

REGULATING UNCERTAIN RISKS OF NANOMATERIALS

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The study analyses the possibilities and bottlenecks for regulating nanomaterials with uncertain risks, in the EU and Dutch legislation concerning environmental protection, consumer protection and occupational health and safety legislation. The study was conducted by researchers of the Law Faculty of the University of Amsterdam (the Amsterdam Centre for Environmental Law and Sustainability and the Hugo Sinzheimer Institute).

Summary

Introduction

This report contains the results of a study into the regulation of nanomaterials. The study examines the possibilities and limitations for such regulation under existing legislation covering the environment, consumer protection and occupational health and safety, given the uncertain risks attached to the use of nanomaterials. The central research question is which powers authorities hold to regulate production, processing, use and the waste phase of nanomaterials (and products containing them) and the obligations that companies have to assure the safety of man and the environment.

Nanomaterials are used in numerous products because of their special properties. The very small particles and specific forms of nanomaterials affect the behaviour and properties of the materials. Although this results in important new application possibilities, it may also give rise to new health and environmental risks. Much remains uncertain about the effects on man and the environment. Existing risk assessment methods are partially unusable for nanomaterials and new test methods are still under development. The uncertainty surrounding potential risks is exacerbated by the fact that it is usually not known whether nanomaterials are being used.

The study was conducted on behalf of the Dutch Ministry of Housing, Spatial Planning and Environment in association with the Ministry of Social Affairs and Employment and the Ministry of Health, Welfare and Sport. Its purpose is to provide an insight into the powers for authorities to regulate the production and use of nanomaterials with uncertain risks so as to protect man and the environment, plus to provide an insight into the obligations of employers to take measures to protect workers. The questions addressed in the study concern the uncertain risks of nanomaterials and cover the following subjects:

- powers to require companies to disclose information (including risk information);
- powers to impose requirements, like licensing or general rules;
- powers to take measures to exclude products suspected of involving great risks from the market and the role of the precautionary principle in this respect;
- obligations for an employer to take the uncertain risks of nanomaterials into account in its occupational health policy;
- possibilities for including within the framework of the Working Conditions Act provisions covering work performed with nanomaterials;
- liability of employers for health damage caused by working with nanomaterials.

The study takes stock of and analyses the main national and EU legislation. Reference was made to legislative history, explanatory documents, national/EU case law, policy documents and literature. Talks were held with experts from organisations including the Netherlands National Institute of Public Health and the Environment. The supervisory committee of the study included representatives of the Ministry of Housing, Spatial Planning and the Environment, the Ministry of Social Affairs and Employment and the Ministry of Health, Welfare and Sport.

Role of precautionary principle in measures concerning nanomaterials

The study examines the role that the precautionary principle could play in administrative decision-making on measures that intervene in the market due to suspected risks of nanomaterials. The precautionary principle essentially means that scientific uncertainty may not be a reason for deferring measures when there are impending risks.

The precautionary principle exists widely at *EU level* in legislation, case law and policy. The principle is embedded in the Treaty on the Functioning of the European Union (TFEU) and in a lot of secondary legislation. The case law of the Court of Justice and the Court of First Instance with regard to substances and products includes conditions developed for observing precautions and also requirements imposed for taking measures.

The case law shows that the precautionary principle allows measures to be taken for risks whereby the existence or scale of the risk cannot be determined conclusively. However, the EU courts do impose stringent requirements. A purely hypothetical risk, without scientific evaluation, is not enough. Authorities must demonstrate that the scientific evaluation, preferably based on international research, was performed as prudently as possible and provided them with sufficient scientific indications of a potential risk. If the risk were to materialise, real damage has to be probable. No specific requirements have been laid down for the nature of the damage and degree of uncertainty. The case law makes clear that the degree of uncertainty is not the decisive factor in the review by the courts, but the degree to which research, insofar as it is possible, was actually conducted.

EU courts also apply the precautionary principle to interpret provisions embodied in legislation that does not include a precautionary provision. If legislation contains evaluation criteria or evaluation procedures, however, these cannot be set aside by seeking recourse to the precautionary principle. Therefore, the legislation must be suited to the courts' application of the principle. Restrictive measures must be proportionate, non-discriminatory and objective. Given these requirements, more stringent requirements will be imposed as measures become more far-reaching.

The place of the precautionary principle is less clear in *national* legislation, case law and policy than it is at EU level. The principle has been codified sparingly. Under the Dutch Environmental Management Act, the principle was laid down in an implementing regulation for implementation of the IPPC Directive¹. Another example can be found in the Animal Feed Framework Act. Essentially, the act allows provisional measures to be laid down in certain situations, pending further scientific data for a more comprehensive risk assessment. Dutch courts occasionally and restrictively apply the precautionary principle.

Insofar as the principle has not been codified in national legislation, it has to be assumed that the legal review will remain restrictive.

With a view to careful decision-making, in the Dutch judicial system case law has developed

¹ IPPC stands for Integrated Pollution Prevention and Control.

based on the General Administrative Law Act concerning such matters as chemical substances and high-voltage power lines. The duty of research resting on the competent authority, as embedded in Section 3:2 of the Act, regularly leads to a situation where research (or additional research) is required when there are environmental or health issues before permission may be granted for certain activities. Section 4:2 of the Act obliges the applicant to provide required information. It is up to the competent authority to decide which information is needed and the authority must ensure that the right information has been disclosed. Consequently, the authority needs to possess the knowledge necessary to make this assessment.

As yet there is no case law on the role of the precautionary principle with regard to uncertain risks of nanomaterials. Given the foregoing, the principle is likely to play an important role in administrative decisions and their reviewing by the courts in respect of measures to address uncertain risks of nanomaterials, both as regards their production and application and as regards use of products that contain nanomaterials.

Besides this legal significance of the precautionary principle to administrative decision-making, the study addresses the significance of the precautionary principle in a more policy-driven context. Various policy recommendations, including those made by the Netherlands Health Council, have elaborated on this significance. In more general terms this wider significance focuses on control of processes in society. A wide interpretation has been given to the obligation to identify risks. A relatively large amount of attention is also devoted to such matters as the involvement of stakeholders and transparent decision-making. This policy-driven significance of the concept is also in evidence in the health and safety legislation because of the obligations that rest upon an employer.

EU chemicals legislation and their relevance to nanomaterials

An analysis of the EU CLP² Regulation and REACH³ Regulation reveals significant bottlenecks and lack of clarity concerning the regulation of nanomaterials. A key issue is the absence of a definition of nanomaterials and of specific provisions requiring the provision of information about and evaluation of the risks of the materials. This has created gaps in knowledge. There are also practical knowledge gaps concerning the application of nanomaterials. Their production and application are not subject to notification obligations.

An important bottleneck is the lack of clarity about identifying nanomaterials as a separate substance: when is a nano form of a substance considered a separate substance in relation to the conventional (i.e. non-nano) substance, or in relation to a different nano form of the same substance? There are no unambiguous indicators for this determination. As will be shown later, this obscurity has consequences for application of legislation.

The systems for submitting and evaluating information under the REACH Regulation, where the information that must be supplied leans heavily towards quantity, are focused

² CLP stands for Classification, Labelling and Packaging.

³ REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemical Substances.

insufficiently if at all on the special features of nanomaterials. When it comes to evaluation methods, for example, it is unclear when data may be extrapolated and to what extent. Instruments like registration and authorisation are not tailored or insufficiently tailored to nanomaterials, so the regulation of the materials under existing legislation is problematic. It is uncertain whether the registration dossiers will concern the nano forms of a substance. Moreover, dossier requirements are focused insufficiently on determining the specific properties and effects of nanomaterials.

Another bottleneck is that the exceptions and transitional provisions of REACH restrict or delay the effect of this regulation. Given the REACH transitional periods for introduction of the registration obligation, it may take until 2018 before registration data become available for some low-tonnage substances.

It appears from the study that REACH does not intend to regulate exhaustively all areas of chemicals legislation, which allows a certain latitude for national measures, particularly to protect workers, human health and the environment. That REACH is to be applied 'without prejudice to' EU directives covering the protection of workers can be seen as an important addition to REACH, for example.

What risk information about nanomaterials used in products can be required from industry in Europe and which legal frameworks define the scope that exists for doing this?

The answer to this research question can be summarised as follows. The legal frameworks for requiring risk information are the EU CLP Regulation and REACH Regulation. Information submitted by companies is managed by the European Chemicals Agency (ECHA). Competent authorities of Member States are allowed to request from the companies concerned the information used for the purposes of these EU regulations. Companies are under obligation to keep the information available and to submit it on request. They do not need to submit the same information twice, so a competent authority should approach the ECHA to obtain the information disclosed to the agency. Under the REACH registration system, the nature and quantity of information that becomes available varies according to the quantity of a substance that each manufacturer puts on to the market each year. The present information requirements in the REACH appendices, which state the information that companies must provide at the time of registration, address few if any nano-specific characteristics. Therefore, it is doubtful whether sufficient nano-specific information will emerge from the evaluation system, even if a dossier addresses the nano form of a substance.

Material Safety Data Sheets (MSDS) form a central information instrument. Using MSDS and disseminating information in other ways in the supply chain (under article 31 and article 32 of REACH) may result in little if any information becoming available about nanomaterials. The information obligations do not cover all substances and concern only a limited amount of data. Consequently, there is no guarantee that workers will get access to information about nanomaterials that they use during their work. That is why it is important that REACH shall apply 'without prejudice to' the EU's occupational health and safety regulatory regime (among other regulations). Directive 98/24/EC (Protection of the health and safety of

workers from the risks related to chemical agents at work) explicitly gives Member States powers to take measures to assure that employers receive from the producer or supplier all information necessary to assess the risks. The Netherlands has not yet used this scope for policy.

Under the REACH system Member States can help assure the availability of information on nanomaterials by urging the prioritisation of nanomaterials for the assessment of dossiers and by evaluating dossiers on nanomaterials. Where necessary for this purpose they can require additional information.

Insofar as REACH does not harmonise or regulate a matter exhaustively, Member States are allowed to request additional information, provided that they remain within the limits of other EU regulations and the Treaty on the functioning of the EU (hereafter: the Treaty). REACH contains no nano-specific regulations, so a case can be made for Member States having a certain degree of latitude in their policy on this matter, for example by means of a scheme for notification of the use of nanomaterials, thus making it possible to the competent authority to obtain basic information for the purposes of supervision, enforcement and policymaking. Powers under national law to require risk information is dealt with below.

Other EU environmental legislation and its relevance to nanomaterials

Based on the evaluation of important EU environmental legislation (IPPC Directive, Water Framework Directive, Waste Framework Directive, Seveso II Directive, Environmental Information Directive and Environmental Liability Directive), the conclusion that may be drawn is that it is usually problematical to regulate nanomaterials under these regulatory regimes, particularly because bottlenecks occur when applying them.

None of the prevailing directives examined contains specific provisions for nanomaterials. The directives are not tailored to fit the specific characteristics of the materials. Although nanomaterials in principle are covered by the directives, the applied standards, dose metrics or instruments often fail to take into consideration specific characteristics, like particle size or surface/weight ratio. The standardisation and the monitoring requirements of various regulations contain certain 'thresholds' that limit or impede the regulation of nanomaterials. The size units based on weight or quantity may cause nanomaterials to fall outside a regulatory regime. This might be the case with capacity thresholds for the applicability of a regulatory regime, for example, as with the IPPC Directive, PRTR Regulation and Seveso II Directive. It may also concern standards, like the emission limit values contained in the Waste Incineration Directive and in the IPPC Directive. Under the Water Framework Directive, the normative guidelines (for concentration limit values and environmental quality standards) are aimed at 'significant quantities' and at the results of monitoring. Such requirements expressed in weight or quantity will be unusable or usable only to a limited extent to regulate risks of nanomaterials. After all, these are materials whose effects may be determined by features unrelated to weight, such as particle size or surface. Nanomaterials that even in low concentrations have potentially high toxicity will usually fall outside these regulatory regimes. A problem encountered with monitoring requirements is that analysis

methods are still under development.

Similarly, the scope, system and instruments of various regulations limit their significance to nanomaterials. For example, the IPPC Directive and PRTR Regulation cover mainly industrial production companies, so they do not cover research laboratories for example. The Seveso II Directive offers few reference points for precaution for substances with uncertain risks because the directive leans heavily towards calculations for substances with *known* risks that are placed in known hazard categories. Another obstruction occurs in BREFs (Best Available Techniques Reference Documents) under the IPPC Directive. The study shows, based on a limited fact-finding exercise, that nanomaterials (and their possible emissions) lack a clear place in these documents.

The absence of a waste classification for nanomaterials is a basic problem in EU waste legislation. Another bottleneck is that the categorisation used in chemicals legislation may contribute to a situation where nanomaterials will probably not easily be considered *hazardous* waste. Awareness of the presence of nanomaterials in the waste is obviously a precondition for being able to regulate the materials in the waste phase. This clarity does not yet exist.

To give these regulations practical relevance to regulating potential hazards and risks of nanomaterials, it will be necessary to make additions or adjustments to the applied criteria and standards to reflect the links that exist between the substance properties and effects of nanomaterials.

A number of the regulations contain possibilities to tailor EU or national legislation more to nanomaterials. Given the precautionary principle, the Water Framework Directive, for example, provides scope for selecting nanomaterials as priority substances at EU level. This directive further allows Member States to take additional national measures. Similarly, the Waste Framework Directive allows Member States to take national measures, in particular with a view to the responsibilities of producers. The PRTR Regulation yields information about emissions of substances and of waste, albeit that the Regulation's scope is limited. However, the Regulation does explicitly offer Member States the regulatory power to make additions to the substances list and to amend threshold values for substances at national level, so more information may become available.

National environmental legislation and its relevance to nanomaterials

National legislation contains neither definitions of nor specific regulations for nanomaterials, such as notification regulations. This is one of the reasons why at national level there are also gaps in practical knowledge of the use of nanomaterials. By consequence it will not always be clear that nanomaterials are involved. Under current legislation the handling of nanomaterials can be regulated only to a limited extent. Under the Dutch Environmental Management Act and the Water Act, it is in principle possible to regulate by laying down conditions and requirements in the licensing of activities involving nanomaterials with uncertain risks. Given the limited scope of the licensing obligation, however, activities involving nanomaterials will not always be subject to licensing. Unlicensed activities may fall

under the general rules of the Environmental Management Act, in particular the Activities Decree. As will be explained, there are problems to regulating nanomaterials under these general rules. In other regulations, too, like waste regulations and reporting and monitoring regulations, there are limitations or obstacles that in some cases prevent them from covering nanomaterials.

The absence of legislation specifically for nanomaterials has consequences for the possibilities that exist to regulate nanomaterials and work performed with them. In various cases, also at national level due in part to EU legislation, the emission and quality standards and the reporting and monitoring obligations contain dose metrics or criteria based on quantity or weight that are not tailored to specific nanomaterial characteristics such as the surface/weight ratio. The same applies to threshold values in various regulations. For that reason the standards or criteria in these regulations might have a deficient relationship with the effects of nanomaterials, which makes the standards or criteria unsuitable for regulating the potential risks of the materials. This subject will be examined below. It needs to be borne in mind that undesirable effects could occur even with very small quantities or concentrations of nanomaterials.

Which notification, information and research requirements must or can be imposed on companies, under general rules or licensing? Which restrictive measures can or must authorities take with regard to production, trade, use and the waste phase?

Activities Decree

Insofar as activities with nanomaterials are subject to the Activities Decree, the conclusion must be that in its present form the Decree provides very little scope for regulating the uncertain risks of nanomaterials. Notification requirements in the Decree do not concern substances. Under the Decree competent authorities may only enquire about data on substances to the extent necessary for the 'tailor-made provisions' of the Decree. Besides there is no obligation for companies to conduct research. Tailor-made requirements have to be applied restrictively. Under the duty of care, too, the possibilities afforded by the Decree to lay down tailor-made requirements appear limited. For laboratory and classroom activities with substances covered by the Activities Decree, this regulation has no specific provisions for activities involving nanomaterials or emissions of nanomaterials.

Licensing obligation in Chapter 8 of the Environmental Management Act

Insofar as activities with nanomaterials fall under the licensing obligation of establishments within the meaning of Chapter 8 of the Environmental Management Act, there must be clarity at the time of granting the licence about the potential risks of the establishment's possible emissions of substances. As regards potential emissions of nanomaterials with uncertain risks, it is possible to lay down various measurement, registration, saving and notification obligations. An establishment that switches to the use of nanomaterials may require a revised licence. Notification under Section 8.19 of the Environmental Management Act will suffice only if it can be demonstrated that switching to nanomaterials will not give rise to any other or greater environmental effects. The power for the competent authority formally to update a licence that provides for use of nanomaterials - for example because of new insights - finds an obstacle in the case law-based prohibition imposed by the

Administrative Law Division of the Council of State on deviating from the application made for the licence.

The situation concerning activities that fall under general rules and activities that require licensing is that obligations laid down under Chapter 8 of the Environmental Management Act must be explainable by the need to protect the environment. In addition to environmental protection, the protection of human health is a standalone goal of the possibilities discussed below with regard to Chapter 9 of the Environmental Management Act.

Measures under Chapter 9 of the Environmental Management Act

For activities involving substances, Title 9.2 of the Environmental Management Act contains various instruments that, in addition to REACH, may be important when regulating nanomaterials. Section 9.2.1.3 of the Environmental Management Act provides an ample basis for the Minister to require information about substances (and about preparations and genetically modified organisms) from manufacturers and importers and from handling and processing companies. Companies are obliged to provide the information that they possess or by reasonable standards are capable of possessing. Further rules may be laid down by means of a General Administrative Order. This power to require information is exercisable for matters not exhaustively regulated by REACH.

The other instruments of Title 9.2 of the Environmental Management Act require regulation by General Administrative Order, such as the notification requirement and the licensing requirement. The same applies to the requirement to maintain and save records. This obligation, previously enshrined in legislation for a person who handles substances professionally, under the present Act *can* be regulated for categories of substances by General Administrative Order. No regulation has occurred to date. An explicit requirement to save records therefore only applies under REACH for the covered substances. An implicit requirement to save records might possibly be embodied in Section 9.2.1.3 of the Environmental Management Act discussed earlier.

Section 9.2.2.1 of the Environmental Management Act contains a very comprehensive and non-exhaustive list of rules that can be laid down by General Administrative Order for such matters as the production, import, use, treating, processing, sale and disposal of one or more substances. To do this there must be a 'reasonable suspicion' that activities performed with a substance will have undesirable effects for human health or the environment. The term 'reasonable suspicion' indicates that conclusive evidence is not required. Parliamentary history shows that 'reasonable' implies a weighing up of the seriousness of the hazards against the degree of likelihood of their occurrence. The list includes a prohibition of named activities, a prohibition to operate without a licence and a requirement to notify an activity, or to notify an *intention* to perform an activity, in each instance concerning one or more substances designated in the regulation.

When using instruments under Title 9.2 of the Environmental Management Act, such as notification or licensing requirements, the first question that always arises is to what extent REACH contains an exhaustive regulation. As stated earlier, it could be argued that REACH is

not exhaustive for all aspects of chemicals legislation so that certain national measures may be allowed.

Waste

Neither policy nor legislation on waste contains a specific approach towards nanomaterials. It is problematic to track nanomaterials in the waste phase as it is usually not known whether they are being used and because waste coding has no codes for nanomaterials. Moreover, the emission limit values, such as those for waste incineration, and other waste management standards are not always tailored to fit the features of nanomaterials. The Waste Framework Directive allows Member States to take certain preventive measures.

Reporting and monitoring obligations

The reporting obligations for companies under the Environmental Management Act, such as those for the Pollutant Release and Transfer Register (PRTR), and the monitoring obligations for authorities under the Water Act (Quality Requirements and Monitoring Decree 2009) contain criteria or threshold values that in practice mean that nanomaterials may not be covered effectively by these regulations. The PRTR reporting obligation applies only to industrial production companies.

In the registration regulations for the external safety register it is possible in principle to designate certain nanomaterials as a hazardous substance. However, the calculations that subsequently must be made with regard to external safety appear poorly suited to materials with uncertain risks.

Similarly, the water quality monitoring system, which may in principle apply to nanomaterials, appears to contain obstacles for monitoring nanomaterials, in terms of normative guidelines and measurement methods. Within the EU frameworks, however, Member States have discretion to adjust their policy to make these reporting and monitoring obligations more suited to reporting on nanomaterials as regards substances, thresholds and norms.

External safety

The regulatory regime for external safety provides limited possibilities for regulating nanomaterials nationally. The system of the external safety regulations, whereby allowance must be made for known risks, is poorly suited to regulate nanomaterials with uncertain risks. Additional regulation based on the licence is possible in some cases, insofar as the External Safety (Establishments) Decree does not exhaustively regulate the subject. Further requirements appear to be possible in some situations under the Major-Accidents (Risks) Decree. In the event of disasters like runaway reactions, the requirements in the Establishments and Licences (Environmental Management) Decree are not tailored to uncertain risks. The regulation of unusual incidents within the meaning of Title 17.1 of the Environmental Management Act might be important in licensing situations, also preventively, namely for *threats*, in order to require the submission of risk information – even in the case of uncertain risks.

Duty of care

The duty of care provisions in the Environmental Management Act for substances and for waste may be important when dealing with nanomaterials that have uncertain risks but for which there are no specific requirements. Under certain conditions these provisions can fulfil their safety net function for such time as regulation is not geared to new developments. However, there must be a situation of 'reasonably capable of knowing' or 'reasonably capable of suspecting' possible hazards or adverse effects of the activities concerned. The regulation of liability for environmental damage (under Chapter 17 of the Environmental Management Act) appears to be of limited significance to nanomaterials with uncertain risks, because of the limited concept of environmental damage, because of the requirement for substances to be *classified* as 'hazardous' and because of the *state-of-the-art recourse*.

Legislation for consumer products and relevance to nanomaterials: the Dutch Commodities Act viewed in the light of the EU General Product Safety Directive

The research shows that the Commodities Act provides a wide basis for a large array of instruments potentially useable to take measures. Given the objective of the law, these measures must be for the purpose of ensuring health or safety, or providing clarity to consumers of products. Partly in the light of the General Product Safety Directive, the law as it stands appears to offer limited possibilities for regulating uncertain risks and for intervening in the market with regard to products that contain nanomaterials. The law has no specific provisions for nanomaterials.

The established definitions used in the Commodities Act were not adapted to the definitions used in the General Product Safety Directive at the time of its implementation. Consequently, implementation is not always clear. The Directive's obligation to market only a safe product, for example, has been worded in the Commodities Act as the prohibition of trading goods capable of producing special hazards.

The General Product Safety Directive contains a limited but exhaustive list of obligations for companies. It does not clearly regulate how, on this basis, the key obligation of the Directive must be fulfilled, i.e. the obligation to market only safe products. The risk information that may be required from companies is limited because they have no obligation actively to conduct research. The Directive is premised on information that 'is available' and information that a party 'should know professionally'. Given the obligation to market a safe product, this prompts the question of which risk information companies should know professionally and which information they are deemed to possess. According to case law concerning product liability and liability for hazardous substances, the premise is the current scientific and technical knowledge, i.e. the most advanced level, insofar as the information is accessible. This same level is likely to apply to 'should know professionally'.

Besides the General Product Safety Directive, there might be powers and obligations under other EU legislation, such as the REACH Regulation (for the health and environmental aspects of certain substances in products that meet the REACH conditions) and the Regulation covering accreditation and market surveillance, so measures might also be possible within these frameworks.

Other than under the EU General Product Safety Directive, the guidance provided to consumers under the Dutch Commodities Act is a standalone objective that is unrelated to the health and safety objectives. In this context labelling obligations may be imposed. The Directive refers to informing consumers about 'inherent risks'. In that context one could refer with regard to nanomaterials to the 'inherent uncertainty' associated with the materials, which might be a reason for making labelling mandatory. In the case of products that contain nanomaterials, there is no question of an inherent risk, because uncertainty exists on this point, although one could refer to an 'inherent uncertainty' regarding the characteristics and effects of nanomaterials. It might be important to inform consumers of these matters. The General Product Safety Directive contains only very limited provisions for dissemination of information to consumers. These provisions specifically concern safety. This makes it defensible to adopt the position that the Directive does not exhaustively regulate the dissemination of information. A national measure taken in this field will then have to satisfy the Treaty requirements, including those concerning free movement, so they must be proportionate and non-discriminatory.

Under existing product legislation are suppliers obliged on request to communicate that they have used nanotechnology in a consumer product?

Section 8 of the General Product Safety Directive provides ample power to require 'all necessary information' for 'all products'. This power has been implemented in Sections 25 to 31 of the Commodities Act concerning inspection and enforcement, according to its explanatory memorandum. While the inspections task implies obtaining information (and Section 5:20 of the General Administrative Law Act also comes to mind in this respect), there is no *explicit* provision as in the Directive for requiring information about all products.

However, Section 21b of the Commodities Act does stipulate that rules may be laid down by General Administrative Order for certain information that must be provided. This relates to a specific situation, i.e. the trading of goods that pose a hazard to human health or safety. The party trading the goods must on request cooperate with the Minister in action undertaken to avoid risks. The Minister will lay down rules for this subject. The providing of information referred to in Section 21b does not appear to apply to materials with *uncertain* risks. A more general power to require information could be based on this provision only with a wide interpretation of Section 21b. A basis for doing this can be found in the Commission's guidelines on this subject. The guidelines state that it is important to consult competent authorities, also *where doubt exists*. This points towards a wide interpretation. The final sentence of Section 5, subsection 4 of the General Product Safety Directive, concerning a product safety dialogue with manufacturers and distributors, also points towards a wide interpretation. Member States must draw up a procedure to this end. Under the procedures referred to in Section 5, it will be logical for companies to inform competent authorities of the use of nanomaterials. After all, knowledge of this matter is a basic condition for policy, measures and inspection.

For categories of products, a power to require information might also stem from Section 11 of the Commodities Act. The information must then form part of measures to promote

proper compliance with the law.

A notification obligation may necessitate an importer to take measures to obtain information about the usage of nanomaterials in order to provide clarity on this subject. Information of this kind is likely to fall under the information that an importer should know professionally. Section 11 of the Commodities Act might be suitable for regulating this matter by means of a General Administrative Order where necessary. This could also be used to implement the market control measures under the EU General Product Safety Directive (Section 9) and the Regulation concerning accreditation and market surveillance (Section 19, subsection 1).

Can a notification obligation be introduced under existing legal frameworks for products that contain nano particles?

The Commodities Act contains only in Section 21b a notification obligation that stems directly from the law. It concerns traded goods that pose a hazard, i.e. whereby the risk is no longer uncertain. Certain nanomaterials may fall under this provision, but a notification obligation for materials with uncertain risks can be based on this section only if it is interpreted very widely (see above). Section 21b implements the notification obligation for products that pose risks incompatible with the safety requirement. Such a notification obligation appears possible especially for products that contain nanomaterials for which there are certain risk indications or uncertainties of high concern about risks.

For products with nanomaterials that have uncertain risks, a requirement to notify the use of nanomaterials in products or the trading of products that contain nanomaterials could be introduced by General Administrative Order, among other things under Section 4 or Section 11 of the Commodities Act. The wording of Section 4 of the Act ('may' be harmful) makes the section suited to measures associated with uncertain risks. However, it must be possible to explain the need for notification for the purposes stated in this section concerning health or safety. The prime consideration in Section 11 of the Act is proper compliance with the law. Among other things this concerns measures for subjecting goods to an investigation and checking goods, which appears appropriate to materials that have uncertain risks. A notification requirement could be given a place in this part of the law.

A notification requirement will tie in with the power under Section 8, subsection 1 of the General Product Safety Directive to require the necessary information for all products from the parties concerned. The obligation would also be in tune with the cooperation procedures that the Directive assumes to exist at various places with a view to avoiding risks. Although the Directive does not provide a clear basis for doing this, the powers listed in Section 8 are not stated exhaustively. This means that measures apart from the listed ones are possible, provided that in all other respects they are in accord with the requirements of the Treaty. With a view to various Member State obligations embodied in the Directive, a notification requirement appears to be an important basis for meeting those obligations.

If a notification requirement were to be for the purpose of informing consumers about

inherent uncertainties of nanomaterials, a basis for doing so might lie in Section 8 of the Commodities Act. Section 8 contains numerous powers and instruments aimed at providing clarity to consumers that can be regulated by General Administrative Order. It is conceivable, for example, to introduce under Section 8, subsection 1c of the Act a requirement to provide notification of certain nanomaterials for the purpose of a register for consumers. For cosmetics that contain certain nanomaterials, the EU's new Cosmetics Regulation includes an obligation to notify the Commission prior to marketing, plus an obligation for the Commission to establish a public register.

Is it possible to prohibit the trading of 'nano products'?

With regard to trading an *unsafe* product, the Act provides powers for government action, among other things in Section 18 under (a). Various provisions of the Commodities Act make it possible to prohibit by General Administrative Order the trading of a product harmful to health or safety. In view of the radical nature of a measure of this kind, it seems in the case of *uncertain* risks to be proportionate and appropriate only by way of precaution if there are clearly indications of potential risks of high concern.

Given the system of the General Product Safety Directive, it is doubtful, for such time as no specific standards exist for products with nanomaterials, whether a product with nanomaterials with uncertain risk is a 'safe product'. After all, a safe product must not pose any risks, or only limited risks that are commensurate with the use made of the product and that must be considered acceptable in terms of human health and safety. This prompts the question of whether an uncertain risk is deemed acceptable from a health and safety point of view. Where there is an *uncertain* risk, it can be difficult to establish that there is only a *limited* risk.

For such time as European standards are absent, the Directive provides scope to establish national product safety standards. Given the radical nature of a prohibition, the setting of clear standards seems to be a condition for taking such a measure, also bearing in mind the requirements of proportionality and non-discrimination of measures. Establishing a definition of the nanomaterials will be a first step in this direction.

A less far-reaching instrument is the *temporary* prohibition of trading products that are the subject of an ongoing inspection, investigation and/or evaluation. This instrument embodied in the Directive, which might be important for products with uncertain risks like nanomaterials, has been implemented only to a very limited extent in Section 32k of the Commodities Act, where it mainly concerns sampling. The scope of the temporary trading prohibition under Section 8 of the Directive is broader, given the formulation. It is uncertain whether an interpretation in conformity with the Directive would allow a widening of the scope of this provision. Clarification of the provision, for example with a view to certain ongoing research projects into specific nanomaterials with uncertain risks, would be a more logical way forward.

The EU recently initiated a review of the General Product Safety Directive. This offers

opportunities to give the uncertain risks of nanomaterials a clear place in this legislation in due course.

Biocides legislation and nanomaterials

Certain nanomaterials like nano-silver are used as biocides. The nanomaterials are marketed as a biocide or in a product treated with a biocide. It is not always clear whether they are subject to biocides legislation, especially in the case of treated products. Other legislation may apply (such as cosmetics legislation) or the product may not be covered by the legislation. This will depend on such matters as the primary or secondary function of the product as a biocide and the internal or external effect of the biocide. A condition for being a biocide within the meaning of the biocides legislation is the existence of an 'active substance'. The proposed Biocide regulation, currently under debate, will replace the Biocides Directive and will widen the scope of the biocides legislation. The European Parliament and Council are seeking a further widening, partly with a view to nanomaterials and inclusion of nano-specific provisions.

Under the existing legislation it is uncertain whether the authorisation authority will be informed of the presence of a nanomaterial in a biocide. There appear to be similar gaps and uncertainties in decision-making on biocides as those that exist within the REACH registration. The legislation has no notification obligation for the use of nanomaterials. The dossier requirements do not address nano-specific information. Adequate tests will not always be available. Therefore, the risk assessment will be problematical, making it impossible to establish whether a biocide satisfies the authorisation requirements. The EU Biocides Regulation, in the proposed form, does not address these gaps. Additionally, there are specific problems in the case of biocides. One is that the registration conditions (the simplified procedure for 'biocides with a small risk') do not rule out the possible presence of nanomaterials among active substances that may be used in 'biocides with a small risk'.

An important difference compared with the registration of chemical substances is that the authorisation authority must evaluate biocides based on a dossier submitted by the applicant and the dossier must be used to determine compliance with the authorisation criteria. These criteria and the related dossier requirements are not geared to nano-specific characteristics at present. However, the competent authority does hold the power to translate the approval criteria into nano-specific dossier requirements. In other ways, too, conditions and requirements can and must be laid down for approval, for example with regard to analysis methods. These powers provide important capabilities for regulating the uncertain risks of nanomaterials.

EU and national biocides legislation provide no possibilities to grant a *conditional authorisation* subject to research requirements for the uncertain effects, like the one currently under preparation in the United States at federal level for usage of nano-silver.

The *provisional approval* of substances by Member States based on a new active substance does not seem to lend itself to authorising a substance whose effects are uncertain, because

for provisional approval it must have been established that the active substance complies with the Directive requirements and that the biocide is likely to satisfy the criteria.

In certain situations it might be possible, in the case of nano-biocides, *to grant exemptions for the purpose of research and development subject to certain conditions.*

Given the numerous uncertainties and the technical developments, it seems important to lay down basic requirements for nanomaterials in the biocides legislation and additionally to develop and keep up to date a system of Guidance Documents on how to deal with nano-biocides.

Working conditions legislation concerning nanomaterials

At the heart of the legislation in the field of occupational health and safety (working conditions) there is the employer's duty of care for work performed with hazardous substances. According to the definition given in the Dutch Working Conditions Decree, the term 'hazardous substances' must be interpreted widely, i.e. substances that *may* pose a health or safety hazard. This definition is significantly wider than in the provisions contained in chemicals regulations (CLP, REACH). In principle, the definition used in the Working Conditions Decree says that provisionally substances must always be considered hazardous unless they are known not to pose any health or safety hazards. The mandatory risk analysis and evaluation will have to determine whether there is in fact a hazardous situation while working with nanomaterials. It may not be presupposed beforehand that there is no potential hazard in situations involving unknown or uncertain risks. The opposite is true.

Case law on employer's liability shows that a high level of protection must be maintained, precisely in situations where uncertainty exists. The same may be concluded from literature on the management of uncertain risks. However, the measures taken must be proportional to the degree of certainty regarding the risks and to the chosen level of protection. There is a continuum here, with a wide interpretation being given to the employer's duty of care if necessitated by the importance of protecting the health of workers and according to the degree to which the first signals of possible risks need to be taken more seriously.

Must an employer make allowance in its health and safety policy for suspected or as yet partially unknown hazards and risks (Section 3 of the Working Conditions Act) and in performing the statutory risk analysis and evaluation (Section 5 of the Working Conditions Act)?

Working conditions legislation covering 'hazardous substances' (in the case in hand this means Chapter 4 of the Working Conditions Decree and EU Directive 98/24/EC) prescribes an employer's obligation to conduct a policy on working with substances that *might* pose a health hazard. The obligations do not apply only if it is clear that the risks are minimal. To establish whether this is the case it will in any event be necessary to carry out an adequate risk analysis and evaluation. Therefore, a risk analysis and evaluation is also obligatory for substances for which there is no prior suspicion of harmfulness: any harmfulness will have to

be revealed or rebutted by the risk analysis and evaluation. In cases where the risks of nanomaterials are uncertain, it is not allowed to presuppose that there are no risks. The opposite is true. The employer will actively need to establish this. This is also evident from the system of the regulatory regime, which requires that a risk analysis must first be conducted before determining whether or not measures must be taken.

The scope of the obligation to conduct a working conditions policy ultimately depends in part on the circumstances of the case. There is a continuum here, with a wide interpretation being given to the employer's duty of care if necessitated by the importance of the protection of the health of workers and according to the degree to which the first signals of possible risks need to be taken more seriously.

Should the existing provisions concerning protection of workers against exposure to hazardous substances also be deemed applicable to exposure to nano-particles and, if so, which provisions and to what extent?

The existing provisions concerning working with hazardous substances must provisionally be deemed to apply to nanomaterials for which it cannot be conclusively established that there is a safe situation. Jurisprudence on employer's liability shows that, also in situations where uncertainty exists, it is necessary to maintain a high level of protection. The same may be concluded following a wide interpretation of the employer's duty of care. The employer is not only under obligation to take specific preventive measures, as mentioned earlier, but is also bound to take measures to limit as far as reasonably achievable, any actual damage that has already occurred (secondary prevention).

The extent to which an employer is under obligation to take measures depends on the specific circumstances of the case, according to the case law. Apart from the risk analysis that must be conducted, there are several general prevention principles, in particular the minimising of any exposure. If the risk analysis and evaluation shows that there are or may be specific risks, the employer is required to take measures to address those risks, taking into account the state of the art. The employer is bound to take those measures that may reasonably be required of an employer. What is 'reasonable' will depend on the plausibility and seriousness of any risks on the one hand and the technical, operational and economic feasibility of the measures on the other.

Do the existing principles in the Working Conditions Act provide sufficient possibilities for including if necessary in the Working Conditions Decree provisions that specifically address working with nano particles?

In situations of uncertainty it may be concluded, based partly on case law, that there must be a wide interpretation of the employer's duty of care (Section 3 of the Netherlands Working Conditions Act, Article 7:658 of the Dutch Civil Code). As general duty of care provisions leave scope for interpretation, however, it is not always possible to indicate precisely which measures are or may be required of the employer. Where general

formulations may cause interpretation (and enforcement) problems with regard to the employer's duty of care, it might be possible to create greater clarity by means of more specific provisions concerning this matter. If there is a need to specify such control measures in more detail in Chapter 4 of the Working Conditions Decree, Section 16 of the Working Conditions Act provides an adequate basis for doing so. In this context a precautionary provision may also be considered.

To what extent does existing legislation and related case law offer possibilities to claim damages from companies, employers, etc..(including health-related damage) possibly incurred by workers or other persons through working with nanomaterials?

Where uncertain risks exist, the employer has a far-reaching duty of care. For an employer's liability for exposure to a potential hazard, it is important to ascertain whether the employer possesses sufficient knowledge to be able to speak of a known hazard. This is not about knowledge *actually* present at the employer's organisation, but about a normative opinion of the knowledge that the employer may be expected to possess. Case law shows that an employer is expected to adopt an active approach to research, also in respect of *suspected* potential hazards. As various recent research reports have referred to potential hazards and as there are also indications that certain forms of nanomaterials are harmful to health, it may be concluded that an employer will be liable not only in respect of nanomaterials that are known or are likely to be harmful if the harmful effects actually occur. Liability may also exist in the case of nanomaterials where the possibility exists of their being harmful.

To what extent the employer will ultimately be held liable will depend on the circumstances of the case, with one important consideration being the degree of certainty in the literature regarding the risks of nanomaterials and the seriousness of the hazard.

Voluntary structures of regulation

Effective and efficient regulation for controlling nanotechnology risks can be developed by stimulating voluntary regulatory structures. This is argued in chapter 8 of this study, based on literature and research in the fields of public administration and legal sociology. These voluntary structures can add to and support government regulation. One possibility is to have mechanisms of new governance, i.e. a form of regulation whereby lawmakers establish, in consultation and cooperation with stakeholders, a jointly supported result of addressing the risks of new technologies.

Three mechanisms can be mentioned in this context. Firstly, there is the mechanism of developing voluntary internal structures for risk management, as expressed in *nano codes*, covenants and similar codes of conduct and arrangements. However, it is important for these to be properly controlled and for there to be some form of sanction for non-compliance. Nano codes supplement the frameworks within which government regulation currently operates. Consequently, they can fulfil a role as added value in the validation of policy, against the background of a comprehensive regulatory framework of the

government. The literature refers to a Responsible Nano Code as a vehicle for approaching regulation pragmatically, taking into account fast revisions and growing knowledge of nano risks. Such a document is also under consideration in Dutch nano technology policy.

The second mechanism is adherence to international standards, like ISO standards. These standards enable companies to respond to constantly developing scientific knowledge, while application of ISO standards, for example in licences, gives further legitimacy to general rules and policy rules.

Finally, the communication and participation of stakeholders can be promoted and the public must be made aware of the benefits and the potential risks of nanotechnology. Many reports on nano regulation call for the improvement of communication strategies, aimed at getting an interested public to feel engaged and giving significance to participation in the preparations of regulations. The broadly-based discussion should be focused on which applications of nanotechnology are desirable and acceptable. This might avoid the backlash that dominated debates about the regulation of GMOs (genetically modified organisms). It should be noted, however, that not every government attempt to involve the public in legitimising applications of nanotechnology will be successful. Educational projects may prevent public opinion shifting too far towards rejection of, or indifference about, nanotechnology. The government cannot send out a coherent message and seek agreement with all stakeholders unless there is a substantial level of scientific consensus about the risks and benefits of nanotechnology.

It has to be said, however, that it is not yet possible to say with any certainty what does and does not work in terms of new governance, a point also made in the literature. Nano codes will need to be developed with creativity and daring. This must not be done through pure self-regulation, whereby the administrative body looks on but without commitment, but through co-regulation whereby the different parties lend legitimacy and support to the ultimate regulatory product. Based on the literature mentioned in this chapter, it is possible to obtain a good picture of how research needs to be carried out into a form of regulation based on new governance and the tools needed for that purpose.

Concluding remarks

The report closes with some final remarks that sketch similarities, differences and interfaces between the three examined areas (i.e. the environment, consumer protection and occupational health and safety at work). In all three fields there are scientific and practical gaps in knowledge and an absence of definitions and nano-specific provisions. Research and information delivery obligations for companies differ in each area. Bottlenecks in EU substances legislation have an extended effect in the environmental, consumer protection and working conditions legislation.

Gaps caused by regulatory instruments not being tailored to nano-specific characteristics play a role particularly in legislation covering substances and the environment. Policy latitude for additional national rules exists especially in the areas of occupational health and

safety and the environment. Working conditions regulations provide a basis for further rules. Possibilities to lay down requirements to address uncertain risks of nanomaterials exist under the current environmental and water licensing system. In national legislation covering substances and products, the possibilities are closely related to the scope for national policy making provided by the relevant EU legislation. As EU legislation does not exhaustively regulate the subject of nanomaterials, there are possibilities for additional national regulations. Given the uncertain risks of nanomaterials, the precautionary principle will play an important role in all three areas that were examined.

CHAPTER 9.

CONCLUDING REMARKS

9.1. INTRODUCTION

This report draws conclusions in each examined area – environmental protection, consumer protection and occupational health and safety – and answers research questions about the possibilities and bottlenecks that exist in regulating risks associated with nanomaterials. For these conclusions and answers, we refer to the individual chapters of the report (in Dutch) and to the translated summary in this document. This chapter rounds off by presenting a number of items in which the conclusions from the areas are compared. While there are similarities between the three areas, there are also differences and interfaces. It is important to note that the type of EU legislation and the extended effect of this law in the three areas differ, which means that the degree to which national regulation is possible, supplemental to EU legislation, also differs.

Nano-specific legislation is not in force in any of the examined areas. In all three areas the legislation lacks a definition of the term 'nanomaterials'. A definition for certain nanomaterials was only recently included for the first time in EU legislation (and will apply in 2013) for cosmetics, making notification prior to marketing as well as supplementary labelling obligatory for cosmetics that contain nanomaterials. The ISO (International Standardization Organization) is developing definitions, however. An unambiguous definition of nanomaterials may be considered a precondition for regulating these materials.

9.2 KNOWLEDGE GAPS

Significant knowledge gaps exist in all three areas. The gaps concern primarily scientific uncertainties. There is uncertainty about the potential risks of nanomaterials, among other things because of the absence of suitable tests for assessing the risks in some cases. Additionally, research requirements in chemicals legislation do not address the specific characteristics of nanomaterials, or address them insufficiently, so it is uncertain whether relevant information will become available based on these requirements. Secondly, there are practical gaps in knowledge, because it is usually not known whether nanomaterials have been or are being used. The regulatory regime has no notification regulations for the production or the use of nanomaterials, nor are labelling regulations in force in this field. Experience with voluntary reporting in various countries has not been very promising to date.

The knowledge gaps, concerning both the potential risks of nanomaterials and also their presence, have an extended effect in other policy fields. An example is that the REACH requirements for providing information in material safety data sheets do not concern nano-specific characteristics (although a limited amendment of REACH is under preparation in this respect). Due to the absence of nano-specific information in the material safety data

sheets, it is possible that users will not be aware that use is being made of the nano form of certain materials. In such cases, it is difficult to take the preventive measures necessary to control or to limit effectively the risks involved in working with nanomaterials (risk assessment, technical measures, ventilation, personal protective equipment, and zoning). Where it is unclear that use is being made of nanomaterials (and the producer is not obliged to communicate this to users downstream in the supply chain, in many cases workers as well), this will seriously obstruct the application of occupational health and safety rules.

A specific knowledge gap is the lack of clarity as to whether or not a nanomaterial is identifiable as separate substance (compared with the non-nano form of the same substance or with a different nano form of the same substance) and whether or not the nano form has been classified in a hazard category. A consequence of non-identification as a standalone substance might be that nano applications (and their risks) are not separately incorporated in the risk evaluation and decision-making. Classifying them in a hazard category can be decisive when it comes to the question of which regime of environmental legislation applies. Therefore, the lack of clarity in the chemicals legislation extends into other environmental and consumer protection legislation. This matter is less problematic in the field of working conditions. Under OHS legislation nanomaterials fall within the wide definition of 'hazardous substance', so a number of general provisions will in any case apply. Whether there is an actual *risk*, however, will be indeterminable until the obligatory risk analysis and evaluation has been performed.

9.3. RESEARCH OBLIGATIONS FOR COMPANIES

The REACH Regulation for substances requires producers and importers to actively conduct research, either by carrying it out or by commissioning it. Under the precautionary principle, these obligations also apply to *uncertain* risks. Companies downstream in the supply chain may have research obligations for deviating applications of a substance.

The scope of obligations to conduct research is less clear in the consumer protection regulations. Although the central consideration is the obligation to market only safe products, this is premised on the data that is 'available' and data that companies 'should know professionally'. So it is important to know the scope of, and the case law on a concept like 'current scientific and technical knowledge' that producers or distributors should be aware of.

When it comes to the field of occupational health and safety, it can be concluded – based on case law and literature regarding dealing with uncertain risks – that an employer has an obligation to carry out a risk analysis and evaluation and to acquaint himself *actively* with the latest scientific knowledge. This obligation may possibly be regarded as an instrument for filling up gaps in the research obligations in chemicals legislation. Given the case law, however, the employer's research duty is also fulfilled to a significant degree by gathering information that must be assumed to be known 'in his circle'. The decisive factor is what the employer should 'reasonably' be aware of.

9.4. PROVIDING INFORMATION BY COMPANIES TO PURCHASERS OR WORKERS

EU consumer protection legislation contains in the General Product Safety Directive a limited number of obligations for producers and distributors to provide information to purchasers as well as consumers. There is no clear regulation of the extent to which this provision of information also applies to *uncertain risks*. REACH contains detailed obligations for the provision of information about risks by companies within the supply chain of a substance. As mentioned earlier, this does not necessarily mean that sufficient specific information about nanomaterials will actually become available. In the field of occupational health and safety an employer is required to inform its employees about the risks of working with nanomaterials and to provide adequate instruction regarding safe working procedures. The employer is also required to acquaint himself with the information possessed by the manufacturer. Here again, the manufacturer or distributor might not always report that the product contains nanomaterials, so there is no way of guaranteeing that the working procedures are sufficiently safe and that the instruction and guidance are adequate.

As regards the provision of information, there is an interesting interface between the regulatory regime for substances and the one for health and safety. REACH states that the EU regulatory regime for the protection of workers applies in full. EU Directive 98/24/EC, for the protection of workers against risks of chemical agents in the workplace, stipulates that if the substances regulatory regime does not make it mandatory to provide information about hazardous chemical agents, the Member States may take all necessary measures to ensure that employers can obtain, at their request, all information necessary for the performance of a risk evaluation – preferably from manufacturers or suppliers. On this basis, the Member States are able to impose information obligations supplementary to the chemicals regulatory regime, including REACH it must be assumed. It is likely that this may also concern information about nanomaterials. This is all the more important now that the REACH registration procedures appear to yield insufficient nano-specific information and the obligations for providing information contain limitations with regard to nanomaterials. The Netherlands has not yet exercised the regulatory power that Directive 98/24/EC offers a Member State to take certain measures for the purpose of providing information to employers.

9.5. LIMITS IN THE EXISTING REGULATORY REGIME

Both the chemicals regulatory regime and the environmental regulatory regime contain certain barriers for applying those regimes to nanomaterials. In terms of quantity or weight, the listed substances or the threshold values in the regulations are in some cases such that nanomaterials will not be covered by the legislation. This situation occurs, for example, with the IPPC Directive, the PRTR Regulation and the Seveso II Directive (and in the implementation or execution thereof in national law). Regulations sometimes contain standards, or monitoring metrics, on a *weight* basis not geared to specific characteristics of nanomaterials. This situation arises with emission limit values and environmental quality standards, as with concentration limit values in the waste and water regulatory regimes, and with monitoring obligations, like those for the Water Framework Directive. A limitation

occurs in the waste regulatory regime where there is no coding for nanomaterials in the waste phase, and in the Best Available Techniques framework (as laid down in 'BREF' documents), where nanomaterials appear to lack a clear place. All of these criteria and standards can have as a consequence that nanomaterials are not or not effectively covered by legislation. This is particularly problematic if even in low quantities the materials have effects of high concern.

There are no such obstructions or limitations in OHS legislation; whether or not nanomaterials qualify as a 'hazardous substance' is not dictated here primarily by threshold values. The definition of a hazardous substance in the Working Conditions Decree is very wide, i.e. any substance that *may* pose a health or safety hazard.

Other limitations for regulating nanomaterials stem from the scope of the legislation, the system used, or the nature of the instruments. Within the national environmental regulatory regime, for example, only a small number of activities with nanomaterials will be subject to licensing, because only few establishments are required to hold a licence. In the substances regulatory regime, the tonnage-based registration system of REACH, where the system of supplying data is linked to quantities, is not geared to the regulation of nanomaterials. After all, the effects of nanomaterials are likely to be determined by factors other than weight.

OHS conditions legislation contains relatively little scope or system limitations relevant to the matter under discussion here. The circumstance that nanomaterials are not explicitly named as a separate group of substances in working conditions legislation does however leave it unclear in which situations the registration of workers who work with nanomaterials and/or the monitoring of their health is required. This kind of registration is not currently prescribed in the Working Conditions Decree, except for substances known to cause cancer. If the registration of workers is deemed desirable, however, this obscurity must be eliminated by giving a clear definition in the Decree (under Section 16 of the Working Conditions Act).

9.6. POLICY MAKING AND REGULATORY POWERS AT THE NATIONAL LEVEL

Given the identified barriers and limitations in the regulatory regime, a relevant question is what room EU legislation offers Member States to regulate the risks of nanomaterials. In the substances and product regulatory regimes – usually having as a legal basis Article 95 of the EC Treaty (now article 114 of the TFEU) – the room to diverge in policy from the EU legislation is limited or nonexistent. Only where EU directives or regulations do not, or not exhaustively, regulate a matter supplementary national measures are possible, within the limits of the Treaty.

Chapter 3 stated that the REACH Regulation does not exhaustively regulate the subject of nanomaterials, so that there is room for substance or product measures at Member State level, supplementary to REACH. Section 128 subsection 2 of REACH *explicitly offers competences* for setting or maintaining national rules for substances in cases not harmonised by the Regulation, not only with a view to protecting workers, as illustrated by the aforementioned example concerning information providing, but also for protecting

human health and the environment.

For consumer products, there is limited policy latitude under the General Product Safety Directive for deviating Member State measures. However, this Directive does not exhaustively regulate products with uncertain risks, which means that other regulations – including REACH – may also be applicable as a basis for taking measures.

Environmental EU legislation – such as the IPPC Directive, the Water Framework Directive, the Waste Framework Directive, the PRTR Regulation and the Seveso II Directive – which have their legal basis in the Environmental Title of the Treaty, contain minimum harmonisation, so in principle Member States may take supplementary or more stringent national measures to regulate nanomaterials, for example by including nano-specific criteria or dose metrics in their legislation.

The OHS regulatory framework also includes directives that call for minimum harmonisation. This gives the Dutch government the freedom to lay down detailed rules, provided that they are compatible with the Treaty. If detailed rules are desirable, for example by substantiating the employer's duty to be alert to the first signals of health effects of working with nanomaterials, then Section 16 of the Working Conditions Act provides the basis for laying down rules aimed specifically at nanomaterials, either under or pursuant to a General Administrative Order.

9.7. POSSIBILITIES BASED ON EXISTING NATIONAL REGULATION

Given the bottlenecks identified earlier, there are limited possibilities within the current regulatory regime for imposing requirements or taking measures at the national level. As part of environmental (planning) and water licensing, it is possible to lay down conditions and requirements for regulating activities with nanomaterials within establishments, on account of potential adverse environmental effects, also in the case of uncertain risks. Limitations here stem from the limited scope of the licensing obligation under Chapter 8 of the Environmental Management Act.

In the working conditions field, an employer has, based on a wide interpretation of the duty of care, the obligation to take stock even of uncertain risks. Additionally, again based on a wide interpretation of the duty of care, it may be assumed that a high level of care may be required of the employer. This could mean that the employer, depending on the seriousness of the possible risks, must also implement proactive controls if there are *uncertain* risks. Section 16 of the Working Conditions Act provides the basis to clarify, in specific provisions in the Working Conditions Decree, which specific measures an employer may be expected to take.

The national substances regulatory regime (Chapter 9 of the Environmental Management Act) and commodities laws contain an array of instruments for taking measures. Within the substances regulatory regime, this concerns, for example, the power to obtain data and to lay down further rules for this by General Administrative Order. Various measures are possible under or pursuant to a General Administrative Order, such as a temporary prohibition to supply and various information obligations under the Commodities Act. It will

be necessary to weigh up not only the policy latitude offered by EU regulations, but also to what extent powers are suited to taking measures in the case of *uncertain* risks. Similarly, if the existence or the scale of a risk cannot be determined conclusively, it may be possible, given the case law to take certain measures by applying the precautionary principle.

As regards possibilities for regulating nanomaterials the biocides regulatory regime occupies a special place under environmental legislation. On the one hand, there are the same gaps and uncertainties as those identified with regard to chemical substances in general, while on the other, this regulatory regime provides sufficient powers and obligations to lay down nano-specific requirements, such as dossier requirements, in order to carry out a proper risk evaluation and to determine compliance with the approval criteria before allowing the marketing and use of the nano-biocides.