



Information from Industry on Applied Nanomaterials and their Safety

Background Paper on Options for an EU-wide
Reporting Scheme for Nanomaterials
on the Market

prepared for

European Commission
DG Environment

milieu
ENVIRONMENTAL LAW & POLICY

RPA

September 2009

This Report has been prepared by Milieu Ltd. and RPA Ltd, under Contract NV.D.1/SER/2008/00105r. The views expressed herein are those of the consultants alone and do not necessarily represent the official views of the European Commission.

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1. Introduction

Nanotechnologies have been one of the most exciting areas of technical innovation in recent years, leading to an array of new manufactured nanomaterials as well as improvements in production processes. The wide range of applications is expected to grow in the near future, with many additional applications underway at the research stage or even near market access.

At the same time, the unique properties of manufactured nanomaterials have given rise to concerns about the potential adverse effects of some nanomaterials on human health and the environment. Regulators are grappling with how to deal with these risks. There is debate about how to maximize benefits from these exciting technological developments while at the same time ensuring a high level of protection for human health and the environment. In order to strike the right balance in this regard, regulators need more information about the potential uses of these materials and any associated risks.

The background paper on experiences with reporting mechanisms describes the efforts of several Member States including the United Kingdom and France to implement voluntary or mandatory schemes for collecting information on these new materials and their uses. This report considers options for an EU-wide reporting scheme for nanomaterials marketed within the EU, including the potential benefits, drawbacks and organisational (including legal) aspects of such a scheme.

2. What are the concerns

Nanomaterials are being developed and used because they may have new physico-chemical properties compared to the same chemical in its conventional form. There may be changes in chemical reactivity, mechanical properties (stiffness and elasticity), catalytic properties, and material and structural surface properties (strength, weight reduction, increased stability). Or they may have different optical, electrical or magnetic behaviours. These characteristics can lead to improved functionality in the materials used.

However, some of these new properties may also be potentially harmful to human health and the environment. While it is likely that many nanomaterials may not pose significant risks beyond those of the bulk material from which they have been derived, evidence is emerging that other nanomaterials may give raise to concern. For example, recent studies have indicated that rigid, thin and longer than 20 μm carbon nanotubes, if inhaled, may pose health risks similar to asbestos exposure¹. Moreover, silver in nano form – used in an increasing number of applications for its antimicrobial properties – may prove harmful to aquatic organisms or to wastewater treatment processes. In any case, information on the potential health and environmental risks posed by use of nanomaterials in various applications remains limited.

The OECD Working Party on Manufactured Nanomaterials is the main international forum for the development of internationally agreed standards and test methods for regulatory purposes. In relation to human toxicology, substantial progress has been achieved within the OECD-WPMN as part of (i) reviewing the current test guidelines; and (ii) a guidance

¹Poland, C.A., Duffin, R., Kinloch, I., Maynard, A., Wallace, W.A.H., Seaton, A., Stone, V., Brown, S., MacNee, W. and Donaldson K. (2008) Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study, *Nature Nanotechnology* Vol. 3, pg. 423 - 428

document for sample preparation and administration including dosimetry². In relation to ecotoxicology, some of the test guidelines for degradation and accumulation are not applicable to the testing of nanomaterials, while some others are applicable with limitations or under specific test conditions. General guidance documents should therefore be developed for testing the fate and degradation of nanomaterials. It is also important to perform a detailed review of the OECD bioaccumulation methods.

Another OECD-WPMN project on Safety Testing of a Representative Set of Manufactured Nanomaterials is aimed at developing a better understanding of the kinds of information on intrinsic properties that could be relevant for assessment of exposure and harmful effects of nanomaterials. Because of the particular relevance of the inhalation route for exposure to nanomaterials, and the anticipated difficulties in assessing the effects of nanomaterials by this route, a document on “Non-inhalation exposure methods for studies on the pulmonary toxicology of nanoparticles” was produced for use within the OECD sponsorship programme. However, this process is proving slow, and there is concern that the rapid developments taking place in the field of nanotechnologies may outrun the international efforts to develop the testing protocols needed to identify the risks posed by a particular nanomaterial.

3. Policy Context

The Commission Communication on regulatory aspects of nanomaterials³ from June 2008 concludes that current legislation, namely REACH-CLP⁴, covers *in principle* nanomaterials, but notes the need for a rapid improvement of the knowledge basis to support the work of regulators, particularly in areas underpinning risk assessments and risk management, such as data on uses and exposures throughout the lifecycle of nanomaterials or products containing nanomaterials, data on toxic and eco-toxic effects (as well as test methods to generate such data), and characterisation of nanomaterials.

The resolution from the European Parliament from 24 April 2009 commenting on the Commission Communication acknowledges that the use of nanomaterials and nanotechnologies promises important advances with multiple benefits in innumerable applications and can make an important contribution to the competitiveness of the European Union’s economy and to the achievement of the Lisbon strategy. On the other hand, the resolution notes that they potentially present significant new risks, possibly leading to increased toxicity in combination with unrestricted access to the human body, and possibly involving quite different mechanisms of interference with the physiology of human and environmental species. The resolution goes on to note that current discussions about nanomaterials are characterised by a significant lack of knowledge and information, there is no clear information about the actual use of nanomaterials in consumer products and a major debate relates to the possibility of assessing the safety of nanomaterials.

The Parliament resolution asks the Commission to review all relevant legislation within two years to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle. The Parliament considers it particularly important to address nanomaterials explicitly and at a minimum within the scope of legislation on chemicals, food, waste, air and water and worker protection. For REACH, the

² <http://webdomino1.oecd.org/comnet/env/wp-nano.nsf>

³ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on regulatory aspects of nanomaterials, COM (2008) 366 final.

⁴ Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (1907/2006/EC) and the Regulation on classification, labelling and packaging (CLP) (1272/2008/EC).

Parliament asks the Commission to evaluate the need to review REACH concerning *inter alia*:

- a) simplified registration for nanomaterials manufactured or imported below one tonne,
- b) consideration of all nanomaterials as new substances,
- c) a chemical safety report with exposure assessment for all registered nanomaterials, and
- d) notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles;

The Commission, together with the REACH Competent Authorities, established in March 2008 a subgroup on nanomaterials (CASG Nano) to assess the implementation issues of REACH to nanomaterials. Its mandate is to address relevant issues related to the REACH implementation. CASG Nano has agreed on a Work Programme for 2008-2012. The first document on nanomaterials in REACH was endorsed by the Competent Authorities in December 2008 and made available on the Europa website. The document reflects the current state of ongoing discussions within the subgroup on nanomaterials on how REACH applies to nanomaterials. Further updates are expected following continued discussions. Stakeholders are invited to take note of the content of the document and to follow its further development.

The Commission has also launched a REACH Implementation Project on nanomaterials (RIPoN). The project will provide further advice to the Commission and to the European Chemical Agency (ECHA) on how to address nanomaterials issues related to substance identification, information requirements and chemical safety assessment in the current guidance.

4. What information will we get via REACH-CLP & what might not be covered

The REACH and CLP Regulations provide the overarching mechanism by which EU regulators currently receive information about the substances on the EU market – whether on their own, in preparations or in articles - and their potential hazards to human health and the environment. Whereas under previous EU chemicals legislation the burden of proof was on the regulator to show that a chemical was harmful before control measures could be taken, REACH-CLP shifts the burden to manufacturers, importers and downstream users to ensure that the substances they manufacture, place on the market or use do not adversely affect human health or the environment. It also gives the right to downstream users, including final customers, to obtain information on whether hazardous substances are present in the products that they purchase.

While there are no provisions in REACH-CLP explicitly referring to nanomaterials, the Communication on regulatory aspects of nanomaterials clarifies that these are covered by the “substance” definition in REACH-CLP as nanomaterials can be considered as a form of a substance or a distinct substance. REACH requires manufacturers and importers placing a substance on the EU market to provide downstream users with a Safety Data Sheet (including hazard classification). The CLP Regulation requires manufacturers, producers of articles and importers who place on the market a substance to notify the classification and labelling of that substance to ECHA, generally by 3 January 2011. This should provide information on all hazardous substances on the European Market, independently of the tonnage in which the substance is placed on the market. However, companies are not expected to conduct additional testing for the classification, but to make use of available information, even if the tests were not carried out on the substance or mixture in the form(s) or physical state(s) in which it is placed on the market. Given that the hazards associated with substances can vary

between the bulk form and the various nanoforms (an example being the relatively benign bulk form of gold and the seemingly more toxic nano-gold), there may be cases where specific information on the hazards associated with the nano forms is not available and therefore not provided.

In the case where a substance is manufactured or imported in quantities greater than 1 tonne per year, it must be registered with a dossier of information on that substance, including health and safety information the volume of which is dependent on the tonnages. The total tonnage of a substance determines the tonnage trigger and respective obligations. Most currently known nanomaterials are probably produced together with the bulk form substance; the registration dossiers of the substance should therefore also cover nanomaterials.

In theory, the potential data gaps of the REACH-CLP reporting requirements refer to substances that are notified, but not registered and are put on the market in volumes less than one tonne per year or only registered in many years to come. Taking into account the fact that majority of nanomaterials on the market refer to nanoforms of phase-in substances commonly marketed above 1 tpa, the data gaps would in many cases relate to small companies specialized in nanotechnology applications.

There are, however, the additional concerns that 1) the nanomaterials may be registered but only at the end of the registration timetable and not necessarily with an obligation to perform a chemicals safety assessment or an exposure scenario and 2) the registrations will not with sufficient precision address the fact that the nanoforms may be different from the bulk form in terms of their intrinsic properties.

The first concern relates to the fact that the so-called “phase-in” substances (*i.e.*, substances that were considered 'existing substances' in the earlier chemicals legislation before the entry into force of REACH) can benefit from extended registration deadlines, provided they have been pre-registered. While substances manufactured or imported in volumes exceeding 1000 tonnes a year or being CMR (≥ 1 tpa) or PBT/vPvB (≥ 100 tpa) substances must be registered by 30 November 2010, substances manufactured or imported in volumes between 1000 and 100 tonnes a year do not need to be registered until 1 June 2013, and for volumes between 100 and 1 tonne a year until 1 June 2018. While this time lag before submission of registration dossiers is significant, the CLP Inventory and the first registration of the substance by the Lead Registrant should provide ECHA with existing data on potential hazards by 2011.

The second concern relates to the comprehensiveness of information submitted in the registration dossier. Information submitted at the time of registration should cover the substance not only in its conventional form, but also nanoforms that are manufactured or imported in case the nanoform properties differ from the bulk one. This information should include any specific properties exhibited by the nanoform of the substance, including any evidence of possible risks to health and/or the environment. If the substance is manufactured or imported in a quantity above 10 tonnes a year, it will need to be the focus of a chemical safety report that documents the results of a chemical safety assessment.

A chemicals safety assessment starts with a hazard assessment, which assesses hazards relating to human health, physiochemical properties, and environment as well as overall toxicity, *e.g.*, whether the substance is persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB). Should the substance meet the criteria for

classification as dangerous⁵ or PBT/vPvB, the chemicals safety assessment must also include an exposure assessment and a risk characterisation.

The exposure assessment involves estimating the potential human and environmental exposures to the substance for a range of conditions as defined in exposure scenarios for all uses of the substance identified by the registrant. The risk characterization then combines the information on any intrinsic hazards with the information on potential exposures to determine whether the potential risks from manufacture/import and/or uses of a substance exceed the threshold values designed for human health and environmental endpoints. In such a case, iterative steps are then undertaken to refine/improve risk management measures to ensure that risks are below the accepted level.

The concern with respect to conducting these various assessments for nanomaterials is that the criteria for the hazard assessment and the methodologies for the exposure assessment have been developed with the bulk form in mind. As such, there exists the possibility that they do not capture all properties and possible behaviours associated with the nano form. Nanomaterials having specific properties may in fact require a different classification compared to the substance's conventional form. However, as already noted above, in order to address the specific properties, hazards and risks potentially associated with nanomaterials, some of the current OECD test guidelines may have to be modified as they may not be adequate to determine the risks associated with the specific properties of certain nanomaterials. Without international agreement on what testing is needed for the particular characteristics of a substance in nanof orm, an additional information gap is likely to arise because of the lack of testing for those particular characteristics.

REACH-CLP require a manufacturer or importer to submit any new information concerning possible health and environmental risks to ECHA as and when a manufacturer or importer becomes aware of such information. Moreover, ECHA can request further information if there are concerns about a particular substance.

In sum, the information gaps regarding nanomaterials on the market could relate to the REACH-CLP reporting of substances that are notified, but not registered and are put on the market in volumes less than one tonne per year as well as information on potential risks of currently covered nanomaterials. The Task 1 report concluded that the majority of 'parent' substances for nanomaterials on the market would be registered by 1 December 2010. Since most of the current nanomaterials are produced together with their 'parent' substances, this should provide data on volumes of nanomaterials on the market, as well as existing data on their potential hazards, exposure and risk management. Potential shortcomings in data would, after the first registration, be mainly due to:

- low-tonnage (1-100 tpa) substances benefitting from a longer registration deadline;
- nanomaterials that are exempt from REACH, such as those based on polymers and bipolymers; and
- incomplete information in the hazard assessments on the physiochemical properties, toxicology and ecotoxicology, and potential risks of all nano-forms of a substance in the absence of specific guidance from ECHA and reflecting shortcomings in the current test guidelines for certain nanomaterials.

⁵ CLP Regulation (1272/2008/EC).

5. Building blocks for an EU-wide reporting mechanism on nanomaterials

5.1. What additional information is needed?

Efforts to date to compile a comprehensive overview of the nanomaterials and the products in which they are being used have had only partial success. Thus at a minimum, an additional EU-level reporting mechanism could collect information on nanomaterials being manufactured in or imported into the European market. This would necessarily include information on:

- Substances available in nanoform, how to identify them (CAS#, chemical name, nanoforms); and on
- Who is manufacturing and importing these nanomaterials, and in what quantities.

Second, it will be important to understand how these nanomaterials are being used. This will help the EU and its Member States to gain a better understanding of potential patterns of exposure, one of the key elements of risk assessment and management. An alternative approach towards getting an overview of the applications and uses for various nanoforms would be to request information on the functionality for which the particular nanomaterial has been engineered.

In addition, regulators may need information to help them develop an understanding of the potential hazards posed by particular nanomaterials.⁶ This would include information on:

- Physical-chemical properties (physical form & particle size range, surface area, amount & identify of any impurities, etc.);
- Fate and behaviour data (water solubility, bioaccumulation potential, persistence, etc.); and
- Health and environmental effects (data from acute and chronic toxicity studies; potential to penetrate cell membranes, reactivity).

While it is possible that this information may be found in the registration dossiers for those substances covered by REACH, it remains uncertain as to whether comprehensive information will be provided in the absence of clear guidance from ECHA. The publication of the first registration dossiers by ECHA in November 2009⁷ will provide an opportunity to clarify exactly what information Lead Registrants have included on nanoforms. This should be a step towards clarifying whether additional reporting is required for substances that are covered by REACH-CLP, as should information prove to be comprehensive, additional reporting for such substances would then be redundant.

Ideally, the information received by the regulator would be sufficient to enable a chemicals safety assessment of nanomaterials. However, as noted earlier, internationally agreed test methods for determining all intrinsic hazards that might be posed by nanomaterials are not yet in place. Without such test methods, it may be more cost-effective and timely to focus on setting in place measures aimed at minimising human exposures in the workplace or for

⁶ See OECD: Working Party on Manufactured Nanomaterials, Report of Project Five: Cooperation on voluntary schemes and regulatory programmes, ENV/CHEM/NANO(2008)8.

⁷ http://www.eu-reach.ca/index.php?option=com_content&view=article&id=204:first-list-of-reach-registered-substances-to-be-published-in-september&catid=42:news&Itemid=78

consumers, as well as any releases to environmental media where there may be cause for concern.

Thus another key type of information which should be collected by an EU-level reporting mechanism would concern risk management measures under consideration or already in place, such as health surveillance and monitoring systems, any uses of personal protective equipment (and their effectiveness), and any safety data sheet information specific to nanomaterials. A proactive and precautionary approach to risk management helps to address concerns about knowledge gaps about the potential risks of nanomaterials, until more detailed scientific data concerning intrinsic hazards and exposure become available. Finally, any EU-level reporting mechanism should request submission of all other information held by the manufacturer, importer, research institute or downstream user which could be relevant for assessing and managing potential risks.

Furthermore, in view of the rapid developments taking place with respect to nanotechnologies, it would be important to provide for submission of any new information on behaviour or on health and environmental effects as soon as it becomes available.

In order to avoid imposing an excessive administrative burden upon companies dealing with nanomaterials and considering the uncertainty of potential risks, it should be sufficient in the short term to require only readily available information rather than requiring specific testing to take place that might involve great costs. Requests for additional testing could be considered at a later stage when they can be tailored to the properties of specific nanomaterials.

5.2. Who should provide this additional information?

In order to obtain a comprehensive set of data that would enable the authorities to gather an overview of the nanomaterials on the market and thus of the potential exposure to these materials, information is needed from producers and importers. Their data, particularly on types of nanomaterials, quantities and uses, would enable the authorities to gather an overview of the nanomaterials on the market and thus of the potential exposure pathways. The Commission could consider requesting information from all companies placing a product on the EU market in order to get as comprehensive a picture as possible of the substances in circulation.

Information on the properties of manufactured nanomaterials should be provided by the parties most suited to provide this information, i.e., the producers of the substances. However, many nanomaterials are imported into the EU from third countries and it would therefore be necessary to include importers in any future reporting scheme, in order to obtain a realistic overview of the quantities of nanomaterials on the EU market and their properties.

In addition, it may also be relevant to obtain information from companies and research institutes conducting research and development on nanomaterials, particularly with respect to pre-commercialisation research and development. Not only will this provide useful information about potential hazardous properties of the nanomaterials they have developed, but it could assist in identifying upcoming applications. This will help to define potential risks as well as build understanding concerning future risk management needs, including with respect to occupational exposures.

5.3. Who could manage the information & how would it be used

The objective of gathering information on nanomaterials on the market is to provide a comprehensive and representative understanding of what manufactured nanomaterials are in commerce and any risk-relevant information that may be available, so that appropriate regulatory action can be taken should it be required. This implies that there must be active assessment and analysis of the information received, both via the REACH-CLP reporting and via any additional reporting scheme, with a view towards informing policy decisions.

Another reason for an additional information gathering scheme could be to ensure that the public has access to the information needed to participate in informed discussions about possible regulatory interventions, as discussed in the next section, while respecting data confidentiality as required to protect innovative developments. It makes sense therefore that all existing reporting mechanisms have been established and managed by government authorities.

There are three possible options for the management of the potential additional information gathering:

- through ECHA through the technical system designed for the current REACH reporting;
- through Joint Research Centre (JRC) in Ispra through an additional reporting system similar to REACH-IT; or
- through a private company with special arrangements for managing confidential business information and intellectual property rights.

At EU level, the ECHA has been established precisely to gather and manage data on the substances being placed on the European market, via the registration mechanism. It would be logical therefore for the ECHA to be the agency to also manage an additional EU level reporting scheme and to compile information on nanomaterials on the market and their safety. However, it already has a huge data management task at hand with the 2,7 million pre-registrations received at the end of 2008, and with the first registration deadline under REACH and CLP notification of all hazardous substances, including their forms coming up during 2010. Therefore, it would be necessary to assess the additional costs of extended data collection, processing and management as well as helpdesk functions related to companies not yet familiar with REACH provisions and IT systems.

Another possibility could be for the additional information gathering and management by the Joint Research Centre at its facility in Ispra, Italy. The JRC in Ispra played an important role in management of European chemicals data until the establishment of the ECHA, and it might be able to take on a similar foundation role in setting up an additional EU-level reporting mechanism for nanomaterials. It would be necessary to assess the costs of the establishment of an additional IT system.

Still another possibility would be to outsource the data collection and data management task to an external company, which would then gather and collate the additional data and forward the results to the relevant EU institutions. It would be necessary to find an agreement of the intellectual property rights aspects and confidential business information requirements, as well as costs of establishing a new data IT system, and the training of the personnel.

For both the latter two options, it would necessary to coordinate with ECHA regarding assistance provided to companies, as well as on actual data collection and management as

well as provision of them to ECHA for their final report on nanomaterials on the market and their safety.

The information would be used to inform the decision making process of the regulatory authority about nanomaterials. An understanding of what nanomaterials are on the market, in what volumes and for what uses will provide regulators with a picture of potential exposure pathways. Information on risk management may reveal current practice in managing risks and may reveal something about the kinds of risks anticipated by actors in the supply chain. In sum, the information will be invaluable for considering whether or not particular regulatory measures are required to manage risks associated with nanomaterials.

5.4. Who else will have access to the information?

Another balance that can be difficult to strike is that between the principle of public access to information held by governments, particularly when related to risks to health or the environment, and the need to protect the commercial interests of undertakings, especially in new competitive sectors where significant investments are made. The REACH Regulation recognises the essence of confidential business information and specifies provisions for that while guaranteeing the access to the EHS data. REACH mentions in its recital 117 that EU citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals, specifying the content of the definition of environmental information. REACH also includes specific provisions concerning information on chemicals and documents held by the ECHA.

For example, REACH Article 119 establishes an obligation for ECHA to make some information on substances publicly available through the internet, free of charge. This would include *inter alia* the name of the substance, its classification and labelling, physiochemical data concerning the substance and on pathways and environmental fate; the result of each toxicological and ecotoxicological study; any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with REACH Annex I, and any guidance on safe use provided in accordance with Sections 4 and 5 of Annex VI. REACH also specifies that certain additional information, including total tonnage band and the information contained in the safety data sheet, is to be made available publicly over the internet except if justification had been submitted as to why disclosure was potentially harmful for the commercial interests of the party concerned.

At the same time, Article 118 specifies what will be considered confidential business information, i.e., disclosure of which would normally be deemed to undermine the protection of the commercial interests of the concerned person. This includes (a) details of the full composition of a preparation; (b) the precise use, function or application of a substance or preparation, including information about its precise use as an intermediate; (c) the precise tonnage manufactured or placed on the market; and (d) links between a manufacturer or importer and his distributors or downstream users. Unless where urgent action is needed to protect human health, safety or the environment, such as in emergency situations, this information will not be disclosed.

Given the coverage of nanomaterials by REACH and the similar nature of the information, it is recommended that similar rules be applied to access to additional information on nanomaterials. This would be in line with the Better Regulation approach promoted by the European Commission, and would avoid any unnecessary administrative burden upon companies having to be familiar with two separate sets of rules on access to information for information relating to chemical substances. Any additional information other than that

specifically mentioned under REACH as confidential would then be made public, ensuring the balance between the public's right to information and the need to protect commercial interests in a very competitive and innovative market. More precisely, the information on the full composition of a preparation or the precise use or tonnage, for example, would be reported to the Community institutions, but would not be available to the public as a whole.

Note that the Community institution or body is obliged to consult a third party when its documents are concerned, in order to assess whether one of the exceptions to the disclosure of information are applicable, unless it is clear that the document shall or shall not be disclosed. Consequently, in cases of doubt regarding the specific rules of doubt, the third party will always be consulted before any information is made public.⁸

6. Legal aspects of a reporting scheme

As outlined earlier in this paper, one of the concerns with respect to whether the necessary information on nanomaterials will be gathered under REACH-CLP relates to the length of the registration period allowing registration dossiers to be submitted for substances on the market in quantities between 1-100 tonne until 1 June 2018. Another concern relates to the comprehensiveness of registration dossiers in addressing the intrinsic properties and potential hazards of nanoforms. Any effort to amend REACH to take into account the specific properties etc. of manufactured nanomaterials would have to be brought in line with the timelines for the next REACH review, as it is unlikely that a separate amendment to REACH would be made specifically for this aspect. This would imply a considerable delay, given the years needed to go through the EU legislative process and the additional time needed to ensure implementation and enforcement infrastructure. One option to consider that could be set into place quite quickly is that of a voluntary agreement.

6.1. Voluntary agreement to report

In its Action Plan "Simplifying and Improving the Regulatory Environment"⁹, the Commission stressed that appropriate use can be made of alternatives to legislation without undermining the provisions of the Treaty or the prerogatives of the legislators. In particular, it mentions alternatives such as self-regulation, co-regulation, voluntary sectoral agreements, or the open coordination method.

A voluntary agreement at the EU level can be initiated by a representative group of the relevant industry and be acknowledged by the Commission, an approach called self-regulation, or it can be based on a legislative instrument initiated by the Commission called co-regulation. Specific attention has been given over the past years by the EU institutions to the use of environmental agreements, as they were considered by some to be a useful and less burdensome option in this area of EU law.¹⁰ Environmental agreements should aim at achieving the environmental objectives of the EC Treaty. This approach is however often criticised for being less democratic and transparent than the legislative instruments available at the EU level. The legal framework for these alternatives to 'classical' legislation has been

⁸ Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention to Community institutions and bodies, which applies Regulation (EC) 1049/2001 to all Community institutions and bodies and sets out the practical arrangements of and exceptions to this right.

⁹ COM (2002) 278 final.

¹⁰ Commission Communication on Environmental Agreements at the Community level within the framework of the Action Plan on the simplification and improvement of the regulatory environment, COM(2002) 412 final.

elaborated in some more depth in the 2003 Interinstitutional Agreement on better law-making.¹¹

Self-regulation consists, as the word indicates, of that situation in which economic actors or civil society regulate their own activities. As such, self-regulation starts from a stakeholder initiative, which can then be acknowledged by the European Commission. For example, the voluntary agreement for the car industry, often been referred to as an example of voluntary initiatives at the EU level, followed this approach.¹² Self-regulation does not involve any legislative acts. It is initiated by the stakeholder, sometimes following an encouragement of the EU institutions, and can be acknowledged by the Commission through a Commission recommendation or a simple exchange of letters. Any later monitoring obligations of the results of the agreement can be introduced on the basis of a Council Decision.

The advantage of self-regulation is its flexibility, as it can easily be adapted to better suit the needs or to address new challenges, and is often less costly and faster to implement than legislative initiatives.

The clear drawback of this approach is the complete absence of any legally binding instruments setting up the scheme and objectives, as the system legally consists of a mere exchange of non-binding instruments. As such, it is not clear that a reporting scheme based on self-regulation would capture all the information needed by regulatory authorities to assess the risks. Participation would be limited to those companies that chose to sign the agreement establishing the scheme and as such would likely capture only a small number of the larger and more visible actors on the market who could absorb the costs and seek benefits through publicity to promote their participation in the scheme. The incentives for smaller companies with a lower public profile to participate would be very limited as the costs of reporting would tend to outweigh any benefits from publicity. In addition, such a scheme would likely operate within only one group of actors in the nanomaterials market, such as producers, and fail to draw in other actors such as importers or R&D institutes.

Finally, an initiative that is designed and delivered by private actors independent from the regulatory gives the industry exclusive control over the type of information to be reported. The regulator therefore loses the ability to shape the scheme and determine data requirements.

The option of **co-regulation** places voluntary agreements in a regulatory context. In other words, a legal framework is established to determine the essential frame, objectives, deadlines, monitoring mechanisms to verify any results and, if applicable, enforcement measures. The voluntary agreement then implements, in a more practical manner, the legal act and sets out the practical aspects of the agreement. The main frame remains a piece of EU legislation but an important component is voluntary. Apart from the area of social dialogue, for which there is a legal basis for such agreements in the EC Treaty,¹³ the legal nature of voluntary agreements following the co-regulation approach in other sectors and policies is unclear.

From a positive point of view, the initiative for these voluntary agreements can come from both the Commission and the particular stakeholder, *i.e.* industry in the framework of this report. However, as the legal status of such agreements is not entirely clear and legislation

¹¹ Interinstitutional agreement on better law-making, *O.J.* C 321 , 31 December 2003, p.1

¹² Note however that the results were not satisfactory and the EC had to enact legislation later on establishing the measures that the car industry needed to take to reduce CO₂ emissions.

¹³ Article 139 EC Treaty

needs to be adopted in order to endorse and frame the agreement, it seems that only little advantage can be offered by this approach compared to the adoption of classical legislation (of course on the condition of strongly involving stakeholders in the legislative process).

In either case, it is of maximal importance to respect the institutional balance between the European Commission, the European Parliament, the Council and consultative bodies in order not to touch upon the fundamentals of the EU decision-making process. In addition, any voluntary approach must not only include incentives for participation, it also needs to make sure it is representative. Thus it should include a minimum target for participation and a deadline as a threshold for adopting legislation, should the voluntary system fail to reach its targets. For example, an agreement could specify that if after six months or one year a certain number of respondents or a minimum amount of information had not been gathered, the Commission would immediately table a legislative initiative.

It is worth noting that, so far, the EU's experiences with voluntary environmental agreements have not been promising. In 1998 the EU signed an agreement with the European, Japanese and Korean car industries in which they committed to reduce CO₂ emissions from cars sold in the EU to an average 140 g/km by 2008 for European manufacturers and 2009 for Japanese and Korean ones. An accompanying action provided for a mandatory CO₂ emission label on cars, to enable consumers to inform themselves and decide accordingly.

Though significant improvements in car emissions occurred after this agreement, it became clear in 2005 that the initially fixed objective would not be achieved: from 186 g/km in 1995, the average CO₂ emission had fallen to 163 in 2004. In view of these disappointing results, in 2007 the Commission proposed new legislation requiring reductions in CO₂ from cars, and Regulation (EC) No 443/2009 setting emission performance standards for new passenger cars was adopted two years later.

The EU's experience with the voluntary agreement for CO₂ reductions from passenger cars mirrors to a certain extent the disappointing number of responses received by the voluntary reporting mechanisms for gathering information on nanomaterials on the market set up by the UK and the USA. As the background paper describes, the UK's Voluntary Reporting System received only thirteen data submissions during the two-year trial, eleven from industry and two from academia voluntary. Similarly, an interim report on the status of the USEPA's voluntary Nanoscale Materials Stewardship Programme (NMSP) noted that nearly two-thirds of the chemical substances from which commercially available nanoscale materials are based and some 90 per cent of the different nanoscale materials that were likely to be commercially available were not reported.

6.2. Additional mandatory reporting scheme

Another option to consider would be the establishment of an additional mandatory EU-level reporting scheme for nanomaterials on the market, including sanctions for non-compliance with reporting requirements. This could take place as an extension of the framework of REACH-CLP or even be partially voluntary, with the possibility of requesting additional toxicological information that might not be readily available at the date of entry into force of the relevant legislation. The system could be designed to include an incentive to encourage concerned companies to undertake specific toxicological or other testing of the nanomaterial.

A mandatory reporting mechanism could be established by an EU-wide regulation, either as part of the upcoming REACH review or as a separate regulation. The development of a

separate regulation would need to consider how such an additional system could be made compatible with REACH-CLP (e.g. common tools for submission). Such regulation would need to set out the information requested from industry, the body that would collect and collate the data, how they would use the information as well as any other aspects of a practical nature, such as access to information, confidentiality and incentives. It would be relevant to include a reporting form in an annex to the regulation. Among the drawbacks would be the administrative burden, both on the regulated industry and the regulators, and the length of time it could take to set in place

In moving forward with a mandatory scheme, regulators would also need to increase their scientific understanding of the particular risks associated with nanomaterials due to their intrinsic properties, with the aim of developing and achieving consensus on adjusted OECD test guidelines tailored to nanomaterials. Obtaining this information will require additional scientific investigation and close cooperation with independent scientific research institutes.

The advantages of an additional mandatory reporting scheme could include the likelihood of getting a much more comprehensive picture of what nanomaterials are on the market, in what quantities and for what uses, and so on. Manufacturers, importers, downstream users and R&D institutes would also have more certainty concerning what information they would need to gather and report. Depending on the scope set for the confidential business information issues and the evaluation process, other stakeholders such as consumers could have the possibility of better access to the relevant information, including health and safety data.

Another advantage of a mandatory EU-level scheme would be the avoidance of barriers to the free movement of goods. With France well along in establishing a mandatory reporting scheme for nanomaterials and other Member States also looking at this option, there is a risk of distortions occurring in the internal market. A mandatory reporting system at EU level would ensure that all manufacturers, importers, downstream users, etc. would be subject to the same requirements, and thus help to preserve the internal market.

7. Incentives for reporting

In any future additional reporting mechanism, it will be important to encourage and facilitate industry's participation through a variety of incentives, aiming at increasing the benefits for respondents to participate in the scheme, on the one hand, and at minimising the administrative burden on the other hand.

The incentive to comply with mandatory mechanisms lies of course in the threat of sanctions for non-compliance. For voluntary mechanisms, incentives for participation are a significant factor in the failure or success of such programmes to meet their objectives. Suggestions made by stakeholders as to how to encourage participation in voluntary reporting mechanisms on nanomaterials include, for instance, the streamlining of reporting requests with already existing obligations to report.

An important incentive for participation in additional reporting schemes consists of the possibility of influencing regulatory initiatives to take account of particular difficulties and situations that are of relevance to them. It is important for companies to describe their regulatory needs and thus inform and influence governmental decisions, whether concerning the design of future measures or to reduce the administrative burden that new measures would imply. A demonstration of corporate social responsibility, through reporting the properties of

their substances, would provide a ground for the balanced consideration of their views during the adoption of regulatory initiatives.

An additional incentive for participation relates to the insurance of risks and future liability claims for environmental and product liability. It is important to underline here that under REACH, all manufacturers, importers and downstream users of substances in nanoform and the products in which they are used are responsible for ensuring that such applications of nanomaterials will not harm human health or the environment.

Several insurance companies active in insuring the risks associated with emerging technologies have noted that it is a great challenge for this sector to quantify the potential risks of a new technology of which so many factors are yet unknown. A number of frontrunner firms in the insurance industry, including Lloyds¹⁴, Swiss Re¹⁵ and Munich Re¹⁶, have published materials examining the risks associated with nanomaterials and flagging the many unknowns. For the insurance industry, it is of vital importance to understand the losses a new technology could entail. While such future losses are usually calculated on the basis of reasonable extrapolations and historic evidence, the lack of information on manufactured nanomaterials and their entirely unique properties make it impossible for insurance companies to assess the actual risks the development of some of these materials could entail and the potential losses the sector could face. As one analyst noted, “a common theme in nanotechnology risk assessment is that there is lack of data to understand the exposure or even the hazard itself.”¹⁷ In brief, current thinking and research may not be sufficiently sophisticated to capture potential risks of nanomaterials.

A sufficient understanding of the potential risks of manufactured nanomaterials will not be found in the immediate future. Therefore, insurers will adopt a worst case scenario approach to assess the potential losses that could occur when determining the premiums for insurance to be paid by manufacturers. However, more information about the properties of a specific nanomaterial will generate a better understanding of the potential risks and could, at least for some manufactured nanomaterials, potentially reduce the premiums companies have to pay to ensure their activities with respect to nanomaterials against future liability. In addition, the contribution by companies to a greater understanding of the properties and risks of these materials by regulatory authorities may be considered as a demonstration of their will to collaborate and to prevent unsafe products from continuing to be on the market. This could reduce the future liability claims they would face if their product proved to be hazardous.

The lack of knowledge concerning potential risks is also expected to influence the attitudes of the financial services towards investment in the nanomaterials market. In their joint report on investigating a positive relationship between environmental, social and governance considerations and portfolio performance across a range of sectors, the UNEP Financial Initiative and Mercer include a chapter on nanotechnologies. The authors (from Oddo Securities) recognise the new opportunities associated with nanomaterials but they “view

¹⁴ Lloyds, 2007, “Nanotechnology: Recent developments, risks and opportunities,” Lloyds Emerging Risks Team Report, http://www.lloyds.com/NR/rdonlyres/B9C7371E-83D4-49DD-8268-5D6C800FBDDF/0/ER_Nanotechnology_Report.pdf.

¹⁵ Swiss Re, “Nanotechnology: Small matter, many unknowns,” Swiss Re Risk Perception, http://www.swissre.com/resources/31598080455c7a3fb154bb80a45d76a0-Publ04_Nano_en.pdf.

¹⁶ Munich Re, “Nanotechnology – what is in store for us?” Munich Re.

¹⁷ Baxter, D. 2008, “Nanotechnology: An insurer’s perspective,” Lloyds of London, <http://www.safenano.org/NanoInsurancePerspective.aspx>.

nanotechnology as a sensitive subject strategically in terms of potential applications, and from the perspective of potential exposure to societal and HSE risks.”¹⁸

A final consideration for participation in an additional reporting scheme is of a more practical nature. Some companies involved in manufacturing nanomaterials may be small or medium enterprises and the administrative burden created will have a discouraging effect if the additional reporting requests are too extensive. In addition, smaller companies may not have in-house knowledge on how to adequately fulfil their reporting requirements or be aware of any such initiatives. For these reasons, industry should be involved in developing the reporting requirements, information to be reported should be carefully selected and the forms used for reporting should be easily accessible and easy to fill out. In addition, efficient information campaigns will be necessary to make industry aware of the benefits of reporting and the modalities of the scheme.

8. Drawbacks of an additional reporting scheme

In considering whether an additional reporting scheme for nanomaterials is required, it will be necessary to undertake a thorough review of all possible costs and benefits. The benefits relate primarily to an increased understanding amongst regulatory authorities regarding the nanomaterials on the market and the potential associated risks, as a basis for information decision making on possible next steps. While a detailed examination of costs goes beyond the scope of the current document, it is possible to identify some potential drawbacks, including administrative burden, both on the regulated industry and the regulators. Regarding costs on industry, it would be relevant to consider the nature of the affected companies and consider the provision of assistance to SMEs to facilitate their participation and reduce the cost burden. With regards to administrative costs on the regulatory authorities, it will be important to consider how the costs will be minimised and ultimately through which means they will be met.

Furthermore, it would be necessary to agree on how to deal with issues relating to intellectual property rights, as well as to define parameters around confidentiality issues. Moreover, a series of detailed questions would need to be resolved, for example regarding a detailed definition of nanomaterials and minimum thresholds for reporting.

¹⁸Palmier, H. & Desmartin, J.P. “Nanotechnologies: There are still plenty of opportunities and uncertainties at the bottom,” In: UNEP FI and Mercer, (2007) *Demystifying Responsible Investment Performance*, http://www.unepfi.org/fileadmin/documents/Demystifying_Responsible_Investment_Performance_01.pdf

9. Conclusions

The review of the REACH-CLP system with respect to manufactured nanomaterials undertaken by RPA and presented in the Task 1 Report suggests that reporting under REACH-CLP is unlikely to lead to a full provision of the range of information that regulators need to assess the risks to public health and the environment potentially posed by nanomaterials. Specific information gaps relate to the possibility of certain nanomaterials being produced in amounts that imply that while they are covered by CLP notification requirements, they do not fall within the registration requirements of REACH. Another concern is the possibility that in the absence of specific references in the REACH Regulation and associated guidance, companies will fail to provide information on the specific uses of nanomaterials in registration dossiers.

Moreover, given the current shortcomings in scientific knowledge on the specific properties of nanomaterials, there still remain uncertainties over the potential risks associated with nanomaterials. This is partially due to the preliminary nature of the conclusions on the appropriateness of the current OECD test guidelines and the lack of internationally agreed ISO/CEN standards for some of these properties. Finally, there are concerns that the assessment criteria applied in hazard assessment and exposure assessments may not be tailored to capture all specific properties and potential risks associated with nanomaterials. While ECHA is in a position to request additional information in specific cases, it seems that this would apply to exceptional cases rather than all cases where a substance is manufactured in nano forms, since relying upon specific requests for more data whenever a registration included a nano form of the substance would entail a high administrative burden for ECHA.

This leads Milieu to the conclusion that the REACH-CLP system may not be sufficient for gathering all the information needed to address the potential risks of some nanomaterials. Without a better understanding of the manufactured nanomaterials on the market or about to be commercialised, EU and Member State regulators will continue to have difficulties fully determining whether additional regulatory measures are needed to ensure protection of human health and the environment and, if so, which measures. Therefore, an additional EU-level reporting system for nanomaterials on the market could be justified, either as part of the upcoming REACH review or as a separate reporting system.

An additional or modified EU-level information gathering exercise will require careful consideration in terms of the actual shortcomings in the current REACH-CLP reporting, costs and benefits of the possible additional EU-level data gathering, its legal basis (extended REACH-CLP, separate system) and optimal methods for the generation and collection of additional data from companies, as well as aspects relating to intellectual property rights and confidential business information.

The question is whether such a system should be voluntary or mandatory. An advantage of a mandatory scheme is the quality of information, in other words regulators can be surer that they will get the information they need. A voluntary system can be established relatively quickly, but the experiences so far have not been promising (see background paper on experiences with reporting schemes). As discussed above, the flexibility and the prospect of being able to gather information on these new materials is an attractive prospect. However, if a voluntary reporting mechanism is put in place and it fails to collect the information needed, another two years will be needed at the least to establish a mandatory mechanism.

The analysis of some of the incentives for securing widespread voluntary participation in an additional EU-level nanomaterials' reporting scheme indicates that these incentives are the

same as for earlier national schemes which did not prove sufficient to ensure good enough participation of British and American manufacturers and importers of nanomaterials. Therefore it is difficult to foresee how an EU-level voluntary system could achieve a better participation rate. The fact that the US is moving towards a mandatory reporting scheme is another indication of the difficulty of using voluntary instruments

Perfect information about nanomaterials and their potential risks is not possible to achieve, particularly given the rapid technological developments in this field. Any EU-level reporting system will need to be dynamic and evolving. In view of the experiences of the US and the UK, it seems that a way forward could be to consider the options for a mandatory information-gathering scheme. However, the EU legislative process is lengthy. This opens the door for considering a two-track approach. Until the legislation to establish a mandatory scheme can be enacted, it would be possible to move ahead with a voluntary information-gathering scheme. Setting up and implementing a voluntary scheme could be a useful way to go through the initial practical steps of deciding what information to collect, how to gather it and how to manage this information - while at the same time moving forward on a proposal for establishing a mandatory scheme.