



APPENDICES



Ministerie van Sociale Zaken
en Werkgelegenheid

To the Chairman of the Working Conditions
Committee
of the Social and Economic Council of the
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Request for advice regarding dealing with nanoparticles

Dear Mr Linschoten,

I hereby request that you provide advice regarding what should be done, in an occupational environment, to deal with the uncertain risks associated with the use of nanotechnology, specifically working with persistent synthetic nanoparticles.

Prior to making this request, I commissioned a study by the Centre of Expertise on Life Sciences at Zuyd University on the measures taken by Dutch companies and knowledge institutions when working with nanoparticles, and the existing best practices. The various groupings within your Committee provided recommendations in the context of that study via the liaison group. I enclose the study report as an appendix to this request, asking that you take account of it when providing your advice.

Background

Potential opportunities and risks

“Nanotechnology” is the collective term for the relatively new disciplines that concern themselves with studying and manipulating particles at nanoscale. Nanoparticles have special mechanical, optical, electrical, and magnetic properties, which may differ significantly from those of “normal” materials made up of larger particles. The application of nanotechnology can offer major economic and societal opportunities. By 2014, a global market worth some 2000 billion euros is expected. Applications that can contribute to solving societal problems can be found, for example, in more efficient energy generation, the development of light and strong materials, and the more closely targeted administration of medication.

The special properties of nanoparticles do not only make them interesting as regards innovations, however, but may also create new risks when people or the environment are exposed to those particles.

Their small size and different properties (including high reactivity) means that they may be more harmful for people and the environment than larger forms of the same chemical substance. Animal experiments have shown that certain nanoparticles can have harmful

effects. Existing tests to determine the risks posed by “ordinary” substances would not seem to be sufficient in the case of nanoparticles. There is however, a serious lack of knowledge regarding the risks. The Knowledge and Information Centre for Risks of Nanotechnology (*KIR-nano*) is expected to bring out its report *Nanotechnology in Perspective* [*Nanotechnologie in perspectief*] on or about 15 September. That report will give you an extremely up-to-date overview of the current knowledge (and gaps in knowledge) regarding the risks posed by nanoparticles.

Need for research

There will certainly continue to be gaps in our knowledge for years to come. There is expected to be progress quite soon as regards agreement on standards for definitions, but where measurement methods, standards, and possible toxicological effects are concerned, clarification is expected to take many years. In order to contribute to filling in these gaps, the Dutch Government has stated in its “Nanotechnology Action Plan”¹ that it intends investing more in risk assessment, reserving at least 15% of the total investment budget for this aspect. The Netherlands is also an active member of the OECD’s Working Party on Nanomaterials, which is working towards international coordination of the necessary research efforts. All this is intended to lead in the long term to filling in the gaps in our knowledge. The Netherlands is also contributing actively to a recently established EU working party that will advise on how the EU’s new REACH Regulation and its subordinate implementation instruments can guarantee the safe use of chemical substances at nanoscale. Here too, results are only expected to become available in the long term.

In the meantime – precautionary measures

Given the fact that the gaps in our knowledge regarding the risks can be expected to continue for some time – even though nanoparticles or products containing nanoparticles are already being used – it is an obvious step to take precautionary measures. In 2006, the Health Council of the Netherlands advised that precautionary measure should be taken when working with persistent synthetic nanoparticles.² The principle of precaution is also subscribed to in the letter that the Minister of Housing, Spatial Planning and the Environment, Jacqueline Cramer, sent to the Dutch House of Representatives in February 2008, also on my behalf.³

Given that safety at work is primarily a matter for employers and employees, I have notified

¹ Dutch House of Representatives 2007–2008, 29338, no. 75, 4 July 2008

² *Betekenis van nanotechnologieën voor de gezondheid*. The Hague: Health Council of the Netherlands [*Gezondheidsraad*] 2006: publication number 2006/06: “For persistent synthetic nanoparticles, the committee believes that it should be recommended that exposure in the workplace and emissions into the environment should be avoided, or at least minimised.”

³ Dutch House of Representatives, 2007–2008, 29338 no. 70, 14 February 2008: “In order to achieve this, an approach has been selected – in accordance with the policy on substances and the Government’s policy document ‘A Level-headed Approach to Risks’ [*Nuchter Omggaan met Risico’s*] – that can be characterised as dealing with nanoparticles in a sensible, careful, and cautious manner. This approach not only provides a general policy framework but also space for a more tailor-made approach. This may mean that for some applications of nanoparticles, for example in medicine, the result of consideration of the risks and benefits from the point of view of civil society will be different to that in the case of other applications. It is also possible that advancing scientific understanding will lead to certain applications being prohibited.”

you that I intend requesting your advice on the best way to go about this in actual practice. I requested Zuyd University to carry out a study in order to gain a better understanding of what Dutch companies are already doing and of the measures that are being taken and that could be taken.

Study by Zuyd University

Results

At least 400 people in the Netherlands are currently working with nanoparticles at knowledge institutions and producers and suppliers of nano-applications; this is particularly in the fields of surface treatments and coatings and research. Expectations are that that number will increase greatly within the next few years. The same applies to the as yet unknown number of professional users/downstream users of products created using nanotechnology. Nanoparticles that are used in great quantities include carbon black, amorphous silica, and a number of metal oxides; other nanoparticles encountered during the study are used on only a small scale. These include carbon nanotubes, nano-silver, and iron oxide.

Companies and knowledge institutes are in general aware of the potential risks and carry out a risk analysis; in only a minority of cases, however, is this required by the RI&E. Almost all companies and knowledge institutions (92%) take measures to restrict exposure. Specifically, ventilation and personal protection equipment are frequently used. Enclosed systems are used by 40% of the companies and knowledge institutions, more (or much more) by large companies and knowledge institutions than by small ones. The effectiveness of the measures taken was only studied in a limited number of cases by means of exposure measurements.

Information exchange within the chain (between the producer/supplier and the customer) about the risks of nanomaterials is inadequate, with some form of communication only taking place in half of cases. Safety information sheets generally give little or only insufficient information. Companies and institutions have a clear need for information regarding good practices when working with nanoparticles. According to the researchers, it is therefore vital for best-practice guidelines to be drawn up and communicated. They give an indication of the content of best-practices guidelines based on observations during their study and on various recommendations/guidelines that have appeared very recently. These comprise the following components:

- hazard assessment;
- choice of manifestation;
- identify and score tasks and actions, exposure scenarios;
- prevent exposure according to the occupational hygiene strategy, with a more stringent package of measures than in the case of larger particles;
- validation of the measures by means of exposure measurements;
- information and training;
- health monitoring.

The researchers also say that they believe that an independent, “virtual” centre of expertise can fill a need. They also consider it important for a database of companies to be created, with

this being used to disseminate knowledge and to keep track of matters.

The request for advice

This request for advice concerns how to deal with the uncertainties regarding the risks associated with nanotechnology, in particular with persistent synthetic nanoparticles, in an occupational environment.

For the moment, I am assuming the existing legislation and regulations in the field of working conditions. The fact that the Dutch legislation and regulations are to an important extent based on European legislation means that any necessary amendment or supplementation of that legislation and regulations will in my view need to take place primarily at European level.⁴ Like the Ministry of Justice, the Ministry of Social Affairs and Employment is aware of the possible necessity of amending or supplementing the relevant legislation and regulations. Supplementing (temporarily) the national legislation and regulations is not the preferred approach but – depending on the extent of the risks identified – is not entirely excluded.

1. Approach to precautionary measures

My basic position is that the Working Conditions Act [*Arbo-wet*] lays the responsibility for creating a safe and healthy workplace on the employer. The employer is required to ensure the safety and health of its employees as regards all aspects associated with the work. The employee has various responsibilities derived from this. If the employer does not shoulder its responsibility pursuant to the Working Conditions Act, the Labour Inspectorate can hold it responsible. Moreover, if an employee has sustained damage to his health as a result of exposure in the course of his work, the employer may be held liable for that damage under civil law. Whether an employer has failed to comply with its duty of care and whether it can be held liable for damage to an employee's health will be determined in the light of the knowledge available to the employer and the measures that it could take in the light of that knowledge. Pursuant to the Working Conditions Act, it is the current state of scientific knowledge that determines whether the employer can reasonably be required to put in place measures to prevent or restrict the possibility of damage to health.

The above also applies to working with nanoparticles. The provisions of the Working Conditions Decree [*Arbobesluit*] regarding working with hazardous substances (Chapter 4) apply. This means in any case that employers that produce or use nanoparticles or products containing nanoparticles are obliged to take account of the risks associated with possible exposure to nanoparticles in their RI&E (Section 4.2 of the Working Conditions Decree). Employers are also required to put in place measures to prevent or control exposure (Section 4.1(c) of the Working Conditions Decree) and employees who work with nanoparticles must also be given information and instructions regarding the associated risks

⁴ In a recent review by the European Commission of the European legislation and regulations, the Commission concluded that the existing regulations are sufficient but that they may need to be amended if scientific developments make that necessary (*Regulatory aspects of nanomaterials*, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, [SEC (2008) 2036]).

and the measures to be taken.

At the moment, the gaps in our knowledge mean that it is impossible to take measures that are *specifically* aimed at the risks; it is not possible, for example, to determine the safe level of exposure. In order to guarantee a safe and healthy workplace, some type of precautions will need to be put in place. In your advisory document *New Risks [Nieuwe risico's]*,⁵ you already indicated that it may be necessary to take precautionary measures in situations where we do not have sufficient knowledge regarding new risks but where there are well-founded misgivings regarding potential health risks. In the case of nanoparticles, these conditions have been complied with as indicated, for example, by the Health Council of the Netherlands.

- In the light of the above, I request that you indicate what precautionary measures the SER considers should be taken with regard to working with nanoparticles.

2. Best-practices guidelines

The researchers make recommendations as to the content of best-practices guidelines (Section 4.2 of their report). They consider that best-practices guidelines can clarify the measures that need to be taken. I believe that when the guidelines are published, the Labour Inspectorate can also take account of the provisions that they contain. If a health and safety catalogue is drawn up, it can serve as a frame of reference for enforcement, after being checked by the Labour Inspectorate. I would consider that to be a good development, fitting in with the responsibility of the social partners and with the basic principles of the new Working Conditions Act.

- Does the SER agree with the researchers that best-practices guidelines can create the necessary clarity, and if so, subject to what conditions?
- How do you believe the social partners should give expression to their responsibility in this regard?

In your advice, you can perhaps also take account of the ISO publication “Health and safety practices in occupational settings relevant to nanotechnologies” (ISO PRF TR 12885). (This is supposed to appear within the next two months).

3. Knowledge and knowledge dissemination

The Government’s Nanotechnology Action Plan assumes that there will be investment in risk assessment. This will help fill in gaps in our knowledge. But *disseminating the knowledge* that we do in fact have is important. At the moment, the Ministry of Social Affairs and Employment (via *KIR-nano* and the group of experts on working conditions set up by *KIR-nano*) is already facilitating the identification of risks in the context of the working environment and the dissemination of knowledge in that regard. Disseminating knowledge is naturally also very much a matter for the social partners. Businesses have their own responsibility to ensure that information regarding the risks and the measure to be taken is communicated to employees. Unions can ensure that information is provided for their

⁵*Nieuwe risico's*, SER, publication number 6, 17 May 2002

members. The Action Plan already points out that the Government considers it important that knowledge should be shared between companies, institutions, and the authorities, and that knowledge that is present in the chain should be passed on. The Action Plan also points out that the Government intends promoting such interaction. The Ministry of Social Affairs and Employment foresees a potential role for itself in bringing together the parties so as to exchange knowledge and/or arrive at agreements. The exchange of knowledge between various sectors can be encouraged, for example, and it might also be possible to support a platform/knowledge network for companies.

- Does the SER believe that extra efforts are necessary to ensure that there is sufficient attention and knowledge regarding the risks associated with nanoparticles and the way that those risks should be controlled in the workplace environment?
- If so, how should the social partners shoulder their responsibility in that regard?
- What should the specific role of the Ministry of Social Affairs and Employment be as regards disseminating knowledge?

Please take account of the recommendation by the researchers regarding setting up a centre of expertise and creating a database of companies.

Conclusion

Your advice is intended to make a major contribution to clarifying the precautionary measures that need to be taken. I wish it to be clear, and generally known, what the consensus is regarding how nanoparticles should be dealt with in the workplace for as long as we do not have sufficient knowledge to implement specific measures aimed at the associated risks. In this regard, clarity should ideally also take the form of concrete points of departure for employers and employees to determine that there is sufficient protection for the health of employees in situations where they are actually exposed to nanoparticles. This would also facilitate transparent enforcement by the Labour Inspectorate. As I have already indicated, it is not only clarity regarding the measures to be taken that is important but also clarifying and publicising the risks and measures.

I would be grateful if you could provide your advice in January 2009.

Yours sincerely,
The Ministry of Social Affairs and Employment,

(J.P.H. Donner)

Appendices:
Report *Dealing with Nanoparticles in the Workplace*
Cc:
House of Representatives

Dealing with Nanoparticles in the Workplace (abridged survey)¹

SUMMARY AND CONCLUSIONS

Applications of nanomaterials and more specifically, engineered nanoparticles, are expected to enable huge economic and technological possibilities. Nanotechnologies are being increasingly used in science and industrial development in widely different applications. Some of these special properties of engineered nanoparticles, in particular their reactivity, have raised concerns regarding human health. Due to these concerns scientists, regulators, and industry have initiated efforts to gain knowledge about worker exposure and to define safe uses of the different engineered nanoparticles. The definition of engineered nanoparticles, i.e. poorly biodegradable particles having a diameter between 1 and 100 nm and intentionally engineered, produced or applied because of specific properties, which may be based on shape, size, surface properties, or chemistry. For the purpose of our investigations these particles may be encapsulated in a matrix. The main objective of this investigation was to obtain an overview of the current best-practices, later redefined into good uses of engineered nanoparticles, and the associated occupational hygiene measures, instructions, communication in the economic chain and the disposal of nanoparticle-containing waste. The study was initiated and funded by the Ministry of Social Affairs and Employment and the Ministry of Housing and Spatial Planning and Environment.

Similar to other countries, it appeared very difficult to map institutions and companies that are active in Nanotechnologies. In this survey we approached 122 potential candidates, of which 62 were found to be not relevant to our studies since either they did not use engineered nanoparticles (n=42), or since they were not using these materials in a Dutch subsidiary (n= 8). Sixty candidates did meet the inclusion criteria, and 37 of that population participated in our interview based survey. Among these there were 26 companies and 11 academic or research organizations. The number of SME's was 11 out of 26 (42 %), containing both producers (n=5) and users (n=6). All companies were visited by the researchers, at which occasion an interview was completed and the facilities were visually inspected. This led to the following aggregated set of data on conclusions, ranked by original research questions.

Question 1: In which applications and industrial sectors are nanoparticles being used and how large is the group of potentially exposed workers?

The most frequent use of engineered nanoparticles were found in surface and coating technology (including inc and paints), and research applications are a good runnerup.

1 *Omgaan met nanodeeltjes op de werkvloer, Survey naar goede praktijken in omgaan met nanomaterialen in de Nederlandse industrie en kennisinstellingen. Paul Borm (Hogeschool Zuyd, Centre of Expertise in Life Sciences (CEL), Heerlen), Remko Houba (Arbo-unie, Expertise Centrum Toxische stoffen (ECTS), Roermond), en Fenneke Linker (DSM Arbodienst, Geleen).*

By far the most important application is in materials and material development (15/37). No responses were received that within the field of biotechnology. The nanoparticles that are used in the largest quantities (more than 10 tons/year) are carbon black, amorphous silica and alumina oxides. The use of other engineered nanoparticles (carbon nanotubes, nanosilver, iron oxides) was only in small quantities. Within the total worker population that is employed by all participants (n= 41.000), only 400 workers have a regular contact with nanoparticles. About half of these workers handle carbon black, amorphous silica and metal oxides or combinations thereof. In the academic and research sector a total of 137 was observed to handle many different nanoparticles in experimental stages. The amounts of these latter classes of nanoparticles do not exceed 1-100 grams/year.

Question 2: Which occupational hygiene measures are used by the participants in this survey to control exposure to nanoparticles?

There is a clear awareness of the potential risks of nanomaterials among the participants in this survey. Almost all (92 %) of participants performed or are in the process of performing a hazard and risk assessment analysis. However, in most cases this assessment is not included in the formal process to comply with Dutch law. Most companies and institutions (n=25, 68 %) have done this assessment on application level or responsible company unit. Five of these (25 %) indicate that they have not yet completed their judgment and the rest (75 %) has come to the conclusion that this procedure and measures fully covers the potential risks of exposure. Only 3 companies have done additional exposure measurements. Almost 25 % of all participants indicate that have a company policy to deal with potential exposure to nanoparticles. However, the content and background of the chosen policies differ widely, and seem to be based on 1) pre-emptive choice on specific nanoparticles, 2) the general exclusion or handling of nanomaterials as a toxic substance, 3) choices on the physical form of the nanoparticles. The decision not to use nanoparticles as powders, but only in a matrix, or the approach to bring nanopowders as quickly as possible in dispersion appear to be most dominant good practice in general occupational hygiene policies.

Question 3: If applicable, what are the major considerations to not further take measures to reduce potential exposure?

Only 3 companies indicated that they are not currently taking measures to control exposure. Two of these had no production or use yet, and the other company was not sure whether nanoparticles were present in the intermediate product. Other participants indicated that current practices were sufficient and effective, although one had little to no data to support this.

Question 4: What are good use and good practices?

- The type of occupational hygiene measures is related to the extent of use and the physical form (embedded in matrix, dispersion). Participants that were using nanopowders try

- to do this in a closed system. Apart from that local ventilation was the type of measure encountered most frequently.
- As a general principle ventilation seems to be the most frequently applied measure, using fume hoods (n=19) and other forms of local ventilation (n=9), sometimes with HEPA filters as a backup. Recent studies have shown that these filters are very efficient to remove nanoparticles from the air.
 - Logistic measures within the organization, such as reduction of exposure duration or limiting the number of employees that can have contact with ENP is used in 5 companies as a control measure.
 - Participants that use nanoparticles in a matrix apply less control measures than those working with nanopowders. Those participants using nanoparticles in a matrix do this in a closed system in 25 % of cases, and ventilation was the most common (56 %) practice.
 - No differences were observed in control measures between academia and research and private companies. Academia is a bit more active in training and education, but the line of measures is qualitatively similar.

Question 5: what is the effect of current good practices?

- Very little is known about the effect of control measures, since no systematic exposure monitoring is done. In only 8 % of cases some kind of exposure monitoring has been performed, and this is usually a single time measurement.
- The hazard and risk assessment is usually not supported by exposure measurements.
- There is a clear need for more information and guidelines on good practices in handling nanomaterials and nanoparticles. This need relates more specifically to the effectiveness of filters, gloves, and ventilation and inhalation protection.

Question 6: How to disseminate current know-how on best-practices?

- Recently a number of documents and guidelines have been published relating safe handling of nanoparticles at the workplace. The various documents differ in extent of detail, and have been reviewed briefly in this study. The participants in this survey use a number of the guidelines mentioned in these documents. Based on the observed good use and handling and the international guidelines, we have constructed a decision tree that can be used for reflection on current work practices as well as to improve current occupational hygiene measures.
- Most users of nanomaterials indicate that they would benefit from independent support on the use of occupational hygiene practices and environmental monitoring of nanoparticle exposure. A virtual centre of expertise could be an approach to merge the competence and power of available institutions. Such a centre could also disseminate most recent knowhow on best-practices.
- Dissemination needs a target, and therefore a database needs to be generated of companies and institutions that work with nanoparticles or make products that may

release nanoparticles during their lifecycle. Such an initial database can be created from the database generated during this survey, and data from research programs and industrial branches.

- Communication of best-practices guideline is an absolute prerequisite visualizing and improving current good practices to handle nanoparticles, and allow intervention by companies and professional services. The guideline in this report (par 4.2) can be used as a first version.

Question 7: Which health- and safety information on engineered nanoparticles is exchanged in the chain between producers and users?

- The exchange of information in the chain is poor. Almost 50 % of the participants spend no effort at all in information on presence and/or hazards of engineered nanoparticles. This is true in both directions, i.e. between suppliers and users, and with users downstream.
- The safety-information sheets (MSDS) usually do not give information on the presence of nanoparticles and the potential hazards of nanoparticles in their product. Therefore potential risks are very hard to recognize for downstream users of products.

Question 8: What is current common practice regarding the disposal of ENP containing waste?

- Almost all participants (92 %) use regular waste-disposal systems to deliver nanoparticles. Although in single cases nanomaterials are kept separate from other materials, the eventual way of collection and fate are the same as for other waste products.
- The chemical nature of the nanoparticle or the matrix in which it is contained are the major determinants for the waste container that is used.

Conclusions

In summary, 37 companies and research institutions have actively participated in the survey which contained an interview and a site-visit. Compared to other surveys the response is high when denominated to the relevant companies (n=62 %, n=60) or to the total number of companies approached (n=122, 30 %). The response rate in other international studies varied between 7 and 21 %. Independent checkpoints such as patent analysis, tax details from stimulated technology areas show that a number of larger players in the Netherlands (Philips, ASML) did not participate. It is impossible to predict how this has affected the qualitative and quantitative outcomes of this study, but our data are similar to recent international studies (Gerritzen et al, 2006; Tønning & Poulsen, 2007; Schmid & Riediker, 2008). In particular the nature of mostly used nanoparticles shows that currently used nanomaterials are still of the first generation, including carbon black, metal oxides and amorphous silica. Many other materials are being developed or being explored for application. The expected applications and production will start after the R & D phase is closed and lead to a significant increase in use of newer nanomaterials

within the next 3-5 years. These concern new textiles, the automotive sector, ceramics and nanocomposites. Three companies indicated that production will soon follow after successful closure of the R & D phase. The discussions and media-attention on hazards of nanotechnologies have not been unnoticed in academia and private sector. Most of the participants and also those not-participating are aware of ongoing discussions and needs for further research and regulation. Regarding good and best-practices in handling nanoparticles, there seems to be a general principle to use nanoparticles in a matrix or dispersion. The occupational hygiene measures taken to control exposure are largely similar to those observed in other countries (Gerritzen et al, 2006; Tønning & Poulsen, 2007; Schmid & Riediker, 2008), and do not differ between companies and academia. Little data is available on the effectiveness of these occupational measures, since only incidental measurements have been performed. Existing measures and guidelines are not always adequately followed, which is best illustrated by the poor communication between producers and users in the value chain and the lack of information in safety-data sheets.

This survey has exposed a number of issues that deserve attention in future work. First, it is very hard to identify the target group due to the enabling character of nanotechnologies, and future actions towards this group (dissemination, education, regulation) need a better understanding of this dynamic community. Secondly, current applications of nanomaterials are mainly in surfaces and coatings and use mostly first generation nanoparticles such as amorphous silica, metal oxides and carbon black. As opposed to the newer materials that are being developed these first-generation nanoparticles are well characterized from a toxicological point of view and treated as substances. Current developments indicate that in the near future many different nanoparticles will be used, without the toxicological database available for the first generation products. Thirdly, most users and producers have little know-how on the methods that can be used to detect presence of nanoparticles in products or workplace environment.

It is recommended to repeat a survey like this at least twice in the next 10 years to keep up with the rapid developments and implementation of engineered nanoparticles in new processes and products.