take precautionary action, as well as anticipating coming legislation and process innovation. The usefulness is questioned by some end-users with critical remarks on over- or under-protection of the NRVs. They seem to take the attitude of compromise or disengagement.

With regard to social responsibility of the industry interviewees of the chemical and paint industry mention the European Commission’s Code of Conduct (EC-CoC) for responsible nanosciences and nanotechnologies research \(^{(40)}\) and the Responsible Care program of the chemical industry \(^{(41)}\). Companies of the chemical sector argue that a culture of responsibility has emerged on the basis of the Responsible Care program, which has been specified in company-specific CoCs that have been implemented and are controlled and enforced. They stress that the Responsible Care program covers all aspects of corporate responsibility and that there is no need for an additional CoC for nanomaterials and to implement the EC-CoC. Paint industry interviewees mention their “normal” safety, health and environment measures, referring to the policy to keep the components in the product and to prevent release into the environment. This holds as well for nanomaterials and is stimulated by the employers’ association and the trade unions. These organizations pro-actively provide on-line information and organize meetings with companies that use and produce nanomaterials. Furthermore, interviewees feel that the recommendations of the Dutch Social Economic Council \(^{(14)}\), the control-banding tool ‘Stoffenmanager’ \(^{(42)}\) and the Guidance working safely with nanomaterials and nanoproducts \(^{(43)}\) support the development of social responsibility.

With regard to sanctioning, rewarding and other issues of enforcement that can stimulate or hinder the use of NRVs, we draw on an activity that has been run by the Dutch Labour Inspectorate in 2011. \(^{(38)}\) This inspection of companies using manufactured nanomaterials concluded that 86% of the inspected companies pays no or too little attention to MNMs in their risk assessment. These companies were warned and committed to live up with their obligation. The Labour Inspectorate referred also to the Social Economic Council’s advice, to apply the precautionary principle when working with MNMs \(^{(14)}\). It advised to restrict exposure as much as possible and to use the Guidance for safe working with nanoparticles \(^{(43)}\), or a
control-banding tool for risk assessment and to guide risk management. Occasionally the inspectors referred to the NRVs as an optional instrument for risk management of MNMs. However, they doubted whether the Inspectorate has the legal right to enforce the use of NRVs (or other risk management measures) in the context of uncertain risks. They observed strong disagreement amongst Dutch lawyers on the question whether the Dutch Labour Law requires application of the precautionary principle. Due to these interpretation problems of the legal frame, inspectors seem to avoid referring explicitly to the precautionary principle. They rather tend to use the employers’ legal duty of care as an incentive for enforcement of employers.

DISCUSSION

The precondition regarding appropriate information supply is identified as an issue of major concern. Many professional end users seem to be poorly informed about the MNMs in the products they use and their possible release during intended use. At a majority of the inspected companies in the Netherlands MNMs are not taken into account, where mandatory risk assessments are made. The issue of hazard identification, the definition for nanoparticles and the question of what to communicate in the production chain should be addressed to allow for good governance. Within this frame of poor information supply, confidentiality about MNMs used in the products and insufficient knowledge about NPs’ release and possible adverse effects, the NRVs may also be a useful tool for the employer to inform the workers about the potential exposure to NPs (MNMs + PGNPs) and to explain in what way the risk management measures take this source into account.

The matter whether NRVs can easily be applied in regulatory practice, emerges particularly in view of their provisional and pragmatic character and the consequential necessity to consider additional control measures, even if exposure remains below the NRVs. Important in this respect is also that the level of the NRVs was shown to be significantly lower than mass-based proposals for OELs for MNMs. The simultaneous generic assessment of MNMs with PGNPs (simply as particle number concentration), as advocated in the pragmatic measurement strategy from the SER (see Figure 1), accepts as a consequence even lower levels for MNMs. But not withstanding the precautionary approach, a guarantee for an absence of health risks below the NRVs cannot be given. As such, NRVs may be regarded as providing temporary certainty. A precautionary approach implies as well an incentive to stimulate research, to find out under what conditions and to what extent exposure to specific MNMs is acceptable. Such research however may take time in view of the pace of toxicological research on nanomaterials and the fundamental emerging questions in the development of the “new” discipline of nanotoxicology.

An unambiguous acceptance of the NRV-concept by relevant authorities may solve remaining uncertainties. In this respect, international recognition, as reflected by the discussion in the international workshop on NRVs in The Hague 2011 and the recognition of the NRV concept as an “overarching principle” for risk management at the 7th Joint EU/US Conference on
Occupational Safety and Health in Brussels 2012 (47), is a step in that direction. This overarching principle states: “In case exposure limit values are not available for specific nanomaterials a precautionary approach should be applied - generic nano reference values should be considered as a tool for setting provisional limits”.

Figure 1. Strategy for workplace assessment of nanoparticles and use of NRVs

With regard to the willingness to use NRVs, participants of the Dutch Pilot accept that for risk assessment and management of nanomaterials, sometimes non-preferential provisional choices have to be made. The particle number concentration is at variance with the usually mass-based OELs (17,18,48,49), and requires a change of “mind-set”. A change of “mind-set” is also needed for acceptance of the precautionary approach used for NRVs, though it may be noted that precautionary NRVs, as advised by employers’ organizations and trade unions, are perceived as important. However, it might as well be that the provisional and voluntary character of the NRVs, is experienced as less of a threat, which would be in line with findings of Engeman et al (50), who find that an industry may identify the lack of regulation as a problem due to mistrust regarding responsible behavior of other industry. The voluntary character of NRVs is welcomed as well by governmental policy makers since this characteristic assures that it does not interfere with principles used in existing OHS-regulation, being based on health or risk considerations. A reason for the easy acceptance of NRVs might also be the finding that 8hr-TWA exposures to airborne MNMs, as measured in the accompanying pilot project,
generally remain below the NRVs, if conventional risk management measures are used (20). For companies these are reassuring findings. The pre-existing knowledge of the interviewed persons regarding the feasibility of applying NRVs without further organizational or risk management consequences, might lead to a bias favoring acceptance of the concept.

Experience of the labour inspectorate shows that active enforcement is an important driver to use supplied risk management tools as the NRV and the control banding tools. Contrasting findings regarding a pro-active attitude of well-informed industry are published by Engeman et al. (50). These authors conclude that risk perceptions and safety practices are narrow and inconsistent and that because health and safety guidance is not reaching industry a mandatory approach may be the needed. Regarding the interest of companies to forestall more regulation, regulators could clarify that they are forced to come with top-down measures if NRVs, or well-underpinned alternative measures to safeguard occupational health and safety, are not used in the work with nanomaterials.

CONCLUSION
This small pilot study found that most companies working with nanomaterials accept NRVs as a tool to minimize possible adverse health effects among employees. Companies tend to be pro-active and acquiescent toward using the NRVs for risk assessment and management. An important driver to employ NRVs seems to be a temporary certainty employers experience with regard to their legal obligation to take preventive action. A contribution to the positive attitude of companies towards the NRV may be as well the reassuring finding that conventional exposure control measures are generally adequate as well to control airborne MNMs. Although many of the interviewees welcome the voluntary character of NRVs, trade unions and a few companies advocate stronger regulation. Regulators are recommended to take account of technology-related preconditions to compliance, like appropriate and easy available measurement strategies at low cost; appropriate information supply about nanomaterials used in products and their possible release during intended use. The NRV pilot study shows how important these preconditions are for compliance.
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Sozuke Hanai, Norihiro Kobayashi, Makoto Ema, Isamu Ogura, Masashi Gamo, Junko Naganishi


