STUDY

Policy Department
Economic and Scientific Policy

NANOMATERIALS IN CONSUMER PRODUCTS

Availability on the European market and adequacy of the regulatory framework

RIVM/SIR Advisory report 11014

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Executive Summary

This report, describing a study on the use of nanomaterials in consumer products, discusses potential risks for human health and the environment due to the use of nanomaterials in these kinds of products. The main objective of the study is to analyse the adequacy of the current regulatory framework to address these potential risks.

Although different terms and definitions are used in the scientific literature, the term nanomaterials is used here to indicate engineered materials which contain structures of less than 100 nm for at least one dimension. These materials include free nanoparticles as well as nanomaterials that are attached to or incorporated into the matrix of larger structures. Naturally occurring and unintentionally produced nanomaterials are not included in this definition.

Nanomaterials are used in a wide variety of applications (e.g. pharmaceutical, food and consumer products) and technologies (e.g. information and communication, energy and transport technology). Nanomaterials are developed and used because they have new superior properties, such as improved electromagnetic properties, catalytic properties, pharmacokinetic and targeting properties, strength, stiffness, stability, etc. The development of new nanomaterials and applications also stimulates innovation, competitiveness, employment and the economy. In addition, nanomaterials may also be important for environmental sustainability. Environmental benefits may include better means for an improved and more efficient power supply, leading to the conservation of nature and natural resources, a reduction in air pollution and, indirectly, to a sustainable environmental protection.

Just as for all newly developed compounds or products, attention should be paid to potential risks for human health and the environment. This report records the availability of data required to assess the potential risks of the use of nanomaterials in consumer products including: a) an inventory of the available consumer products containing nanomaterials, b) an analysis of the potential risks of these products for the human health and the environment, and c) an assessment of the adequacy of the regulatory framework to address these risks.

Insight into the availability of different types of consumer products containing nanomaterials on the European market is necessary to assess the adequacy of the current regulatory framework. The potential risks of these products depend on the potential exposure and hazards of the nanomaterials in these products. Information on the available products was obtained from different sources to estimate the scale of expected exposures and potential hazards, and to identify other important aspects in the risk assessment. The most important product categories in Europe are expected to be motor vehicles and electronics and computers, followed by personal care and cosmetics, and household and home improvement.

Important characteristics of nanomaterials known for use within consumer products were identified, as well as the important exposure routes and potential toxic effects for humans and the environment. The knowledge on the potential toxicity of nanomaterials, however, is not sufficient to determine the potential risks of consumer products containing nanomaterials. Nevertheless, the available knowledge on the main characteristics of potential exposure is generally sufficient to indicate product categories which have a relatively high or low potential exposure. Potentially high exposures are expected from consumer products containing free nanoparticles with direct exposure to humans or environmental organisms (e.g. cleaning and personal care products, and cosmetics).

In contrast, low potential human exposures are expected from nanomaterials in an embedded form, e.g. electronics and computers (excluding ink and paper), cooking utensils, sporting goods and coatings. Because the knowledge on exposure (and toxicity) to nanomaterials in consumer products is limited, this ranking should not be used as evidence for high exposures or the lack thereof, but as an indication of potential exposures and prioritisation.

Since the safety of (chemical substances in) consumer products is not regulated by one single piece of legislation that covers all these products, several different regulatory documents were used to assess the adequacy of the current framework. None of these documents mentions specific requirements for nanomaterials. Implicitly, the use of nanomaterials is regulated by most of these documents by making industry responsible for the safety of the chemicals or products they produce, thus enabling the authorities to take action if products pose a risk to health, safety or the environment. It is, however, questionable if new risks arising from the presence of nanomaterials will always be recognised by the regulatory system, since the knowledge on the safety of nanomaterials (exposure assessment, toxicity thresholds, test schemes, etc.) is limited. More knowledge is therefore needed to assess the extent to which the current regulations actually address any potential risks. This will necessitate significant progress being made in exposure assessment and testing methodologies, followed by development of guidance documents.

Introduction

1.1 Introducing nanomaterials

What are nanomaterials?

In the scientific literature, different terms and definitions are used to indicate small-scale structured materials, including nanomaterials, nanostructured materials, nanoparticles, nanosized particles, engineered nanostructured materials etc. (The Royal Society and The Royal Academy of Engineering Nanoscience, 2004; Tran et al., 2005; Oberdörster et al., 2005). In this report the term nanomaterials is used to indicate engineered materials which contain structures with a size of less than 100 nm in at least one dimension. These materials include large-scale materials with integrated nanostructures (attached, incorporated, or fixed into the matrix of the large-scale material) and free nanoparticles (including nanowires, nanotubes, nanodots and nanoparticles). Naturally occurring and unintentionally produced nanoparticles, also known as ultra-fine particles (e.g. by volcanic or man-made combustion processes) are not included in this definition. In this report nanomaterials only refer to engineered or deliberately manufactured materials of which some characteristics are described in paragraph 3.3 of this report.

What are nanomaterials used for?

Nanomaterials are used in a wide variety of applications including medical, pharmaceutical, agricultural and material applications (construction, coatings, textiles, etc), applications in information and communication technology, military technology, energy, chemistry, transport, food, consumer products and even environmental remediation applications. This report focuses on the use of nanomaterials in consumer products (non-food products intended for the consumer).

Why are nanomaterials used?

Nanomaterials are developed and used because they have new improved properties, such as improved pharmacokinetic and targeting properties, optical properties, catalytic properties, porosity, electromagnetic properties, mechanical properties (stiffness and elasticity) and material and structural surface properties (strength, weight reduction, increased stability, improved functionality, such as "easy-to-clean", "anti-fog", "anti-fingerprint" or "scratch-resistance"), etc. These properties are generally indicated as the specific "physico-chemical characteristics" of nanomaterials.

What are the benefits of nanomaterials?

Next to benefits from these improved properties, nanomaterials may also be important for environmental sustainability. Environmental benefits may include better means for an improved and more efficient power supply, resulting in the conservation of nature and natural resources, a reduction in air pollution and indirectly to a sustainable environmental protection (Nanoforum, 2005). The development of new nanomaterials and applications also stimulates innovation, competitiveness, employment and the economy.

How about potential risks?

Within the field of nanotechnology the main emphasis has, so far, been on the development of the technology and new applications and not on the potential risks for human health and the environment. However, the specific properties which make nanomaterials so interesting may also lead to specific risks. For instance, smaller particles have a greater surface area per unit mass than larger particles, which may render them more reactive and possibly more toxic. In addition, the small particle size may allow nanomaterials to travel more easily through the body compared to large particles. Unfortunately, so far very little is known about the occurring human and environmental exposures and potential hazards of nanomaterials. More information about the specific properties and potentials risks of nanomaterials can be found in chapter 3.

1.2 Background of this report

The Committee on the Environment, Public Health and Food Safety of the European Parliament was seeking a party who was able to provide an analysis and an assessment of the adequacy of the current regulatory framework to address the risks to human health and the environment due to the use of consumer products containing nanoparticles. After a negotiated call for tender for an external study on "Adequacy of the current regulatory framework to address the risks to human health and the environment of consumer products containing nanoparticles", the study was awarded to the joint tender of the Wageningen Centre for Bionanotechnology for Food and Health innovations (WUR BioNT) and National Institute for Public Health and the Environment (RIVM).

1.3 General objectives of the study

The general objective of the study is to provide an analysis and an assessment of the adequacy of the current regulatory framework to address the risks to human health and the environment due to the use of consumer products containing nanoparticles. The analysis addresses the following key issues:

1. Inventory of consumer products (substances, preparations and articles) in the EU that contain engineered nanoparticles;
2. Adequacy of the current regulatory framework to address the risks to human health and the environment of such consumer products (detection methods, methods for risk assessment);
3. Suggestions for adaptations to the regulatory framework (if found necessary).

1.4 Information to the reader of this study

It is recommended to start by reading the executive summary, which gives a brief summary of the entire report. A more elaborated description of the conclusions, recommendation and limitations of this study is given in the final chapter (Chapter 5).

In Chapter 1 through 4 more details can be found with respect to:

1) nanomaterials in general and the background of this study;
2) the available consumer products on the EU market
    - Table 2.7 gives an overview of the different types of products;
3) the main characteristics determining the potential risks
    - in Table 3.4 potential exposures for product categories are ranked;
4) the adequacy of the current regulatory framework to address the potential risks.

2 Consumer products available on the EU market

More insight in the availability of different types of consumer products containing engineered nanomaterials is necessary to assess the adequacy of the current regulatory framework. Therefore an overview of these consumer products available on the EU-market was made.

2.1 How to find consumer products available on the EU market?

An overview of the nano-consumer products available on the EU-market has proved to be difficult to obtain due to the following pivotal reasons:

- Reports on market research are only available at a charge (see Table 2.1).These expenses were not anticipated within the project budget. Therefore analyses of these reports are not included in this project. However, some general statements from summaries of these reports and other sources are included in the present report;
- Most existing inventories of nanotechnology products contain globally available products. This makes it difficult to distinguish what is specifically available on EU-market.

Table 2.1: Available publications concerning the nanotechnology market

Publishing date	Title	Author/publisher	Price
Sept 2006	The Nanotech Report, 4th Edition	Lux Research	US $ 4795
Aug 2006	Nanotechnology: A Realistic Market Assessment	BCC Research	US $ 4250
Aug 2006	The World Nanotechnology Market (2006)	RNCOS	US $ 1400
Jan 2006	World Nanotechnology Market - Investor Guide™ (2006-2010)	Venn Research Inc.	€ 1605
Aug 2005	Nanotechnology in Switzerland 2005-2006	Institute of Nanotechnology	€ 704
June 2005	Research, Applications and Markets in Nanotechnology in Europe 2005	Institute of Nanotechnology	€ 4400
June 2005	Nanotechnology for Consumer Products	BCC Research	US $ 3950
May 2005	Research, Applications and Markets in Nanotechnology in the UK 2005	Institute of Nanotechnology	€ 1760

Since it would be too time consuming to obtain information on the availability for each individual consumer product mentioned in one of the inventories, the following strategy was followed:

- Use information from (summaries of) the available reports on market research and other sources concerning:
    - the market share of the EU in nanotechnology
    - the number of EU patents in nanotechnology
    - the global value of nano inputs by type of consumer products
- Obtain information from industry by:
    - asking manufacturers to estimate the market share of nanomaterial-containing consumer products within each product category
- Use information from existing inventories on nanotechnology products by:
    - using the number of different consumer products in each category of the existing product inventories as an indication for the importance of the different product categories. An overview of the consulted inventories is given underneath (see Table 2.2). In addition information from several publications and internet sites was used.

Table 2.2: Consulted inventories on nanotechnology (consumer) products

Results from an RIVM project on nanomaterials in non-food products on the Dutch market carried out for the Dutch Food and Consumer Product Safety Authority (Unpublished data)
The Nanotechnology Consumer Inventory of the Woodrow Wilson International Center for Scholars (http://www.nanotechproject.org/44).
The Nanoforum Report: Nanotechnology in Consumer Products by Gleich et al., 2006 (http://www.nanoforum.org/dateien/temp/Nanotechnology%20in%20Consumer%20Products.pdf?19012007151421)
The Nanotechnology Product Directory of Nanoshop (http://www.nanoshop.com/index.php)

2.2 Market research

2.2.1 Market share of the EU in nanotechnology

Nanotechnology is not a technology that can easily be identified and quantified. By using nanotechnology many products can be modified and new products can be developed, but the contribution of nanotechnology to these products is not easily quantifiable.

Lux Research (2004 cited in Hullmann, 2006) predicted a global market share for nanotechnology products of 4 % of general manufactured products in 2014, with nanotech in 100% of the PCs, in 85% of the consumer electronics, in 23% of the pharmaceuticals and in 21% of the automobiles. In the same report, the estimated global sales of products incorporating emerging nanotechnology were broken down by region of origin (Figure 2.1). The most important region of origin for the sales of nanotechnology products is Asia and the Pacific region, followed by the USA and Europe on similar levels.

While Europe is predicted to have a small but continuous increase of its share, the US is expected to decrease until 2008 and increase afterwards, Asia and the Pacific undergo the opposite development. A possible explanation for these developments is that products that primarily originate from strong Asian companies (such as PCs, mobile devices or vehicles) are expected to dominate the world market in the nearest future. After 2008, pharmaceuticals based on nanotechnology are expected to become stronger and these are dominated by US companies (Hullmann, 2006).

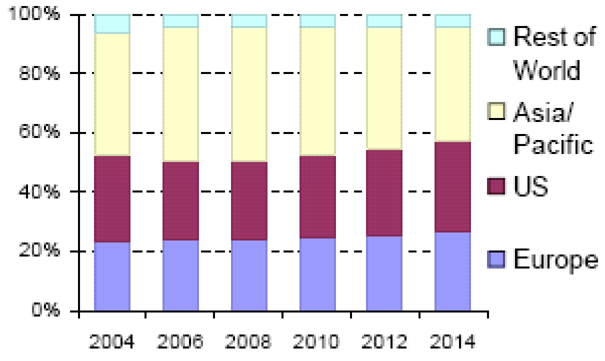

Figure 2.1: Global sales of products incorporating emerging nanotechnology by region – forecast in percent. (Source: Lux Research, 2004 cited in Hullmann, 2006)

2.2.2 EU patents in nanotechnology

Another way to analyse the economic potential and to identify the most promising or active fields of nanotechnology is by analysing the number of patents. Patents reflect the ability of transferring scientific results into technological applications. The European Patent Office (EPO) has developed a methodology in order to identify and classify nanotechnology patents and patent families at most important patent offices worldwide (Hullmann, 2006). Table 2.3 shows the top 10 countries in these different patent families in 2003.

Table 2.3: Top 10 patenting countries worldwide in each nanotech field, 2003

nanotechnology (y01n)

Appl. Country	No.	Inv. Country	No.
USA	1136	USA	1177
Japan	461	Japan	600
Germany	199	Germany	200
UK	59	South Korea	73
France	52	UK	68
South Korea	48	Canada	38
Netherlands	37	France	37
Canada	32	Taiwan	29
Italy	16	Netherlands	29
Taiwan	15	Switzerland	21
ranks 11-25:			
Singapore	13	Israel	19
Belgium	13	Sweden	19
Switzerland	13	Italy	19
China	13	Singapore	17
Sweden	12	Belgium	16
Israel	12	Denmark	14
Denmark	10	China	14
Australia	7	Australia	10
African IPO	7	African IPO	7
India	6	Finland	7
Finland	5	India	6
Spain	3	Russia	5
Brasil	3	Spain	4
Austria	3	Cyprus	3
Russia	3	Brasil	3
Cyprus	2	Austria	3

nanobiotechnology (y01n2)

Appl. Country	No.	Inv. Country	No.
USA	146	USA	188
Germany	25	Germany	27
Japan	14	Japan	17
France	11	Canada	12
Canada	10	UK	10
Italy	8	France	9
UK	6	Italy	9
India	6	India	6
Israel	3	Israel	4
South Korea	2	South Korea	4

nanoelectronics (y01n4)

Appl. Country	No.	Inv. Country	No.
USA	422	USA	413
Japan	192	Japan	258
Germany	55	Germany	60
Netherlands	28	South Korea	40
South Korea	24	Netherlands	19
Canada	11	Switzerland	12
France	10	UK	11
UK	8	Sweden	10
Sweden	6	Taiwan	10
Taiwan	5	Canada	10

nanomaterials (y01n6)

Appl. Country	No.	Inv. Country	No.
USA	303	USA	345
Japan	114	Japan	146
Germany	65	Germany	61
UK	21	UK	21
France	17	South Korea	21
South Korea	15	Taiwan	15
Belgium	8	France	14
Taiwan	8	Canada	9
Canada	6	Belgium	7
China	5	Singapore	7

nanodevices (y01n8)

Appl. Country	No.	Inv. Country	No.
USA	103	USA	106
Japan	30	Japan	35
Germany	21	Germany	19
Switzerland	8	Switzerland	9
South Korea	7	South Korea	8
Singapore	4	Singapore	4
Sweden	4	Sweden	4
Israel	3	Israel	4
France	3	UK	3
Netherlands	2	France	3
Spain	2	Netherlands	3
China	2		

nanooptics (y01n10)

Appl. Country	No.	Inv. Country	No.
USA	171	USA	162
Japan	102	Japan	120
UK	26	UK	25
Germany	16	Germany	18
France	10	South Korea	9
South Korea	6	Canada	8
Canada	6	Denmark	7
Israel	5	Italy	6
Singapore	5	Singapore	6
Denmark	5	Israel	5

nanomagnetics (y01n12)

Appl. Country	No.	Inv. Country	No.
USA	214	USA	191
Japan	112	Japan	166
Germany	29	Germany	27
Netherlands	10	South Korea	7
France	6	Netherlands	5
South Korea	5	France	3
China	2	China	2
India	2	Finland	2
Israel	1	Israel	2
Brasil	1	India	1
Singapore	1	Brasil	1
		Singapore	1
		Belgium	1
		Taiwan	1

"Appl Country" refers to country in which the company is located. "Inv Country" refers to the country in which the researcher is living. Note: the numbers of patents are rounded, ranking refers to fragmented numbers. (Source: EPO, 2006 cited in Hullmann, 2006).

Among the European countries reported in Table 2.3, Germany, UK and France rank high in many nanotechnology fields, but are particularly strong in nanobiotechnology (Germany and France) and nanooptics (UK). Other European countries rank high in nanoelectronics and nanomagnetics (The Netherlands) and nanodevices (Switzerland).

2.2.3 Global value of the nanotechnology inputs used to produce consumer products

According to a report from BCC Research Group[1] from 2005, nanoparticles (used chiefly in the production of automobile catalytic converters and tyres) accounted for more than 90% of the nanotechnology inputs used in the production of consumer products in 2004. Nanomaterials used in Organic Light Emitting Diodes (OLEDs) of mobile phone handsets and other small appliances accounted for most of the remaining part of nanotechnology inputs (Electronics.ca Research Network, 2005).

Excluding food and beverages, the global value of the nanotechnology inputs used to produce consumer products is estimated at $6.0 billion in 2005, and projected to reach $9.5 billion in 2010 (see Table 2.4). Among the various product categories, the share of passenger cars is estimated to be nearly 73% of the total nanotechnology inputs in 2005, followed by household chemicals with 11%.

[1] This BCC report is available at charge at: http://www.bccresearch.com/nan/NAN037A.asp

The share of passenger cars is expected to drop to 53% as electrical and electronic goods is expected to increase its share from 8% in 2005 to 30% in 2010 (Electronics.ca Research Network, 2005).

Table 2.4: Global value of nano inputs by type of consumer product (excluding food and beverages), through 2010

Product segment/year	2004		2005		2010	
	$ Millions	%	$ Millions	%	$ Millions	%
Passenger Cars	4284	73,0	4381	72,5	5026	52,7
Electrical and electronic goods	495	8,4	490	8,1	2859	30,0
Household Chemicals	635	10,8	683	11,3	982	10,3
Others *	452	7,7	490	8,1	678	7,1
Total All Products	5866	100,0	6044	100, 0	9545	100,0

***Includes Photographic Equipment and Film, Textiles and Apparel, Personal Care Products, Sporting Goods and Consumer Optical Products. (Modified from: BCC, 2005 cited in Electronics.ca Research Network, 2005)**

2.3 Information obtained from manufacturers

To obtain a better overview of the extent and nature of available consumer products containing nanomaterials, at least one manufacturer of each important product category was approached with the following questions:

1) Does your company produce consumer products containing nanomaterials?

2) If yes, could you please fill out the table included in the attachment of this e-mail for those types of products that contain nanomaterials? An example on how the table can be filled out is given in the first row of the table underneath.

Table 2.5: Example table to be filled out by manufacturers

nr	product type	nanomaterial	available in EU	estimated % of products within this product type that contain nanomaterials	
				your company	your branch
1	e.g. shampoo	Silver	yes, UK no	approximately 50% of our shampoos contain nanomaterials	approximately 15% of the available shampoos contain nanomaterials

The manufacturers were informed that their response would be treated anonymously and confidentially and that no company or brand names would be included in the research report. If the manufacturers were not able or willing to answer the questions, they were asked to indicate why they could not provide the information.

Of the eight approached manufacturers, six responded. Most of the responding manufacturers did not give detailed information on the different types of products they produce, but only provided some examples of nanomaterials applied. Most of them did not give any information on the percentage of products containing nanomaterials. Only a car manufacturer gave a rough estimation of the percentage of passenger cars that contain nanomaterials in their exterior coatings. Among the more expensive cars, approximately 90% of the cars are coated with coatings or paints which contain nanomaterials. An overview of the information obtained from the manufacturers can be found in Table 2.6.

Table 2.6: Information on consumer products containing nanomaterials obtained from manufacturers

product category	**product type**	**nanomaterial**	**available in EU**	**estimated % of products within this product type that contain nanomaterials**
Electronics & computers				
Household products & home improvement	Waterproofers	Silica		Incidental use
	Paints	Titanium dioxide		
	Glass cleaners		yes	
Personal care products & cosmetics	Sunscreens	Titanium dioxide		The use is declining
	Tooth care		yes	
Motor vehicles	Passenger cars	Nano-coatings	yes	90% of the more expensive cars
Miscellaneous	Powders	Silica		
		Colour pigments		

It appeared difficult to obtain detailed information from some of the manufacturers because:

- they did not want to give away confidential or commercially sensitive information
- the definitions of ´nanomaterials´ and ´consumer products´ were not given
- there was only limited time available

Based on the limited information obtained from the responding manufacturers, no conclusions with respect to extent and nature of the use of nanomaterials in consumer products can be made.

2.4 Existing product inventories

There are several existing inventories of nanotechnology (consumer) products. Most of these inventories contain a wide variety of globally available consumer products, from the well-known sunscreen products to less known applications, like umbrellas. In some products, nanomaterials are incorporated into solid materials (e.g. carbon nanotubes in golf balls) while other products consist of fluids containing nanoparticles (e.g. titanium dioxide particles in sunscreen products). The way the nanomaterials are incorporated into the consumer products is very important with respect to the potential exposure and therefore the potential risks of consumers as well as the environment. This will be further discussed in paragraph 3.3.

Based on the existing product inventories mentioned in Table 2.2, the following product categories are identified:

- electronics and computers,
- household products and home improvement,
- personal care products and cosmetics,
- motor vehicles,
- sporting goods,
- textiles and shoes,
- filtration, purification, neutralisation and sanitisation,
- miscellaneous.

Within these categories, several subcategories and some examples of products were identified (see Table 2.7). In the existing product inventories, the product category personal care and cosmetics generally contains the largest number of products, followed by household and home improvement products, textile and shoes and miscellaneous. Within all sub categories skin care products and coatings generally contained the largest number of products. Coatings (water and/or dirt repellent or antibacterial coatings) and skin creams (or lotions or oils) demonstrate the largest variety of products and also many different suppliers.

For the examples of consumer products (mentioned in Table 2.7) the availability on the European market was examined using the results of an RIVM project on nanomaterials in non-food products on the Dutch market[2].Within this project, for several consumer products information on:

a) the country of origin,
b) the location of distributors,
c) the brand name, and
d) the possibility to order the product on line

was obtained to identify those products expected to be available on the Dutch market. Using this information, those products known or expected to be available on the European market

[2] This project was carried out for the Dutch Food and Consumer Product Safety Authority (unpublished data)

were identified and printed in italic in Table 2.7. Within most product categories some examples of consumer products are available in Europe. For some products it is not clear if they are available on the European market yet, but most of these products are expected to become available in Europe in the very near future and many (if not all) products may already be available for European consumers by ordering via internet.

2.5 Limitations

It is not possible to obtain a complete overview of all consumer products containing nanomaterials that are available on the European market, within the time and resources available for this project, since:

- there are products with the claim "nano" on the market that do not contain nanomaterials and have not been produced with nanotechnology either
- not all producers advertise their products as such and there is (at present) no legal obligation to inform consumers or label products that contain nanomaterials
- the amount of available products containing nanomaterials is large and fast growing
- it is difficult to find out in which countries or parts of the world the products are available, although it could be assumed that via Internet there is almost a world-wide availability of all kinds of consumer products

Therefore, an overview of the different product categories and subcategories was made, including a limited list of examples of products for each of these categories (see Table 2.7). The list of examples probably does not contain all the available products within each category and only includes consumer products which are expected to contain nanomaterials based on the information from one of the existing product inventories. Since it was not confirmed if the products actually do contain nanomaterials, some of these products may not contain nanomaterials.

Table 2.7 Product categories with examples of products*

Category	Sub category	Examples of products
Electronics and computers	Mobile (audio) devices	*MP3 players*, mobile phones
	Large household appliances	*Refrigerators, washing machines, irons, vacuum cleaners*
	Computer hardware	*Processors and chips (e.g. game consoles), memory- and hard disks*, cooling fans, *computer mouse*
	Displays	*LEDs in flashlights, OLEDs in displays*
	Energy related	Solar cells, batteries
	Ink and paper	*Ink for electronic applications, photo paper*

Category	**Sub category**	**Examples of products**
Household products and home improvement	Cleaning products	Dish, hand and fruit washing emulsions, rubber gloves, *disinfectant sprays or liquids*, fabric softeners, *lens, display and optics cleaners,* odour removers
	Cooking utensils and kitchenware	*Cutting boards, table-, cooking and kitchen ware,* teapots, porcelain, baby mugs, baby milk bottles, bottle brushes, frying oil reforming catalytic devices, bowls (also for pets), food storage containers (anti-bacterial), food storage bags, *plastic or aluminium wrappings*
	Construction materials	Locks, door knobs, handles, water taps (anti-bacterial), *glass (self-cleaning),* wooden floors, *cement and concrete products,* toilets, *tiles*
	Paint	*Paint (kitchen, bath, insulation, radio frequency blocking)*
Personal care products and cosmetics	Sun cosmetics	*Sunscreen lotions, sunscreen creams, sunscreen oils,* sunscreen powder, hair protection spray
	Baby care products	Baby sunscreen, pacifiers
	Hair care	Shampoo, conditioner, hair gel/styling products, hair re-growth products
	Skin care	*Razors, facial masks,* facial steamers, *skin creams/lotions/oils/sprays/powders*, deodorant, whitening lotions, *fragrances*, wet wipes, soaps, body wash, shower gels, etc.
	Oral hygiene	*Tooth paste*, teeth cleaner, tooth brush
	Make-up and nail care	Make-up instruments and brushes, make-up removal and cleaning products, lipstick, mascara, make-up base and foundations, blush
	Over the counter health products	*(Sticking)plasters, home pregnancy tests*, thermal patches, joint and muscle pain relief cream, *condoms,* mosquito repellent
Motor vehicles	Exterior	*Glass and windshields, painted or coated exteriors,* tyres
	Other	Engine oils, fuels and *catalysts*
Sporting goods	Rackets and sticks	*Rackets,* bats, golf clubs, *hockey sticks, skis,* snowboards, *bicycle frames and other bicycle parts*
	Balls	Bowling balls, tennis balls, *golf balls*
	Other	Wetsuit, fishing lure, horse shoes

Category	Sub category	Examples of products
Textiles and shoes	Clothing	*Socks*, *pants*, *shirts*, pullovers, vests, shorts (also water shorts), *jackets*, elbow and knee guards, underwear, *gloves*, cap, ear bands, earmuffs, scarf's, ties, heal cushions
	Other textiles	Sheets, *bedding and mattresses*, pillows and cushions, *umbrellas, suitcases and bags*, plush toys, *other fabrics*
	Shoes	Insoles, *shoes*
Filtration, purification, neutralisation and sanitisation	Air or water filtration and purification	Air filtrations and purification devices, masks and respirators, water filtration or purification devices
	Air conditioning	*Air Conditioning and heating systems*
	Sanitizers and neutralisers	Air Sanitizers or neutralizers, chemical (gas/liquid) neutralisers
Miscella-neous	Coatings	*Anti fogging coatings, self-cleaning coatings, water and dirt repellent and antibacterial, waxes, lubricants, protective layers for displays (anti-scratch)*
	Others	Diamonds, watch chain (anti-bacterial), sunglasses

* Products printed in italic are known or expected to be available on the European market

2.6 Conclusions

An overview of important products categories identified from the different information sources is given in Table 2.8. Table 2.8 shows that global market research on the market share of (consumer) products indicate that electronics and computers and motor vehicles are expected to become the most important product categories, followed by household products. European patents indicate that European countries are active in electronics and computers. Although European countries are also active in several other nanotechnology fields, these are difficult to match to specific product categories.

The information obtained from manufacturers was too limited to indicate the share of nanomaterial-containing products within each product category or the availability of nanomaterial-containing consumer products in Europe.

Existing global product inventories indicate that the product category personal care and cosmetics is the most important, followed by household and home improvement products, textile and shoes and miscellaneous. Within the sub categories skin care products and coatings generally contained the largest number of products and also demonstrated the largest variety of products and suppliers.

Table 2.8: Important products categories identified from the different information sources

	Information sources		
Product categories	**Global market (consumer) products**	**European patents**	**Existing product inventories**
Electronics and computers	++	+	
Household products and home improvement	+		+
Personal care products and cosmetics			++
Motor vehicles	++		
Sporting goods			
Textiles and shoes			+
Filtration, purification, neutralisation and sanitisation			
Miscellaneous			++

+ and ++ indicate that this product category is identified as an important (+) or a very important (++) product category with respect to:

the market share and/or value of nano inputs (global market column),
the number of European patents (European patent column) , and
the number different products and suppliers (existing product inventories column).

It seems likely that the availability of consumer products in Europe roughly follows the global market trends, especially when also availability of products via internet is taken into account. Considering the information from the different sources mentioned in Table 2.8 together, the most important products categories in Europe are therefore expected to be motor vehicles, electronics and computers, followed by personal care and cosmetics and household and home improvement.

3 Potential risks for human health and the environment

As is required for all newly developed compounds or products, attention should be paid to the potential risks of nanomaterials for human health and the environment. The availability of data required to assess the potential risks was studied and described in the following chapters.

3.1 How to identify potential risks?

Identification of potential risks is a prerequisite for a proper assessment of adequacy of a regulatory framework. The potential risks are determined by the potential exposure to and hazards of the nanomaterials used in consumer products.

Using the existing product inventories used in the first part of the study and other data sources mentioned below, the nanomaterials known to be used within consumer products were identified. Subsequently a general description is given of the available information on:

- important characteristics of these nanomaterials,
- important exposure routes and characteristics in determining the exposure,
- the potential toxicity and important characteristics in determining this toxicity.

Finally, this information was used to indicate product categories which have a high priority for further examination of potential risks.

With respect to the potential risks of nanomaterials several reports and literature reviews are available. The following sources were used to identify the potential risks:

- The existing product inventories used in the first part of the study and the results of this part;
- The Royal Society and The Royal Academy of Engineering (2004) - "Nanoscience and nanotechnologies: opportunities and uncertainties";
- UK Government research (2006) - "Characterising the potential risks posed by engineered nanoparticles";
- SCENIHR (2006) - "The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies: Modified Opinion (after public consultation)";
- Oberdörster et al. (2005) - "Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particle";
- Borm et al. (2006) - "The potential risks of nanomaterials: a review carried out for ECETOC";
- Kreyling et al. (2006) - "Health implication of nanoparticles";
- Tran et al. (2005) - "A scoping study to identify hazard data needs for addressing risks presented by nanoparticles and nanotubes";

- Umwelt Bundes Amt (2006) - "Nanotechnology: Opportunities and Risks for Humans and the Environment";
- Ostiguy et al. (2006) - "Health Effects of Nanoparticles"; and
- a literature and internet search.

3.2 Nanomaterials known to be used in consumer products

It is almost impossible to make a good overview of which nanomaterials are used in which (category of) consumer products. It is hampered by a lack of information on the use of nanomaterials in consumer products. This information is lacking because manufacturers of consumer products are not obligated to label or notify whether their products contain nanomaterials. However, several nanomaterials known to be used in consumer products and some (categories) of consumer products in which these nanomaterials are used were identified (see Table 3.1). The list of nanomaterials known to be used in consumer products was obtained from several sources (Environmental Working Group, 2007; Allianz, 2006; Aitken et al, 2006). Information on (categories) of consumer products in which these nanomaterials were used was obtained from the different inventories and some other sources (The Royal Society and Royal Academy of Engineering, 2004; Nanoforum, 2006; Thomas et al., 2006; Woodrow Wilson database, 2007). Although this list is not complete, it gives an indication of which type of nanomaterials are used in which category of consumer products.

Table 3.1: Nanomaterials known to be used in consumer products

Nanomaterial	Product category	Examples of consumer products
Metal oxides		
Titanium dioxide (TiO_2)	Personal care products and cosmetics Household products and home improvement Textiles and shoes	Sunscreen Self-cleaning glass Cloths
Zinc dioxide (ZnO_2)	Personal care products and cosmetics	Sunscreen/tanning oil, lip treatment, lipstick
Iron oxides (FeO, Fe_2O_3, Fe_3O_4)	Personal care products and cosmetics	Lipstick
Aluminium oxide (Al_2O_3)	Electronics and computers Motor vehicles	Solar cells Catalytic exhaust gas converter
Silica (SiO_2)	Textiles and shoes Sports goods	Textiles Tennis racket, tennis balls
Zirconia (ZrO_2)	Electronics and computers	Scratch resistance coatings

Nanomaterial	Product category	Examples of consumer products
Cerium oxides (CeO_2, Ce_2O_3)	Motor vehicles	Fuel additive
Metals		
Silver (Ag)	Electronics and computers Household products and home improvement Textiles and shoes Filtration, purification, neutralisation and sanitisation	Optoelectronics, anti-bacterial electronics Cleaning products, food storage containers Socks Air filtration and conditioning devices
Gold (Au)	Personal care products and cosmetics	Home pregnancy test Catalytic applications
Nickel (Ni)	Electronics and computers Personal care products and cosmetics	Batteries Wound dressings
Cadmium telluride (CdTe)	Electronics and computers	Electronic and optical devices
Gallium arsenide (GaAs)	Electronics and computers	Electronic and optical devices
Nanowires (e.g. different metals – including silicon, cobalt, gold and copper- , oxides, sulphides and nitrides)	Electronics and computers	Electronic equipment
Organic nanomaterials		
Nano-vitamins	Personal care products and cosmetics	Bronzer or highlighter, eye shadow, glitter, acne treatment, facial cleanser, facial moisturizer, sunscreen or tanning oil
Nanoclays	Household products and home improvement Motor vehicles Sporting goods	Construction materials Car bumpers Tennis balls

Nanomaterial	**Product category**	**Examples of consumer products**
Carbon nanotubes (CNT) (single-wall SWNT or multi-wall MWNT)	Textiles and shoes Electronics and computers Sporting goods Household products and home improvement Filtration, purification, neutralisation and sanitisation Miscellaneous	Clothes Electronic equipment, batteries, fuel cells Bicycle frames, baseball bats, badminton rackets, hockey sticks Concrete products Water purification devices Coatings , paper, film
Fullerenes (e.g. C_{60})	Personal care products and cosmetics Electronics and computers Miscellaneous	Anti-aging, facial moisturizer and around-eye cream Electronic equipment Additive to grease
Nanospheres, nanosomes, liposome's, delivery systems and capsules filled with e.g. arnica, barley-germ, wheat-germ, germal ii, lyphazome, retinol, alpha-bisabolol, calendula, centella asiatica, ginseng, witch hazel, sodium lactate, urea, hyaluronic acid, fulvic acid, vitamins (pro-vitamin b5, vitamin a, vitamin e)	Personal care products and cosmetics	Around-eye cream, facial anti-aging, moisturising products, nail treatment products, body firming lotion, anti-itch or rash cream, skin fading or lighting products, hair-loss treatment, body wash, sunscreen and tanning oil, and after sun products
Quantum dots containing e.g. CdSe, ZnS, Te, etc.	Electronics and computers	LEDs
Carbide (tungsten, tantalum, titanium, silicon) (also silicon nitride)	Household products and home improvement Motor vehicles	Cutting tools Springs, ball bearings, valve lifters
Carbon black	Motor vehicles	Tyres

3.3 Characteristics of nanomaterials

At nanoscale, the physical, chemical, and biological properties of materials differ in fundamental and relevant ways from properties of individual atoms and molecules of bulk materials (Thomas et al., 2006). These deviating properties make them technologically interesting, but may also lead to altering risks for the human health and the environment when comparing the hazards and risks of nanomaterials to the same substances as large scale or "bulk" materials. Two types of nanomaterials can be distinguished:

1. those where the structure itself is a free particle (nanoparticles), and
2. those where the nanostructure is an integrated into larger materials or structures (integrated nanostructures).

Nanoparticles

A nanoparticle consists of a solid or liquid nanostructure present in the air as an aerosol (mostly solid or liquid phase in air), a suspension (mostly solid in liquids) or an emulsion (two liquid phases). Important characteristics of nanoparticles with respect to their potential risks for health or environment are those properties which determine their fate and behaviour in the environment, humans and other organisms, including:

- particle size,
- surface area per unit mass,
- shape,
- solubility and dissolution,
- reactivity,
- coagulation or aggregation state,
- chemical composition (including coatings and purity),
- others.

Integrated nanostructures

Nanomaterials can be attached to or incorporated or fixed into the matrix of larger materials or structures. Although very little is known on the possibility of adverse effects due to interactions between biological systems and materials containing immobilised nanostructures, the SCENIHR3 concluded that there is at the moment no reason to suppose that these immobilised nanomaterials pose a greater risk for health or environment than the larger scale materials, as long as the nanomaterials are not released from the (surface of) the larger object (SCENIHR, 2006). Therefore the most important characteristics of integrated nanomaterials are those that determine their interaction with living systems and their release from the material or structure they are attached to or incorporated into.

[3] SCENIHR, Scientific Committee on Emerging and Newly Identified Health Risks, managed by DG SANCO (Directorate Health and Consumer Protection) of the European Commission

These include:

- surface area,
- surface structure,
- reactivity,
- resistance to wear and tear,
- degradability ,
- solubility,
- chemical composition (of the nanomaterial and the material or structure they are attached to or incorporated into),
- others.

Some of the characteristics mentioned above are important for the potential exposure while others are important for the potential toxicity. The influence of the same characteristic may be different for the potential exposure as compared to the potential toxicity. With respect to particle size, for example, smaller particles may aggregate more easily than larger particles, which may decrease their availability for exposure. On the other hand, smaller particles have a greater surface area per unit mass than larger particles, which may render them more reactive and possibly more toxic. The influence of the same characteristic may also be different for different organisms. These different influences make it impossible to generalise the potential impact of each characteristic on the potential risks for human health and the environment. Therefore the potential risks of nanomaterials for human health and the environment should be evaluated on a case by case basis.

3.4 Main exposure routes and characteristics

In this report, the term exposure is used to indicate the 'external contact' with nanomaterials that humans or organisms in the environment may directly or indirectly experience when a consumer product with nanomaterials is produced, used or disposed. The uptake and behaviour of the nanomaterials in humans and other organisms is considered under the potential toxicity. The main characteristics for human and environmental exposure were identified using several reviews (Tran et al., 2005; Borm et al., 2006; Tsuji et al., 2006 and Wiesner et al., 2006).

Human and environmental exposure to nanomaterials used in consumer products may occur during several phases of the life cycle of those consumer products, i.e. the synthesis of the nanomaterials, the production and use of the consumer products, and the release of nanomaterials to the environment (through industrial emissions or disposal of consumer products) (Figure 3.1).

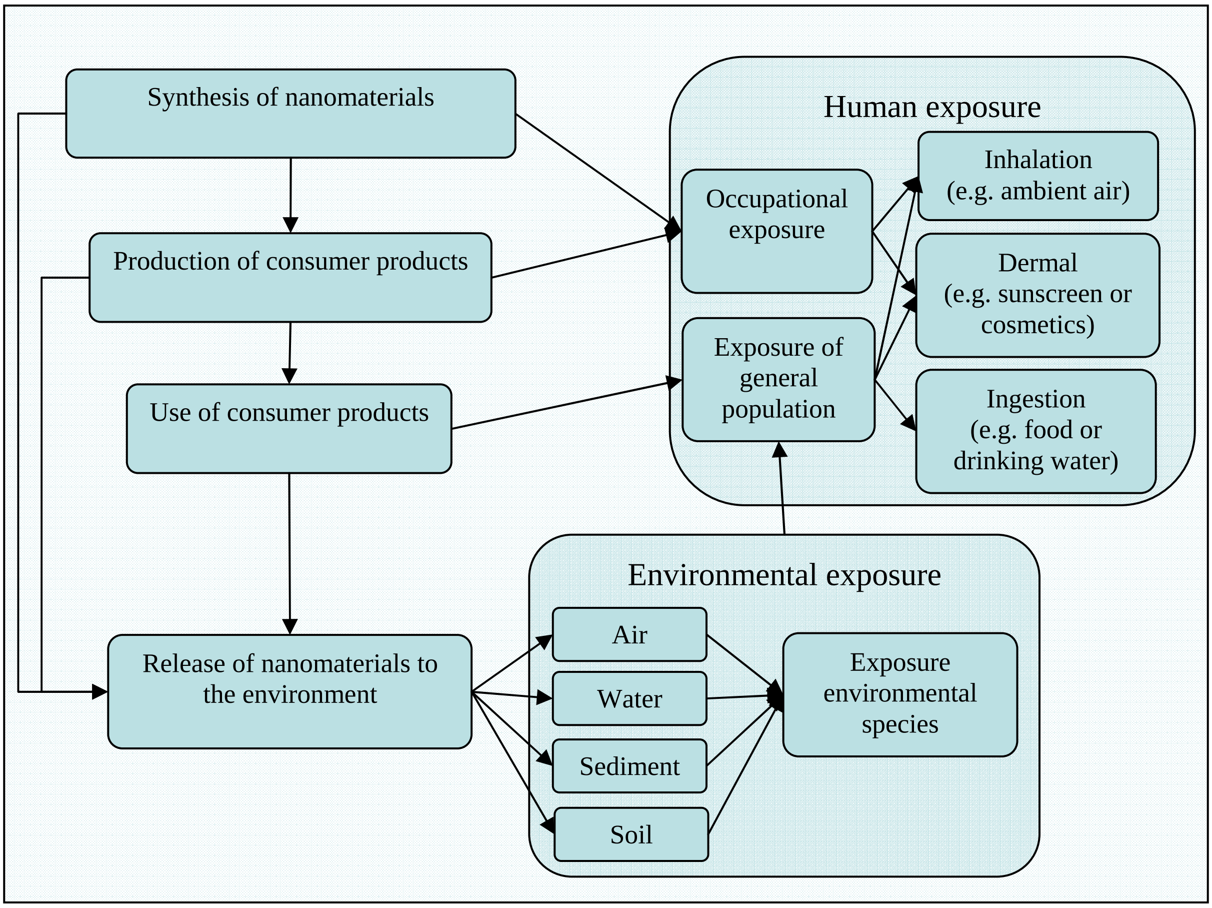

Figure 3.1: Potential exposure in the different life cycle phases of nanomaterials used in consumer products (Modified from Tsuji et al., 2006 and Wiesner et al., 2006).

3.4.1 Human exposure

Within the different life cycle phases, different exposure routes are important. Exposure may occur when air containing nanomaterials is inhaled (inhalatory route of exposure), when nanomaterials come in contact with the skin (dermal route of exposure) and when nanomaterials are ingested (oral route of exposure).

During the synthesis of the nanomaterials and the production of consumer products, the most important route of (occupational) exposure to humans is the inhalatory route of exposure (depending on the extent of aggregation in the air), followed by the dermal route of exposure (occupational exposure). Although occupational exposure may be very important, this is beyond the scope of the present report.

During the use of the consumer products, the most important route of exposure depends on the characteristics of the consumer products. Exposure during the use of consumer products containing nanomaterials integrated into larger materials or structures (e.g. carbon nanotubes incorporated in bicycle frames) is negligible compared to exposure during the use of consumer products that contain free nanoparticles (e.g. cosmetics), as long as the nanomaterials are not released from (the surface of) the larger object. In this respect, there are no important routes of exposure during the use of consumer products containing nanomaterials integrated into larger materials or structures.

For consumer products which contain free nanoparticles the most important route of exposure mainly depends on the physical form and application of the consumer product. For consumer products that produce aerosols containing nanomaterials (i.e. by the use of sprays), inhalation is the most important route of exposure. For consumer products which contain nanoparticles in a suspension or an emulsion which are applied directly to the skin (i.e. sunscreens and other cosmetics), dermal exposure is the most important route of exposure. The oral route of exposure is usually less important when using consumer products, with the exception of consumer products in the category oral hygiene (e.g. tooth paste) and consumer products applied on or around the mouth (e.g. lipsticks). Although ingestion is the most important route of exposure for food and food supplements, these products do not fall under the description of consumer products within the scope of this project (i.e. non-food products intended for the consumer) and are therefore not addressed.

After the release of nanomaterials to the environment, human exposure via the environment, depends on the fate and behaviour of the nanomaterials in the environment, but may occur mainly by inhalation of ambient air and ingestion of contaminated drinking water or food products. This indirect exposure of humans via the environment is expected to be much lower than the direct exposure of humans during the use of consumer products.

The identification of the most important route of exposure does not imply that no exposure may occur by other routes of exposure. When, for example, nanoparticles are inhaled after using a spray, ingestion may be a secondary route of exposure due to the coughing up and subsequently swallowing of inhaled nanoparticles.

Not only the way of incorporation of nanomaterials into the product and the exposure route are important. Also other characteristics determine human exposure to nanomaterials. Table 3.2 provides a summary of important characteristics for human exposure to nanomaterials from consumer products.

3.4.2 Environmental exposure

During several life cycle phases, nanomaterials may be released to different environmental compartments (air, water, soil, or sediment (via water)).

During the synthesis of the nanomaterials and the production of consumer products, industrial emissions may lead to the release of nanomaterials mainly to the ambient air and surface water, but also (indirectly) to groundwater, sediment and soil.

During, but mainly after, the use of the consumer products (through disposal) the release of nanomaterials to different environmental compartments depends on several characteristics of the consumer products. As for human exposure, environmental exposure during the use of consumer products is likely to be much larger for products containing free nanoparticles than for products containing nanomaterials integrated into larger materials or structures. Environmental exposure during the disposal of consumer products also depends on how the consumer product is processed after disposal.

The release of integrated nanomaterials depends on the resistance to wear and tear and the (bio)degradability and solubility of the nanomaterials as well as the material they are attached to or incorporated into. For consumer products which contain free nanoparticles environmental exposure may occur depending on the physical form and application of the consumer product, the concentration of nanomaterials in the consumer product, and the type and use of the consumer product.

After the release of nanomaterials to the different environmental compartments, different groups of organisms (e.g. micro-organisms, plants, invertebrates and vertebrates) may be exposed, depending on the organism and on the behaviour and fate of the nanomaterials within and between the environmental compartments. Although little is known about the fate and behaviour of nanomaterials in the environment, the main characteristics that are expected to influence this fate and behaviour (including bioaccumulation and persistence) and thus exposure of organisms to nanomaterials from consumer products are summarised in Table 3.2.

Table 3.2: Main characteristics for human and environmental exposure to nanomaterials from consumer products

Characteristic	Comments
Type of nanomaterial	Free nanoparticles or integrated nanostructures into larger materials
Exposure route	Inhalation, dermal or oral exposure
Physical form of consumer product	Spray, powder, liquid, emulsion or solid
Application of the consumer product	Applications with direct human exposure (e.g. sunscreen products) or indirect human exposure (e.g. food storage bags, computers). Applications with direct emissions to an environmental compartment (e.g. tooth paste) or without direct emissions to the environment (e.g. computers).
Type, use of the consumer product	Widely used or rarely use product Frequency and amount of product used
Concentration of nanomaterial in product	
Main characteristics influencing the fate and behaviour of nanomaterials in living systems and the environment	Size Surface area Surface chemistry Water and lipid solubility (Kow*) Organic carbon partition coefficient (Koc*) Vapour pressure (mainly important for liquids) Coagulation or aggregation state Chemical composition (including coatings and purity)

* Kow, octanol-water partition coefficient; Koc, organic carbon partition coefficient

3.5 Potential toxicity and important characteristics related to toxicity

The potential toxicity of nanoparticles is determined by the uptake, behaviour and interaction with cells and/or tissues of nanomaterials in humans or other organisms. Important characteristics related to human and environmental toxicity were identified using several reviews (Tran et al., 2005; Kreyling et al., 2006; Borm et al., 2006; Maynard, 2006; SCENIHR, 2006; Oberdörster 2004; Oberdörster et al. 2005; 2006).

Since human and environmental exposures and risks are expected to be much larger for free nanoparticles than for nanomaterials integrated into larger materials, the paragraphs below focus on the human and environmental toxicity of free nanoparticles.

3.5.1 Human toxicity

Most information on the potential toxicity of nanoparticles is available from inhalation toxicity studies in animals and humans. The behaviour and toxicity of UFP (ultrafine particles, usually defined as particles with a diameter < 100 nm) present in ambient air was studied with model nanoparticles like titanium dioxide (Oberdörster et al., 2005; Tran et al., 2005). Both animal and human data show that inhaled nanoparticles can lead to adverse effects in the lungs, including inflammation, the exacerbation of asthma, genotoxicity and carcinogenesis. However, tumour related effects have only been reported in rats and may be related to overload conditions due to irrelevant high exposures (Borm et al., 2006; Tran et al., 2005; Kreyling et al., 2006). There is reason for concern for the nanotube/nanofiber structures in view of the history of asbestos fibres. Carbon nanotubes were found to induce inflammatory reactions in the lung (Maynard, 2006; Tran et al., 2005). The slower the fibre-like structures are cleared (high bio-persistence), the higher is the probability of an adverse response. The main determinants of fibre bio-persistence are physiological clearance and bio-durability (physical-chemical processes). Long non-phagocytizable fibres (in humans longer than 20 micron) will not be effectively cleared from the respiratory tract. The bio-durability of a fibre depends on dissolution and leaching as well as mechanical breaking and splitting (Hoet et al., 2004).

The inhalation of nanoparticles may also have an effect on the cardiovascular system, including pro-thrombotic effects in the blood circulation. It is not clear whether these effects were caused by nanoparticles entering the blood or by inflammatory reactions in the lungs (Borm et al., 2006; Tran et al., 2006).

Some studies indicate that nanoparticles can enter the brain, possibly via nerves in the nose or via the blood through the blood-brain barrier. However, the potential impact of nanoparticles on the human brain and neural tissue is not clear yet (Oberdörster et al., 2005; Borm et al., 2006).

After ingestion, nanoparticles may cross the gut barrier and can be distributed to various organs depending on their size. There is insufficient evidence to determine whether nanoparticles adversely affect the gut or the organs they are distributed to (Tran et al., 2005).

The minimal information available on dermal application of nanoparticles suggests that nanoparticles do not penetrate into the skin beyond the epidermis. However, damaged skin and sites with skin flexion are specifically at risk for penetration of nanoparticles. For certain relatively large particles uptake by Langerhans cells in the skin was found which may indicate the potential for sensitisation after penetration of the skin (Oberdörster, 2005). So far there is not sufficient evidence to conclude whether or not dermal absorption occurs or whether nanoparticles can cause adverse skin effects (Borm et al., 2006; Tran et al., 2005).

Important characteristics

Important characteristics related to (potential) toxicity of nanoparticles are those characteristics that determine the uptake and behaviour of nanoparticles and interaction of nanoparticles with the different parts of the human body. As described in the previous paragraph, very little is known about the uptake and behaviour of nanoparticles in the human body. However, there is some evidence suggesting that besides chemical composition, also particle number and size, surface area, shape, state of aggregation and agglomeration, lipid and water solubility, and charge are important characteristics for the uptake and distribution of nanoparticles in the human body.

Important characteristics with respect to the interaction of nanoparticles with living systems are the surface structure, particle number and size, shape, the use of coatings and the chemical composition (of the core and surface) (Tran et al., 2005; SCENIHR, 2006). Lung toxicity is likely to be influenced by particle number and size, surface area, surface coatings, aggregate/agglomerate state, surface charge, particle synthesis (whether formed by gas phase (fumed) or liquid phase (colloidal/precipitated)) and post-synthetic modifications (Borm et al., 2006). For fibre-like nanoparticles such as nanotubes, nanorods and nanofibers, length, dissolution, leaching and mechanical breaking and splitting are especially important (Hoet et al., 2004). With respect to dose response relationships, the dose expressed in mass concentration (dose in gram per kilogram body weight) seems less important than the dose expressed as number concentration and/or surface area (Oberdörster et al, 2005; Maynard, 2006).

3.5.2 Environmental toxicity

The impact of nanoparticles on environmental organisms is largely unknown. Next to several mammalian studies on laboratory species, there are only a few studies available on ecologically relevant species.

Several studies using different coated and uncoated nanoparticles showed that nanoparticles can have antimicrobial effects (Tran et al., 2005; Borm et al., 2006). In addition, there is evidence that certain nanoparticles are phytotoxic, causing inhibition of root growth in plants. Particle size and particle surface are suggested to be important characteristics with respect to the toxicity in plants (Tran et al., 2005). Studies on algae and water fleas (*Daphnia magna*) resulted in different outcomes, depending on the nanomaterials and test procedures (e.g. the choice of the solvent/carrier), but indicated that harmful effects may occur (Tran et al., 2005; Borm et al., 2006; Oberdörster et al., 2006). Studies with fullerenes in fish also show different results with respect to mortality and lipid peroxidation (in brain and gill) and isozymes (in liver), depending on the fish species and the way the fullerenes were solubilised (Oberdörster, 2004; Oberdörster et al., 2006). In vitro data indicated that surface structure and water solubility are important characteristics with respect to interactions of nanoparticles with biological systems. In addition, synergism for the effects of nanoparticles and metals or organic compounds has been suggested.

Table 3.3: Important characteristics related to human and environmental toxicity

Characteristic	Comments
Particle number	
Particle size	Diameter and length (for fibre-like shapes)
Surface area	This characteristic is related to the particle size (the smaller the particle, the higher the relative surface area).
Particle shape	Bulky, round or fibre like (e.g. nanotubes and nanowires) shapes
State of aggregation and agglomeration	
Particle solubility	Lipid and water solubility
Chemical composition	Some chemicals are associated with lung inflammation (e.g. organics and transition metals)
Surface structure	Reactivity; nanoparticles tend to be more reactive, a property associated with the induction of oxidative stress and inflammation.
Inertness	
Coating	Reactivity
Charge	Negatively charged particles have been associated with a higher dermal absorption in laboratory animals and positively charged particles have been associated with a higher oral absorption in laboratory.

3.6 Ranking of potential risks

The potential risks of nanomaterials are determined by the human and environmental exposure and toxicity. In the previous paragraphs important characteristics of consumer products with respect to their potential exposure and toxicity to humans and the environment were identified. This knowledge is not sufficient to determine the potential risks of consumer products containing nanomaterials. Most importantly, there is not enough knowledge on the toxicity of nanomaterials. In addition, there is not enough information on the important characteristics of the (categories of) consumer products and the nanomaterials they contain. Furthermore, several characteristics may increase potential risks in one instance (or organism), while decreasing the potential risk in another instance (or organism). Finally, the relative importance of the different characteristics is unknown, which makes it impossible to weigh the potential risks of different (categories) of consumer products.

However, the available knowledge on the main characteristics of potential exposure is generally sufficient to indicate product categories which may have a high priority for further examination of potential risks. Therefore, the main characteristics determining the potential exposure were used to rank the potential exposure, provided enough information is available on these characteristics for the different categories of consumer products (see Table 3.4).

If information on the characteristics of the product category is insufficient, the exposure is not ranked. These cases are indicated by question marks. High potential exposure means that there may either be a high possibility of exposure, or a possibility of high exposure, or both. The fact that a product category is ranked with either a high or low potential exposure should not be seen as evidence for absolute high exposures or the lack thereof, but as an indication of potentially high exposures. These rankings are based on the current knowledge and may need modifications when new information becomes available.

Table 3.4: Ranking of the potential human and environmental exposure (due to the use and disposal of consumer products)

Product		**Potential Exposure***	
Category	**Sub category**	**Human**	**Environmental**
Electronics and computers	Mobile (audio) devices	Low	?
	Large household appliances	Low	?
	Computer hardware	Low	?
	Displays	Low	?
	Energy related	Low	?
	Ink and paper	?	?
Household products and home improvement	Cleaning products	High	High
	Cooking utensils and kitchenware	Low	?
	Construction materials	?	?
	Paint	?	?
Personal care products and cosmetics	Sun cosmetics	High	High
	Baby care products	High	High
	Hair care	High	High
	Skin care	High	High
	Oral hygiene	High	High
	Make-up and nail care	High	High
	Over the counter health products	?	?
Motor vehicles	Exterior	Low	?
	Other	?	?
Sporting goods	Rackets and sticks	Low	?
	Balls	Low	?
	Other	Low	?

Product		Potential Exposure*	
Category	**Sub category**	**Human**	**Environmental**
Textiles and shoes	Clothing	?	?
	Other textiles	?	?
	Shoes	Low	?
Filtration, purification, neutralisation and sanitisation	Air filtration and purification	?	?
	Air conditioning	?	?
	Water filtration and purification	?	?
	Sanitizers and neutralisers	?	?
Miscella-neous	Coatings	Low	?
	Others	Low	?

* "High" indicates either a high possibility of exposure, or a possibility of high exposure, or both.

"Low" indicates either a low possibility of exposure, or a possibility of low exposure, or both.

"?"indicates that there is no sufficient information available.

The most important characteristics determining the potential exposure are:

1) the type of nanomaterial used (free nanoparticles or nanomaterials integrated into larger scale materials) and
2) the application of the consumer products (with either direct or indirect human exposure/emission to the environment).

Consumer products containing free nanoparticles with direct human exposure (e.g. sunscreen products) or direct emission to the environment (e.g. tooth paste) are considered to have a high potential exposure, while products in which nanomaterials are integrated into larger scale materials with indirect human exposure (e.g. food storage bags, computers) or indirect emissions to the environment (e.g. computers) are considered to have a low potential exposure. It is stressed that the qualification of 'high' and 'low' potential exposure should be interpreted in relative, but not absolute terms. Product categories with a high potential exposure may have a high priority for further examination of potential risks. However, next to the potential exposure, the priority for further examination of potential risks is also determined by the potential toxicity and the exposed population. So far, the knowledge on the potential exposure (and toxicity) is insufficient to determine potential risks (e.g. as unacceptable high or negligible low risks).

3.7 Limitations

The identification of the potential risks of consumer products containing nanomaterials, is hampered by a lack of information on:

- the characteristics of the nanomaterials in the consumer products
- exposure to nanomaterials from the consumer products
- toxicity data on the nanomaterials (especially on nanoparticles) in the consumer products, including dose response relationships.

Since this information is necessary to estimate the risks associated with each specific consumer product or product category, it is considered too early to perform case studies on the risks of specific consumer products to the human health and the environment.

However, the available knowledge on the main characteristics of potential exposure is generally sufficient to indicate product categories which may have a high priority for further examination of potential risks. Therefore, the main characteristics determining the potential exposure were used to rank the potential exposure. If not enough information on the characteristics of the product category was available, the exposure was not ranked, which means that it is not possible to judge the priority should. The rankings should not be used as evidence for high exposures or the lack thereof, but as an indication of potential exposures and possible prioritisation. These rankings are based on the current knowledge and may need modifications when new information becomes available.

3.8 Conclusion

Potentially high exposures are expected from consumer products containing free nanoparticles with direct exposure of these nanoparticles to humans or direct emission of these nanoparticles to an environmental compartment. Because of these characteristics, cleaning products, personal care products and cosmetics are ranked as products with a high potential human and environmental exposure. On the other hand, the following products likely do not contain free nanoparticles and are therefore ranked as products with a low potential human exposure: electronics and computers (excluding ink and paper), cooking utensils and kitchenware, exteriors of motor vehicles, sporting goods, shoes, air filtration and purification, air conditioning and coatings. If the integrated nanomaterials in these products are not released during the use and disposal of these products, the potential environmental exposure of these products will also be ranked as low. Unfortunately, little is known with respect to the release of integrated nanomaterials during the use or during the processing after disposal. It should be stressed, that since knowledge on exposure (and toxicity) to nanomaterials in consumer products is limited, the above ranking should not be used as evidence for high exposures or the lack thereof, but as an indication of potential exposures and possible prioritisation.

4 Adequacy of the regulatory framework

4.1 How to assess the adequacy of the regulatory framework?

In Europe, there is no single legislation that covers all consumer products. The area of consumer protection involves more than 20 EU Directives, in addition to EU case law and the various legislations of Member States. Therefore, for this project, European legislation on chemicals in general and (the use of chemicals in) consumer products in particular was studied for general or specific provisions related to nanotechnology. The following legislation was considered most important and hence included in the study:

- ‘Existing Substances Regulation’; Regulation (EEC) No 793/93.
- ‘Dangerous Substances Directive’; Directive 67/548/EEC.
- ‘Marketing and Use Directive’; Directive 76/769/EEC.
- ‘REACH’; Regulation (EC) No 1907/2006.
- ‘Biocides Directive’; Directive 98/8/EC.
- ‘Toys Directive’; Directive 88/378/EEC.
- ‘General Product Safety Directive’; Directive 2001/95/EC.
- ‘Cosmetics Directive’; Directive 76/768/EEC.
- ‘Electrical and Electronic Equipment Directive’ (WEEE); Directive 2002/95/EC.
- ‘Preparations Directive’; Directive 1999/45/EC.
- ‘Waste Directive’; Directive 2006/12/EC.

None of the above regulations and directives mentions specific requirements for the production, application, marketing or use of nano-sized chemicals or nanotechnology based products. Nevertheless, implicitly the use of nanomaterials is regulated by most of them.

4.2 New or existing chemicals

The Dangerous Substances Directive and its later amendments (DSD; covers ‘new substances’) and the Existing Substances Regulation (ESR) together cover chemical substances and apply to nano-sized substances as much as to any other form of substances. A substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

Importantly, current chemicals legislation differentiates between new and existing substances and a nanomaterial can either be an existing substance or a new substance. Guidance on this matter was recently added to the Manual of Decisions (MoD) for implementation of the sixth and seventh amendments to Directive 67/548/EEC on dangerous substances (Directives 79/831/EEC and 92/32/EEC). This guidance reflects the opinion of the ‘Working Group of Competent Authorities for the Implementation of Directive 67/548/EEC (New Substances) and Council Regulation 793/93/EEC (Existing Substances) on Nanomaterials in Chemicals Legislation’ that was established in 2006. The MoD entry is as follows:

Substances in Nanoform

The question was raised whether substances in the nanoscale form should be regarded as new or existing substances. It was agreed that the decisive criterion whether a nanomaterial is a new or existing substances is the same as for other substances, i.e. whether or not the substance is on EINECS[4].

Thus, substances in nanoform which are in EINECS (e.g. titanium dioxide) shall be regarded as existing substances. Substances in nanoform which are not in EINECS (e.g. carbon allotropes other than those listed in EINECS) shall be regarded as new substances.

New information on existing substances, including those with nanoforms, shall be submitted in accordance with Art.7 of Regulation (EEC) No 793/93.

New information on new substances already notified, including those with nanoforms, shall be submitted in accordance with Art.14 of Directive 67/548/EEC.

The rationale for this was that nanomaterials are generally engineered taking an existing substance as a basis, but that the size and sometimes forms and properties are changed in order to provide the technological advantage sought for. A substance like carbon has different entries in EINECS, because it was known to have different forms with different properties (e.g. graphite, diamond). Nanomaterials with their specific sizes and shapes may generally not have been listed as such in EINECS, as the new forms in most cases have been developed only recently. However, a nanomaterial derived from a substance listed in EINECS could be considered to be an existing substance. That case could be comparable to e.g. a metal which may have different forms with different properties (e.g. block or powder), different hazards and risks and different risk management, but still be the same existing substance. In such a case, the nanosubstance would fall under the Existing Substance Regulation (ESR), and would be covered by Article 7.1 of the ESR on the updating of reported information:

[4] EINECS, European INventory of Existing Commercial chemical Substances

Existing Substances Regulation (ESR)

Article 7

Updating of the reported information and obligation to submit certain information spontaneously

1. Manufacturers and importers who have submitted information on a substance in accordance with Articles 3 and 4 shall update the information forwarded to the Commission.

In particular, they shall submit, where appropriate:

(a) new uses of the substance which substantially change the type, form, magnitude or duration of exposure of man or the environment to the substance;

(b) new data obtained on the physico-chemical properties, toxicological or ecotoxicological effects where this is likely to be relevant to the evaluation of the potential risk presented by the substance;

(c) any change in the provisional classification under Directive 67/548/EEC.

They shall also be required to update the information regarding the production and import volumes referred to in Articles 3 and 4 every three years, if there is a change in relation to the volumes specified in Annex III or Annex IV.

2. Any manufacturer or importer of an existing substance who acquires knowledge which supports the conclusion that the substance in question may present a serious risk to man or the environment shall immediately report such information to the Commission and to the Member State in which he is located.

There are considerations and limitations regarding Article 7.1:

- it only applies to substances that have been reported to the manufacturers and importers that have reported in accordance with Articles 3 and 4. This limits the reporting to those manufacturers/importers that have reported, and in general to substances manufactured/imported in quantities at or above 10 tonnes per year at least once in the three years preceding the adoption of the ESR and/or the year following its adoption. In general, when based on similar mass, the number of nano-sized particles is 1000-times higher when compared to a 10-fold larger particle of the same composition. For this reason, 10 tonnes is a very high threshold when it comes to nanoparticles with a very low mass;
- the reporting of new uses would apply to nanomaterials. A possible drawback in the implementation of this requirement is that the industry and use categories are quite broad and may not sufficiently catch specific new applications of nanomaterials;
- data to be reported may need adaptations based on the specific properties of nanomaterials, e.g. information about particle size and surface area or specific toxicological data that appears to be especially relevant for nanomaterials.

Alternatively, ESR Article 7.2 asks producers and importers of existing substances to report in case they have knowledge of a serious risk to man or the environment. Article 7.2 applies to any existing substance. This could apply to nanomaterials. However, the effectiveness of this provision may be limited in view of the limited information generally available on nanomaterials.

Substances in nanoform which are not in EINECS shall be regarded as new substances. For these substances, data requirements are dependent on the production or import volume as laid down in the Dangerous Substances Directive (DSD) 67/548/EEC. For new substances already notified, including those with nanoforms, new information shall be submitted in accordance with Article14 of Directive 67/548/EEC (EU, 1992):

Dangerous Substances Directive (DSD)

Article 14

Follow-up information

1. Any notifier of a substance already notified in conformity with Articles 7 (1) or 8 (1) shall be responsible on his own initiative for informing in writing the competent authority to which the initial notification was submitted of:

- changes in the annual or total quantities placed on the Community market by him or, in the case of a substance manufactured outside the Community for which the notifier has been designated as sole representative, by him and/or others,

- new knowledge of the effects of the substance on man and/or the environment of which he may reasonably be expected to have become aware,

- new uses for which the substance is placed on the market of which he may reasonably be expected to have become aware,

- any change in the composition of the substances as given in Annex VII. A, B or C, section 1.3,

- any change in his status (manufacturer or importer).

2. Any importer of a substance produced by a manufacturer established outside the Community who imports the substance within the framework of a notification previously submitted by a sole representative in accordance with Article 2 (1) (d) shall be required to ensure that the sole representative is provided with up-to-date information concerning the quantities of the substance introduced by him on to the Community market.

Especially relevant for nanomaterials is the requirement to notifiers to submit new knowledge on effects and new uses. For this, the second and third consideration indicated above for Article 7.1 of ESR equally apply to new substances.

Therefore, in principle industry would have to report relevant nanomaterials in the framework of the obligations under the ESR and the DSD and to provide all relevant data, including those data that are specific for nanomaterials and may be essential for risk assessment. It is however not clear to what extent industry has actually reported information on nanomaterials that are already produced and/or imported in the EU.

4.3 Classification and labelling

Directive 67/548/EEC approximates the laws, regulations and administrative provisions of the Member States on classification, packaging, and labelling of dangerous substances which are placed on the market in the Member States of the Community. The classification and labelling equally applies to both new and existing substances and is based on the intrinsic substance properties. Annex I of Directive 67/548 lists dangerous substances and their classifications. The index number in Annex I is used in many cases to “split” the traditional EINECS/CAS number into smaller entries based on the differences in intrinsic hazard (e.g. metals and metal dust, substances and their hydrates).

Thus the classification and labelling can deal with substances that are related, but have different intrinsic properties. This system should function equally for nanomaterials having properties that differ from those of the substance from which the material is engineered. However, specific guidelines for application of the rules for classification and labelling to nanomaterials may need to be developed.

4.4 REACH

The current legislation on new and existing substances will be repealed on 1 June 2008 with the entry into force of REACH[5], i.e. Regulation EC 1907/2006. With REACH, the differences in legal requirements between new and existing substances will disappear. No specific provisions regarding nanomaterials are made in REACH. Therefore, as for any other form of substances, the responsibility is upon the manufacturers, importers and downstream users to demonstrate that each substance is handled or used in a safe way, i.e. implicitly for each nano-sized material safe handling or use should also be demonstrated. To this end, for each substance produced, imported or used in a volume of 1 tonne or more per year (on its own or in a preparation) each manufacturer/importer has to prepare and submit a registration dossier to the European Chemicals Agency (Helsinki).

The registration dossier includes a technical dossier and (for substances produced, imported or used in a volume above 10 tonnes per year) a chemical safety report. In the registration dossier exposure scenarios are drawn up. An exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These sets of conditions contain a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users. It could be that specific exposure scenarios with specific risk management and operational conditions need to be developed for nanomaterials. Alternatively, more general exposure scenarios may be developed that cover both the bulk as well as the nano-sized materials. In any case, the responsibility is upon the producer or supplier of nanomaterials to indicate how the material can be used in a safe way.

It is to be noted that an exposure assessment, including the generation of exposure scenarios and a risk characterisation as part of the chemical safety report, is only required for substances that meet the criteria for classification as dangerous in accordance with Directive 67/548/EEC or are assessed to be PBT or vPvB[6]. It is not known whether these requirements generally apply to nanomaterials or not, and thus whether exposure and risk assessment will be made for nano-sized materials. It could be that, given the major knowledge gaps with regard to toxicity of nanomaterials, they might escape an exposure assessment and a risk characterisation, if the normal chemical form is not dangerous.

Importantly, the lower limit for notification of new substances under the DSD was 10 kg per year, in contrast to 1 tonne per year under REACH. It is not clear whether the quantitative thresholds necessary to trigger the registration under REACH (i.e. 1 tonne per manufacturer/importer per year) will be attained, in view of the extremely small individual quantities in which nanomaterials are, in part, currently placed on the market.

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[5] REACH, Regulation on Registration, Evaluation and Authorisation of CHemicals

[6] Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB)

The November 2006 draft Technical Guidance Document (TGD) for identification and naming of substances in REACH (REACH Implementation Project 3.10[7]) is not clear yet on when nanomaterials should be seen as ‘different substances’. The document states: “The current developments in nanotechnology and insights in related hazard effects may cause the need for additional information on size of the substances in the future. The current state of development is not mature enough to include guidance on the identification of substances in the nanoform in this TGD.” (EU, 2006b).

4.5 Other legislation

In the Cosmetics Directive 76/768/EEC (EU, 1976a), Article 2 applies to the use of nanomaterials as much as to any other form of chemicals used in cosmetics: “A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market.”

A comparable general text can be found in the Product Safety Directive 2001/95/EC (EU, 2001). Here, Article 1(1) states that “The purpose of this Directive is to ensure that products placed on the market are safe.” This is further specified in subsequent Articles were a safe product is stated to mean “any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, …”

Also for toys, the relevant Directive 88/378/EEC (Article 2) states that “Toys may be placed on the market only if they do not jeopardize the safety and/or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children.” (EU, 1988). Additionally, the Toys Directive states that “In the condition in which it is placed on the market, taking account of the period of foreseeable and normal use, a toy must meet the safety and health conditions laid down in this Directive.”

There are no restrictions with regard to nanomaterials mentioned in the marketing and use directive (Council Directive 76/769/EEC) (EU, 1976b), nor is there a reference to nanomaterials in the Preparations Directive 1999/45/EC (EU, 1999), the Waste Directive 2006/12/EC (EU, 2006d), the Biocides Directive 98/8/EC (EU, 1998) or the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment 2002/95/EC (EU, 2002).

The OECD Council recently agreed to establish (on a temporary basis) a Working Party on Manufactured Nanomaterials (WPMN) as a subsidiary body of the Chemicals Committee. Within the WPMN, the members were asked to make an inventory of any national regulatory developments on human health and environmental safety including recommendations or discussions related to adapting existing regulatory systems or the drafting of laws/regulations/guidance materials. No national regulatory developments related to nanomaterials were reported by European Member States (OECD, 2006).

[7] http://www.ima-eu.org/fileadmin/downloads/RIP-3-10_TGD-Substance-Identity__November_2006_.pdf

4.6 Legislation in practice

The use of chemicals in the form of nanomaterials is covered by prevailing laws on chemicals and on products for consumers. It has however to be ensured that when new risks arise from the occurrence of a substance in the nanoscale form, the regulatory system will recognize this. It is questionable whether such recognition would always be possible. For example, an inventory made by Friends of the Earth (2006) led to the conclusion that there are at least several hundred cosmetics, sunscreens and personal care products which (as claimed by manufacturers or retailers) contain engineered nanomaterials that are commercially available right now, whereas little is known about the risks.

Independent from the legal requirements, the question arises whether the available test methods and tools are adequate to assess the risks associated with the use of nanomaterials in consumer products. For instance, most experts are of the opinion that the adverse effects of nanomaterials cannot be predicted (or derived) from the known toxicity of material of macroscopic size. There is a need for better information about properties, effects of and exposure to nanomaterials. It is important for industry (and authorities) to ensure that the type of information that is generated sufficiently covers safety aspects of nanomaterials.

In 2006, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) drafted an opinion on ‘The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies’. SCENIHR concluded that “current risk assessment methodologies require some modification in order to deal with the hazards associated with nanotechnology and in particular that existing toxicological and eco-toxicological methods may not be sufficient to address all of the issues arising with nanoparticles. For exposure evaluation, dose requires information on the number of nanoparticles and/or their surface area in addition to traditional mass concentration characterization. Equipment for routine measurements in various media for representative exposure to free nanoparticles is inadequate. In addition, existing exposure assessment methods may not be appropriate to determine the environmental fate of nanoparticles.”

The OECD has recognised the above situation and is developing activities in the area of nanotechnology. For the OECD Working Party on Manufactured Nanomaterials indicated above, a Programme of Work was adopted that is structured in three work areas:

i) Identification, Characterisation, Definitions, Terminology and Standards;

ii) Testing Methods and Risk Assessment; and

iii) Information sharing, Co-operation and Dissemination.

The work areas are intended to describe, in general terms, the work needed by OECD to help ensure human health and environmental safety of manufactured nanomaterials. Based on the outcome of these initiatives a harmonised guidance should be developed on how to assess the risks resulting from the application of nano-sized substances in a.o. consumer products.

4.7 Conclusion

Based on the above inventory, the conclusions are two-fold:

(1) The findings in this study indicate that the regulatory framework in principle gives a good coverage for dealing with safety aspects of consumer products containing nanomaterials; different aspects of production and products are at the same time subject to various Community provisions. Therefore, although there is no legislation specifically relating to nanotechnologies, the generic legislation that also applies to engineered nano-sized materials should in principle enable authorities to take prompt action if products pose a risk to health, safety or the environment;

(2) Many knowledge gaps have been identified regarding the safety of nanomaterials (exposure, toxicity thresholds, test schemes, etc.). Until there are data on which to determine the nature of any risks posed by nanomaterials, it is not possible to assess the full extent to which the implementation of current regulations addresses any potential risks.

5 Conclusions and recommendations

Nanomaterials are used in a wide variety of applications because of their superior properties, such as improved electromagnetic properties, catalytic properties, strength, stiffness, stability, etc. Next to benefits from these superior properties, the development and use of nanomaterials may also stimulate sustainable development, innovation, competitiveness, employment and the economy. However, within the field of nanotechnology the main emphasis has been on the development of the technology and new applications and not on the potential risks for human health and the environment. Since the specific properties which make nanomaterials so interesting may also lead to specific risks, more knowledge about the potential human and environmental risks of nanomaterials is needed.

It seems likely that the availability of consumer products in Europe roughly follows the global market trends, especially when also availability of products via internet is taken into account. Considering the information from market research, patent analyses and existing inventories of nanotechnology (consumer) products together, the most important product categories in Europe are therefore expected to be motor vehicles and electronics and computers, followed by personal care and cosmetics and household and home improvement.

Potentially high exposures are expected from consumer products containing free nanoparticles with direct exposure of these nanoparticles to humans or environmental organisms. As a result, cleaning products, personal care products and cosmetics are ranked as products associated with high potential health and environmental exposures. On the other hand, the following products likely do not contain free nanoparticles and are therefore ranked as products with low potential exposures: electronics and computers (excluding ink and paper), cooking utensils and kitchenware, exteriors of motor vehicles, sporting goods, shoes, air filtration and purification, air conditioning and coatings. If the integrated nanomaterials in these products are not released during the use and disposal of these products, the potential environmental exposures of these products will also be ranked as low. Unfortunately, little is known with respect to the release of integrated nanomaterials during the use or during the processing after disposal. It should be stressed, that since knowledge on exposure (and toxicity) to nanomaterials in consumer products is limited, the above ranking should not be used as evidence for high absolute exposures or the lack thereof, but as an indication of potential exposures and possible prioritisation.

Since the safety of (chemical substances in) consumer products is not regulated by one single legislation that covers all consumer products, several different regulatory documents were used to assess the adequacy of the current framework. None of these directives and regulations mentions specific requirements for nanomaterials. Implicitly the use of nanomaterials is regulated by most of them, by making the industry responsible for the safety of the substances or products they produce and enabling authorities to take action if products pose a risk to health, safety or the environment. It is, however, questionable whether new risks arising from the occurrence of nanomaterials will always be recognised by the regulatory system, since the knowledge on the safety of nanomaterials (exposure assessment, toxicity thresholds, test schemes etc) is limited. Until there are data on which to determine the nature of any risks posed by nanomaterials, it is not possible to assess the full extent to which the implementation of current regulations addresses any potential risks.

Once methods have been developed and validated for the assessment of hazard, exposure and (as a result) risks of nanomaterials, it could be that the regulatory framework turns out not to be adequate.

If that is the case, several options exist to adapt the current regulatory framework. These include:

- The assessment of all nanomaterials as new substances under REACH, even where the properties of larger scale counterparts (bulk material) are well-known.
- The consideration in risk assessment that one and the same substance can have different properties in the nanoscale form than in another form; an appropriately differentiated consideration of these different ‘substance variants’ has to take place.
- The introduction of nano-specific quantitative thresholds for registration under REACH, since the current tonnage levels (1 tonne or more per year per manufacturer or importer) might be too high for nanomaterials.
- The introduction of nano-specific data requirements for registration under REACH, once is has been established that specific testing needs to be performed to assess the hazards of nanomaterials.
- A separate ‘nano’ regulation. A clear advantage would be that all requirements and specifications can be found in a single regulation. A disadvantage would be that there is no longer a uniform regulatory approach for chemicals in general.
- An indication on product labels for products that contain nanostructured ingredients or are made with processes that use nanomaterials to allow consumers to make an informed choice about product use. A disadvantage may be that public concern is unnecessarily raised and that the societal benefits of nanomaterials may not be used to the full extent.

In conclusion, the use of chemicals in the form of nanomaterials is in principle covered by prevailing laws on chemical substances and on products for consumers. It is however questionable whether the available test methods and tools are adequate to assess the risks associated with the use of nanomaterials in consumer products. Therefore, the first need is for better information about properties, effects of and exposure to nanomaterials. Adaptations of the regulatory framework, if needed at all, should only be discussed after this information has become available.

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Glossary

This glossary is based on some definitions from this report and three glossaries available on the internet. The [brackets] indicate the source of the definition.

Agglomeration	The act or process of gathering into a mass [www.answers.com/agglomeration]
Aggregation	Any bringing together of parts or units to form a collective whole [www.answers.com/aggregation]
Colloidal	A system in which finely divided particles, which are approximately 10 to 10,000 angstroms in size, are dispersed within a continuous medium in a manner that prevents them from being filtered easily or settled rapidly [[www.answers.com/colloidal]
Consumer product:	Non-food products intended for the consumer [this report].
CNT:	Carbon Nanotubes (see nanotubes).
Fullerene	A Fullerene is a pure carbon molecule composed of at least 60 atoms of carbon. They are cage-like structures of carbon atoms; the most abundant form produced is Buckminster-fullerene (C60), with sixty carbon atoms arranged in a spherical structure. Because a fullerene takes a shape similar to a soccer ball or a geodesic dome, it is sometimes referred to as a buckyball after the inventor of the geodesic dome, Buckminster Fuller, for whom the fullerene is more formally named [institute nanotech].
Isozymes	Any two or more chemically distinct but functionally like enzymes [www.answers.com/isoenzymes].
Langerhans cells	Dendritic cells in the skin that pick up an antigen (substance that when introduced into the body stimulates the production of an antibody) and transport it to the lymph nodes. [www.answers.com/langerhans%20cells].
LCD:	Liquid Crystal Display, the predominant technology used in flat panel displays [nanotech].
LEDs:	Light Emitting Diode, a semiconductor device that emits visible light when an electric current passes through it [institute nanotech].
Lipid peroxidation	Lipid peroxidation refers to the oxidative degradation of lipids. This process proceeds by a free radical chain reaction mechanism. [www.answers.com/lipid%20peroxidation]
Nanofibres:	Hollow and solid carbon fibres with lengths on the order of a few microns and widths varying from tens of nanometres to around 200nm [institute nanotech].
Nanomaterial:	Engineered materials which contain structures with a size of less than 100 nm in at least one dimension [this report].
Nanometre (nm):	One billionth of a metre [nanoworld].

Nanoparticle:	Nanostructures which are not attached, incorporated, or fixed into the matrix of the large-scale material (including nanowires, nanotubes, and nanodots) [this report].
Nanopores:	Nanoscopic pores found in purpose-built filters, sensors, or diffraction gratings [institute nanotech].
Nanorods	Stick at the nanolevel
Nanoropes:	Nanotubes connected and strung together [nanotech].
Nanoscale:	1 - 100 nanometer range [nanotech].
Nanoscience:	The scientific discipline seeking to increase our knowledge and understanding of nanoscale phenomena, i.e. science on the scale of 0.1 nm to 100 nm [nanoworld].
Nanoshells:	Nanoscale metal spheres, which can absorb or scatter light at virtually any wavelength [nanotech].
Nanosome:	Nanodevices existing symbiotically inside biological cells, doing mechanosynthesis and disassembly for it and replicating with the cell [nanotech].
Nanotechnology:	The application of nanoscience in order to control processes on the nanometer scale, i.e. between 0.1 nm and 100 nm [nanoworld].
Nanotube:	A one dimensional fullerene with a cylindrical shape [nanoworld].
Nanowires:	One-dimensional structures, with unique electrical and optical properties, that are used as building blocks in nanoscale devices [institute nanotech].
Optoelectronics	The technology that merges the sciences of electronics and optics [www.answers.com/optoelectronics]
OLED	Organic LED, a LED made from carbon-based molecules, not semiconductors [institute nanotech].
Quantum Dots:	Nanometer-sized semiconductor crystals, or electrostatically confined electrons. Something (usually a semiconductor island) capable of confining a single electron, or a few, and in which the electrons occupy discrete energy states just as they would in an atom (quantum dots have been called "artificial atoms") [nanotech].
Oxidative stress	A condition of increased oxidant production in animal cells characterized by the release of free radicals and resulting in cellular degeneration [www.answers.com/oxidativestress]
Phagocytosis	The engulfing and ingestion of bacteria or other foreign bodies by phagocytes [www.answers.com/phagytosis].
Pharmacokinetic	The study of absorption, distribution, metabolism and excretion of a drug. [www.answers.com/pharmacokinetics]
Semiconductor:	A substance or object with conductive properties between those of a conductor and a insulator [nanoworld].
SWNT	Single Walled Nanotubes [institute nanotech].
MWNT	Multi Walled Nanotubes [institute nanotech].

Transition metals	Elements characterised by a partially filled d subshell. The First Transition Series comprises silicium, titanium, chromium, manganese, etc. The Second and Third Transition Series include the lanthanides and actinides, respectively [www.ktf-split.hr/periodni/it/abc/t.html]

<u>Sources</u>:

[institute nanotech]	http://www.nano.org.uk/nano/glossary.htm#n
[nanoworld]	http://www.nanoword.net/library/def/index.htm
[nanotech]	http://www.nanotech-now.com/nanotechnology-glossary-N.htm

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