



A report for IRGC

Risk Governance of Nanotechnology Applications in Food and Cosmetics

A report prepared for IRGC by
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Abbreviations used in the text:

ADI	Acceptable Daily Intake
BERR	United Kingdom Department for Business, Enterprise and Regulatory Reform
CIAA	Confederation of the Food and Drink Industries of the European Union
CNT	Carbon Nanotube
COLIPA	European Cosmetic, Toiletry and Perfumery Association
CSR	Chemical Safety Report
DG SANCO	European Commission's Directorate General for Health and Consumer Affairs
EFSA	European Food Safety Authority
EC	European Commission
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
EDF	Environmental Defense Fund
EU	European Union
EPA	United States Environmental Protection Agency
FAO	Food and Agriculture Organization of the United Nations
FDA	United States Food and Drug Administration
GMO	Genetically Modified Organism
GRAS	Generally Recognised as Safe
ICCA	International Council of Chemical Associations
IEHN	Investor Environmental Health Network
IFT	Institute of Food Technologists
IRGC	International Risk Governance Council
IUF	International Union of Food Workers
IFST	Institute of Food Science and Technology
ISO	International Organization for Standardization
METI	Japanese Ministry of Economy, Trade and Industry
NGO	Non-Governmental Organisation
NIA	Nanotechnology Industries Association
NIOSH	United States National Institute of Occupational Safety and Health
NM	Nanometre
NSET	Nanoscale Science, Engineering and Technology
OECD	Organisation for Economic Co-operation and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAS	Synthetic Amorphous Silica
SCCP	European Commission's Scientific Committee on Consumer Products
SCENIHR	European Commission's Scientific Committee on Emerging and Newly-Identified Health Risks
SiO ₂	Silicon Dioxide
TiO ₂	Titanium Dioxide
UNEP	United Nations Environment Programme
US	United States
UK	United Kingdom
VCI	German Chemical Industry Association
WHO	World Health Organization
WTO	World Trade Organization

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The International Risk Governance Council (IRGC) first addressed the risk governance of nanotechnology in a project which began in 2005 and led to the publication of IRGC's White Paper No. 2 on Nanotechnology Risk Governance in 2006.¹

Subsequently, and with the support of the Austrian Federal Ministry for Transport, Innovation and Technology and the Korean National Program for Tera-level Nanodevices, IRGC has conducted project work focusing specifically on nanotechnology applications in food and cosmetics, with the following objectives:

- To explore the different definitions and frameworks that have been used in the debate on nanoscaled material in food and cosmetics;
- To identify the applications of nanomaterials in current food items and cosmetics;
- To review current risk assessments of their use;
- To review current risk management and regulatory activities in different countries and continents;
- To compare judgements of the acceptability of nanomaterials in food and cosmetics made by a range of actors including different countries as well as international organisations;
- To identify gaps and options for global risk governance; and
- To explore the possibilities of a voluntary certification programme of labelling food items and cosmetics for mitigating possible risks.

IRGC's project has explored the interdependencies between the actors involved at the global level, analysed their current roles and responsibilities, and investigated where these interactions, or a lack of them, might lead to deficits in global risk governance. The project has also developed recommendations for improving the risk governance of nanotechnology applications in food and cosmetics and these recommendations will be published in early 2009 in an IRGC Policy Brief.

In the process of developing its risk governance recommendations IRGC organised, in April 2008, an expert workshop in Geneva, Switzerland. In preparation for the workshop a briefing paper was researched and written for IRGC by Dr. Antje Grobe, Professor Ortwin Renn and Alexander Jaeger of Dialogik gemeinnuetzige GmbH.

Reaction to the briefing paper was extremely positive and one conclusion of the workshop was that the briefing paper should itself, after revisions to account for recent developments, be published as an authored report. In order to help with the revisions many of the workshop participants provided the authors with feedback and comments. This report is, therefore, a substantially revised and updated version of the workshop briefing paper prepared by the authors earlier in 2008.

It is also a companion to the IRGC Policy Brief due for publication in early 2009. In particular, sections 2 to 8 of this report provide readers with detailed information to which the Policy Brief refers, but which is not repeated in the Policy Brief.

¹ Available on www.irgc.org

Nanotechnology uses techniques, processes and materials at the supramolecular level, approximately in a range between 1-100 nanometres (nm), in order to create new properties and to stimulate particular desired functionalities.

There is currently a fierce debate on the potential applications of nanotechnologies in food and cosmetics. For the food industry, nanotechnology applications include among others: release systems for pesticides or fertilisers in agriculture; antibacterial or easy-to-clean surfaces in food processing machines; food additives such as anti-caking in salt, powders and coffee creamers; anti-foaming agents for beer; colour additives for lemonades; encapsulated vitamins for dietary supplements; and, micelle systems for low-fat foods. The worldwide market for food using nanotechnology applications is predicted to surge to US\$ 20.4 billion by 2010 [Kaiser, 2004]. China and other Asian markets, with more than 50% of the world's population, are believed to have the largest growth potential in this field.

In cosmetics, nanotechnology applications can be found in: sunscreens with efficient UV protection; long-lasting make-up; anti-ageing creams with an increased intake of vitamins or enzymes; toothpaste; and, hair care or colouring products. BCC Research has forecast that the global market for cosmetics using nanotechnology applications will grow by 16.6% per year, reaching US\$ 155.8 million in 2012 [BCC, 2007].

These forecasts of dramatic market growth are difficult to validate but they provide an indication of the importance of nanotechnologies in food and cosmetics and of the possible degree to which consumers might be exposed to them. Concerns about the potential risks of these materials to human health and to the environment are also increasing and there remains a lack of published data from relevant scientific studies that address the characterisation and safety of nanomaterials used in food and cosmetics.

This absence of information has been one of the main reasons for several calls for temporary bans of nanomaterials in food and cosmetics (moratoria). In 2006, Friends of the Earth in Australia and United States called for a moratorium on the further commercial release of sunscreens, cosmetics and personal care products that contain engineered nanomaterials [Friends of the Earth, 2006]. In 2007, the International Union of Food Workers (IUF) made a similar plea for caution in the use of nanotechnology in food and agriculture [Friends of the Earth, 2007] and later joined 43 other organisations to issue "Principles for the Oversight of Nanotechnologies and Nanomaterials". The first principle calls for "regulations underpinned by a precautionary approach" [IUF, 2007]. By 2008, a number of organisations were beginning to take a firm stance on the use of nanotechnologies in food and cosmetics. In a press release in January 2008, the UK's Soil Association announced that:

"As of January 2008, the Soil Association has banned the use of man-made nanomaterials from all Soil Association certified organic products... we are the first organisation in the world to take regulatory action against the use of nanoparticles to safeguard the public."

[Soil Association, 2008]

In March 2008 Friends of the Earth called for:

"a moratorium on the further commercial release of food products, food packaging, food contact materials and agrochemicals that contain manufactured nanomaterials until nanotechnology-specific regulation is introduced to protect the public, workers and the environment from their risks, and until the public is involved in decision making."

[Friends of the Earth, 2008, p. 46]

It appears, however, that access to information is steadily improving. There are signs that several industrial players are willing to participate in public dialogues and to engage in a positive exchange of information. But significant progress is unlikely without a precise, appropriate and internationally-harmonised definition of nanotechnology and its specific applications in food and cosmetics. The question of what is meant by nanotechnologies and nanomaterials, especially in food and cosmetics, remains one of the key issues in the debate between public authorities, industry, scientists, consumers, environmental groups and the media. The debate about what constitutes a nanomaterial has major implications for the entire risk governance cycle, including problem-framing, the assessment of risks and concerns, risk-benefit evaluation and suggestions for risk management options.

This report will summarise the results of scientific studies and expert interviews on the questions of risk governance for nanotechnology applications in food and cosmetics. It is organised into nine sections:

- Section 1 provides an introduction to the report, to the main issues it addresses and to the key questions it raises.
- Section 2 focuses on the issue of definitions and the need for an internationally harmonised and accepted description of the nature and composition of nanoscaled materials in food and cosmetics.
- Section 3 examines the various types of nanoscaled materials currently being used in food and cosmetics and highlights the lack of data and remaining uncertainties in this field. It also provides information on the efforts to overcome this information gap, and underlines the responses of major Non-Governmental Organisations (NGOs) to these uncertainties.
- Section 4 covers some of the issues raised by the absence of detailed information on the use of nanomaterials in food and cosmetics, and the implications of that information gap.

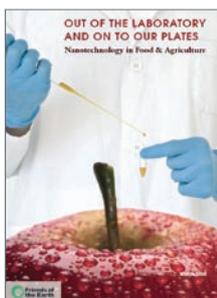
- Section 5 provides an overview of international risk perception studies for nanotechnologies in general, and specifically of attitudes to applications in food and cosmetics. These assessments are formed on the basis of quantitative surveys, qualitative studies and public participation exercises.
- Section 6 addresses the current regulatory background, including requirements and future plans for risk assessments. The focus is on the United States Food and Drug Administration (US FDA) and the European Commission's communications about risk assessment and reporting needs. The regulatory structures of other selected countries are also briefly described.
- Section 7 takes a closer look at three examples of nanomaterials used in food and cosmetics which are currently at the centre of the public debate. The objective here is to assess the state of knowledge on these materials and to illustrate the scientific basis for evaluating risks associated with these engineered materials.
- Section 8 describes the voluntary agreements and codes of best practice that are being developed to address the potential risks associated with nanotechnologies. In addition to describing four such initiatives, this section asks whether voluntary proactive agreements could be suitable tools to balance evidence-based and precautionary approaches, address public concerns and anticipate future regulatory requirements.
- Section 9 provides a summary of the report's major conclusions and insights.

Nanotechnologies allow scientists to understand, control, measure and manipulate matter to change the properties and functions of materials on a nanoscale level. The American National Institute of Occupational Safety and Health (NIOSH) defined Nanotechnology as a “system of innovative methods to control and manipulate matter at near-atomic scale to produce new materials, structures, and devices” [NIOSH, 2007]. Most of the commonly discussed definitions refer, first, to a size range for nanoscaled materials of between 1-100 nanometres (nm) in at least one dimension and, secondly, to their possessing and exhibiting unique properties because of their nanoscaled dimension.

In September 2008 the International Organization for Standardization (ISO) published Technical Specification ISO/TS 27687, “Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate”. This is the first of a planned series of ISO documents on nanotechnology terminology and definitions. The specification refers to core terms such as the nanoscale (size range from approximately 1 nm to 100 nm) and nano-objects, which include nanoparticles, nanoplates, nanofibres, nanotubes, nanorods, nanowires and quantum dots.

Because nano-objects in general – and nanoparticles in particular – often occur in large groups, and are likely to interact for reasons of surface energy, ISO included different assemblies of particles under the term “Nano-objects”. These assemblies are described in the document as “weakly bound particles or aggregates” as well as aggregates that are specified as “strongly bonded or fused particles”. ISO states that these terms “are not restricted to physical size and shape” [ISO/TS 27687, 2008, p.1].

The fact that the ISO specification is not limited to a size between 1-100 nm is crucial for nanotechnology applications in food and cosmetics. This is because many of the nanoscaled materials that are used consist of nanoscaled objects smaller than 100 nm which are dispersed in the product only in an aggregated or agglomerated state, such as micelle systems with a diameter of 300 nm. The ISO is presently examining whether these micro-scaled materials should be defined as nanoscaled materials due to their internal structure. If the current working definition of ISO Technical Committee 229, with its inclusion of aggregates and agglomerates, is adopted as an international standard, requests for a new definition referring to materials smaller than 300 nm [Friends of the Earth, 2008] or a mean particle size less than 200 nm [Soil Association, 2007] would be included.



Friends of the Earth, 2008

In addition to the problem of size, most of the definitions distinguish between naturally-occurring nanomaterials and industrially-

manufactured, human-made ones. This is also a difficult distinction to make, as it is possible to synthesise nanostructures that can also be found in nature, and there are naturally-occurring nanoscaled materials in food and cosmetics that have only recently been detected. It would therefore also be helpful to clarify the definitions of “manufactured” and “naturally-occurring” nanomaterials, as well as what is meant by new properties.

Naturally-occurring nanoscaled materials, for example, play an important role in the food and food processing industry. The Institute of Food Science and Technology [IFST, 2006] has shown that nanoscaled materials can be used as powerful instruments to control, measure and manipulate food ingredients and can constitute an important part of food processing – even if the materials occur naturally. Examples of naturally-occurring nanoscaled materials include: naturally-occurring proteins, which range between 10 and 100 nm in size; polysaccharide (carbohydrate) and lipid molecules, which can also exist at the nanoscale; jellies, which prevent emulsions from separating into oil and water, and which constitute two- and three-dimensional nanostructures; and, starch polysaccharides. These define the thickness of a gel through the re-crystallisation of three-dimensional crystalline nanostructures during the processes of boiling and cooling [IFST, 2006]. At present, experts do not see any critical risk arising from the nanoscaled size of these naturally-occurring systems.

The food industry already uses many nanoscaled materials which consist of such naturally-occurring nanoscaled objects as fine lipid droplets for nanoemulsions and self-assembling encapsulation systems. Nanoemulsions as used in food and cosmetics are not seen as “novel” engineered materials by the majority of risk assessors, because there is long experience of their use [Weiss et al., 2006]. This discussion illustrates the difficulties of distinguishing between well-known chemical or biological nanoscaled structures and “novel” engineered nanoscaled materials or nanosystems. New materials and systems are sought for their novel properties, which may include unknown risks.

In November 2007, the European Commission’s Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) published a scientific opinion on “The scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies” [SCENIHR, 2007]. SCENIHR recommended considering the specific properties of nanoparticles in a systematic way. The experts distinguished several processes involving nanotechnology such as coalescence, agglomeration, aggregation, degradation and solubilisation. Among other recommendations, the group advised risk professionals in this field:

“In order to facilitate risk assessment with nanoparticulate products, the behaviour of the nanoparticles themselves within the various compartments of the environment has to be considered, and certain terms are important for this

purpose. This concerns the manner in which particles diffuse in media, how they interact amongst themselves, where they may reversibly or irreversibly combine into groups of particles and their susceptibility to solubilisation or degradation.”

[SCENIHR, 2007, p. 14]

Overall conclusions for risk governance

Ideally, current work by ISO Technical Committee 229 will result in an accepted and internationally adopted definition of nano-objects and nanostructured materials. ISO TC 229's work is being coordinated with the work of other organisations, including the OECD Working Party on Nanotechnology, which has incorporated into its work programme a project to “develop a framework for internationally comparable and validated statistics, according to agreed definitions and classifications” [IFCS, 2008].

ISO's approach, which includes the establishment of a standard only after approval by ISO's national member organisations, could result in a formal definition and so end much of the debate on this issue. If the current text is adopted, the scope for criticism by such NGOs as Friends of the Earth would be much reduced.

While this issue remains unresolved or if the work of ISO TC 229 does not result in a standard definition, efforts (including such as the following) will need to continue:

- At present, in the absence of a harmonised, internationally accepted definition, industry is required to explain which materials are being used and in which size, and what kind of risk assessment studies have been carried out [EC, Safety for Success Dialogue, 2007]. Companies should develop a scientifically-based characterisation of materials, including definitions, to adequately describe a material as “nanoscaled”;
- It could be helpful for stakeholders from industry, public authorities and NGOs to provide typical characterisations of nanoscaled materials and informed comments on the definitions that are used in the present debate. Industrial federations or associations might use a multi-stakeholder dialogue to produce a blueprint for discussing and communicating the results of the characterisation process; and
- Risk communication to stakeholders and the public about the characterisation and definition of nanomaterials has to be scrutinised at all stages of the risk governance cycle in order to avoid misinformation and inconsistencies. This is not only a task for companies but also for NGOs, public authorities and politicians, whether they address nanotechnologies in general or focus on specific applications such as food or cosmetics.

The absence of an acceptable definition of nanoscaled materials in the context of food and cosmetics has had repercussions on the scientific and public debate on this issue for a long time. Claims that materials are “nanoscaled” are sometimes supported by little scientific evidence. Our examples from the agriculture and food sector (see Section 3.1) and the cosmetics sector (see Section 3.2) suggest that there are probably many products now on the market which contain nanoscaled materials, but no one is in a position to confirm their number. This gap is due to a lack of knowledge about the characterisation of these ingredients, and to the absence of published risk assessments. The lack of scientific testing, and the paucity of reporting on such tests have caused growing concern among stakeholders, including public authorities and NGOs.

3.1 Agriculture, food and smart packaging

The Institute of Food Science and Technology (IFST) introduced its “Information statement on nanotechnology 2006” with the following emphasis on industrial applications:

“It seems almost certain that most major food companies are monitoring or researching the potential benefits of nanoscience in food. Some companies are more willing to discuss this aspect of their research than others, so it is difficult to assess the precise level of interest in these topics. Kraft Foods started the first nanotechnology laboratory in 1999 and its ‘Nanotek’ consortium, involving 15 universities worldwide and national research laboratories was established in 2000. The food department at Rutgers University in New York has appointed what is believed to be the first professor of food nanotechnology. Both Unilever and Nestle have research topics involving potential uses of nanotechnology in food.”

[IFST, 2006, p. 3]

There is still very limited factual knowledge about food and cosmetic products containing manufactured nanoscaled materials, especially given the fact that there has been intensive research on the subject for more than 10 years [Shelke, 2006]. Meanwhile, the number of companies actively communicating the use of nanoscaled materials in their products is increasing from year to year. The Woodrow Wilson International Center for Scholars (the Wilson Center) established an online inventory of nanotechnology goods identified by their manufacturers. It indicated that the number of consumer products using nanotechnology had, at the beginning of 2008, expanded to more than 600; 95 of these products are cosmetic applications and an additional 29 examples are sunscreens [Woodrow Wilson International Center for Scholars, 2008]. 68 food and beverage applications are mentioned, most of them within dietary supplements or as surface treatments for refrigerators or packages. Only three applications are listed as

real food ingredients. But even the validity of these assessments is under debate, because most companies provide very little data on the scientific characterisation of their materials.

In its progress report and position paper on “Nanotechnology in Food Applications” the German Association of the Food Industry, BLL, stated:

“There is currently no food ready for marketing or with market significance for the final consumer which is produced with the use of nanotechnologies or from nanomaterials.”

[BLL, 2008, p. 3]

If this is true, estimates of a worldwide market of US\$ 20.4 billion for food containing nanotechnology applications by 2010 [Kaiser, 2004] seem to be highly unlikely to be accurate.

In the absence of reliable data, the Nanowerk internet portal provides an overview of current or future fields of applications in agriculture, food processing, food packaging and food supplements (see Figure 1, next page) [Nanowerk, Food, 2007].

Several reports identify **agriculture** as a major field of potential for nanotechnology applications. According to nanoforum.org:

“Nanotechnology has the potential to revolutionize the agricultural and food industry with new tools for the molecular treatment of diseases, rapid disease detection, enhancing the ability of plants to absorb nutrients etc. Smart sensors and smart delivery systems will help the agricultural industry combat viruses and other crop pathogens. In the near future nanostructured catalysts will be available which will increase the efficiency of pesticides and herbicides, allowing lower doses to be used.”

[Nanoforum.org, 2006, p. 12]

The Nanoforum report refers to efficiently dissolvable formulations which contain nanoscaled particles within the 100-250 nm size range, and to suspensions of nanoscaled particles (nanoemulsions) in the range of 200-400 nm. Here the problem of definition reappears. This problem is fundamental to the logic by which Friends of the Earth raises the question of an adequate definition (Is this Nano?) which leads to the question of adequate testing (Is it dangerous?) and which, in the absence of reliable information for clarifying this question, underpins their call for a moratorium [Friends of the Earth, 2008, p. 3].

For **food processing** (including ingredients as well as production facilities) the scope of nanotechnologies or nanostructured materials with new properties is difficult to define. This problem was also pointed out by the IFST. In food processing, nanotechnology can lead to a better understanding of how to control the quality of foams and emulsions for beer, sauces, creams, yoghurts, butter and margarine. This might involve the use of expanded micelles for low-fat mayonnaise or “nutraceuticals” containing lycopene, beta-carotene, lutein, phytosterols, CoQ10 or – the last example

Figure 1: Overview on applications of nanotechnology in agriculture and food [Nanowerk, Food, 2007]

			
Agriculture	Food Processing	Food Packaging	Supplements
<ul style="list-style-type: none"> • Single molecule detection to determine enzyme/ substrate interactions • Nanocapsules for delivery of pesticides, fertilizers and other agrichemicals more efficiently • Delivery of growth hormones in a controlled fashion • Nanosensors for monitoring soil conditions and crop growth • Nanochips for identity preservation and tracking • Nanosensors for detection of animal and plant pathogens • Nanocapsules to deliver vaccines • Nanoparticles to deliver DNA to plants (targeted genetic engineering) 	<ul style="list-style-type: none"> • Nanocapsules to improve bioavailability of nutraceuticals in standard ingredients such as cooking oils • Nanoencapsulated flavor enhancers • Nanotubes and nanoparticles as gelation and viscosifying agents • Nanocapsule infusion of plant based steroids to replace a meat's cholesterol • Nanoparticles to selectively bind and remove chemicals or pathogens from food • Nanoemulsions and -particles for better availability and dispersion of nutrients 	<ul style="list-style-type: none"> • Antibodies attached to fluorescent nanoparticles to detect chemicals or foodborne pathogens • Biodegradable nanosensors for temperature, moisture and time monitoring • Nanoclays and nanofilms as barrier materials to prevent spoilage and prevent oxygen absorption • Electrochemical nanosensors to detect ethylene • Antimicrobial and antifungal surface coatings with nanoparticles (silver, magnesium, zinc) • Lighter, stronger and more heat-resistant films with silicate nanoparticles • Modified permeation behavior of foils 	<ul style="list-style-type: none"> • Nanosize powders to increase absorption of nutrients • Cellulose nanocrystal composites as drug carrier • Nanoencapsulation of nutraceuticals for better absorption, better stability or targeted delivery • Nanocochleates (coiled nanoparticles) to deliver nutrients more efficiently to cells without affecting color or taste of food • Vitamin sprays dispersing active molecules into nanodroplets for better absorption

mentioned in the Nanoforum report – canola activa oil in food supplements [Nanoforum.org, 2006, p. 10]. Another application is for coatings in machinery for food processing. Antibacterial or easy-to-clean coatings are expected to be used for machines, containers and transport systems used in food production.

For the application of nanomaterials and nanotechnologies to **packaging**, the emphasis is on the sensing and diagnosing of chemicals, pathogens or toxins in food. What is often called “smart packaging” has the potential to improve the quality of food or inform consumers about the safety or the freshness of their purchases. The examples in the Nanoforum report include ultraviolet protection, lighter and stronger polymer films, protection against spoiling, plastic bottles for beer or water, and bioluminescence detection sprays for salmonella and E coli. IFST has produced a similar list:

“Already, there are attempts to design surfaces that can identify and repel bacteria, and to create novel surfaces that resist contamination, or can be more easily cleaned. New materials should lead to new food packaging and containers. Flexible displays, which are based on polymer light emitting diodes, on packaging and containers offer better ways for displaying information on source, history since production, and nutritional status of products.”

[IFST, 2006, p. 5]

3.2 Sunscreens, anti-ageing treatments and hair cosmetics

A consultation on cosmetics within the Scientific Committee on Consumer Products (SCCP) of the European Union (EU) confirmed the need to focus on nanotechnologies in cosmetics as a major issue of public concern. All products which are intended to be placed in contact with the human body (epidermis, hair, nails, lips and external genital organs) or teeth were regarded as sensitive [Scientific Committee on Consumer Products, 2007]. The consultation process ended in December 2006. In addition to the issue of public concern, the consultation also dealt with scientific objectives such as collecting peer-reviewed research papers and reviews, evaluating data on safety, and processing reliable scientific information.



Acknowledging the need for more information, Friends of the Earth issued a report in May 2006: “Nanomaterials, sunscreens and cosmetics: small ingredients – big risks”. The report listed a number of concrete applications taken from the Wilson Center Inventory:

“Products listed in this database include deodorants, soap, toothpastes, shampoos, hair conditioners, sunscreens,



Friends of the Earth, 2006

anti-wrinkle creams, moisturizers, foundations, face powders, lipstick, blush, eye shadow, nail polish, perfumes and after-shave lotions. Manufacturers include L'Oréal, Estée Lauder, Procter and Gamble, Shiseido, Chanel, Beyond Skin Science LLC, Revlon, Dr Brandt, SkinCeuticals, Dermazone Solutions, and many more. (...) Nanoscale ingredients listed in the database include nano-

particles of titanium dioxide, zinc oxide, alumina, silver, silicon dioxide, calcium fluoride and copper, as well as nanosomes, nanoemulsions and nanoencapsulated delivery systems."

[Friends of the Earth, 2006, p. 14]

The Wilson Inventory, which informed the statements by most of the NGOs, suggests that there are far more cosmetic products containing nanomaterials than there are real applications in food. The materials involved include various metal oxides and different forms of lipid formulations with nanoscaled droplets. These materials improve the smoothness of creams and promise enhanced properties for anti-ageing or hair treatments. But again, there is a lack of publicly available data about the size or properties of these nanomaterials, and about the results of risk assessments of them. It is at the discretion of industry to decide whether they use the term "nano" or not. So the Inventory does not contain the information needed to give a reliable estimate of the full range of current nanotechnology applications.

This gap has been partially filled by a Swiss initiative, called CONANO (COmparative Challenge of NANOmaterials), which provides reliable data and information about applications, characterisation and risk assessment for delivery systems in cosmetics. The initiative focused on a stakeholder dialogue project, jointly organised by the Swiss Risk Dialogue Foundation, Novartis International and Ciba Specialty Chemicals, as well as one German and one Austrian Ecological Research Institute. The project included nano-delivery systems such as associated biodegradable systems (Nanotopes), enzymatic biodegradable systems (Polylactogluconateacids), and delivery systems using stable elements such as fullerenes or carbon nanotubes. The CONANO dialogue assessed the different materials through their life-cycles and issued a clear recommendation for biodegradable delivery systems for use in cosmetics and pharmaceuticals [CONANO, 2007]. The project is an example of a proactive stakeholder initiative to discuss the issues before public authorities feel compelled to respond to public pressure.

Overall conclusions for risk governance

- Factually accurate and publicly available knowledge about the use of manufactured nanoscaled materials in agriculture,

food and food packaging is limited. There is a need for more comprehensive data and information to be provided by industry or independent sources. In its absence, the debate will remain rooted in speculation and fear rather than in scientific evidence.

- In the food industry there is no decisive, let alone unified, communication strategy to deal with the growing requests for more information. Without food companies communicating what they do and what they know, companies and products are likely to be exposed to growing concerns and distrust.
- The cosmetics industry has more products than the food sector that claim or even positively advertise the use of nanomaterials. However, there is no information on whether these products use nanomaterials in the strict sense or just use the term "nano" for advertising purposes. For example, the label "nano" has been used to advertise both new brilliant hair colours and anti-ageing products. These applications are popular among users and might promote a positive image of nanotechnology as being associated with high-quality products. However, if "nano" were to meet with public resentment or rejection and people stopped buying "nano" products, the cosmetics industry would probably remove all "nano" labels regardless of their scientific justification. A rational approach to risk governance will require a knowledge base for nanomaterials, including their characterisation, properties and risk assessment results, which can inform a consistent and complete overview of the types and amounts of nanoscaled materials in cosmetic products.
- This lack of adequate information has additional negative consequences, particularly an increase in distrust. Without an appropriate and reliable set of data it is impossible to initiate a meaningful risk appraisal, conducted or supervised by independent organisations, or to develop a suitable protocol for measuring the effects of scale in food (ingestion pathway) and cosmetics (skin penetration). If there is no common agreement on what data has to be shared, a meaningful risk assessment cannot occur. Concerns and credibility gaps will increase even further until the problem of information sharing is adequately resolved.
- All stakeholders could benefit from the step-by-step approach described in the IRGC risk governance framework's Pre-Assessment phase [IRGC, 2005]. This phase begins with problem framing, reflecting early warnings, and finding agreement on a set of screening criteria and scientific conventions in order to collect, assess and evaluate data on the use of nanoscaled materials in food and cosmetics. It will be important to determine which set of available risk assessment strategies are sufficient to detect these materials and to assess their safety.

The absence of an agreed definition and the blurred distinction between natural and engineered nanoscaled materials mean that it is not a simple task to provide sufficient information on their use and the possible risks. As a result, the food industry has taken the public position that, in general, it does not use engineered nanoscaled materials [EC, Safety for Success Dialogue, 2007].

The cosmetics industry has been less reluctant to communicate the fact that it uses engineered nanoscaled materials. But it too refers to the unresolved problem of definition [EuroNanoForum, 2007]. Industry's decision about whether or not to deny that it is using engineered nanoscaled materials in food and – to a lesser degree – cosmetics has also been the key issue for public information and communications programmes.

Requests from public authorities or the media to provide more information on the use of nanoscaled materials, especially in food, usually receive the answer that such materials are not used [EC, Safety for Success Dialogue, 2007]. Homepages of major companies which NGOs assert are working with nanoscaled materials in food, such as Nestlé, Kraft and Unilever [Friends of the Earth, 2008, p. 11], or sunscreen producers such as Beiersdorf (owners of the Nivea brand), do not provide any evidence to suggest that they use nanomaterials in their existing products. However, others have argued that nanoemulsions, for example in hair products (such as Goldwell) or encapsulated systems (for example Aquanova or BASF), demonstrate significant new properties caused by the use of nanoscaled materials.

The dilemma of what is meant by nanotechnology in these specific applications can be illustrated by the following quotes from a presentation by Sue O'Hagan, Unilever's Science Leader for Food Safety. Speaking at the "Safety for Success Dialogue" of the European Commission in Brussels 2007, O'Hagan, talking on behalf of the Confederation of the Food and Drink Industries of the European Union (CIAA), pointed out that:

"Some man-made nanoparticles do have a history of safe use in food e.g. emulsions & powders" (...)

"Some patents on use of nanotechnology in food are out in the public domain, others patents are applied for" (...)

"BUT – to the best of CIAA knowledge, there is hardly any use of nanotechnologies in food and drink manufacture in Europe at present."

[O'Hagan, 2007]

At the same conference in October 2007, Robert Madelin, Director General of the European Commission's Directorate General for Health and Consumer Affairs (DG SANCO) stressed that confidence had to be built upon an open exchange of information and that:

"there is no excuse for a 'wait and see' attitude by researchers, producers and retailers."

[EC, Safety for Success Dialogue, 2007, p. 12]

Madelin concluded by calling for an innovative and proactive stakeholder communication approach and for the release of publicly available information [EC, Safety for Success Dialogue, 2007].

Alongside efforts to establish an open information process and to initiate stakeholder dialogues between industry, regulators and civil society representatives, the European Commission asked the European Food Safety Authority (EFSA) to conduct an initial scientific opinion of the risks arising from nanoscience and nanotechnology in food and feed with respect to human health, safety and environmental quality. In November 2007 – one month after the Safety for Success Conference – EFSA started the process:

"to identify the nature of the possible hazards associated with actual and foreseen applications in the food and feed area and to provide general guidance on data needed for the risk assessment."

[EC, Revised Request to the EFSA, 2007, p. 4]

EFSA has asked industry for the following information:

- Data on the safety of nanomaterials used in food and feed;
- Food and feed applications and products which contain or consist of nanomaterials or have been produced using nanotechnology;
- Methods, procedures and performance criteria used to analyse nanomaterials in food and feed;
- Use patterns and exposure for humans and the environment;
- Risk assessments performed on nanomaterials used in food and feed;
- Toxicological data on nanomaterials used in food and feed;
- Environmental studies performed on nanotechnologies and nanomaterials used in food and feed; and
- Other data of relevance for risk assessment of nanotechnology and nanomaterials in food and feed [EFSA, 2008].

The OECD is also actively engaged in efforts to improve information flows. One of the projects established by the OECD Working Party on Manufactured Nanomaterials has the objective of developing "a database of research into the safety of manufactured nanomaterials". The OECD's Working Party on Nanotechnology has initiated a project to gather information from OECD members about communications activities and to foster and support good practice in communication and public engagement. In a separate programme, the Working Party will facilitate a policy dialogue involving OECD member and non-member delegates and a number of key stakeholders [IFCS, 2008].

From the industrial side, the CIAA, which represents the European food and drink industry, has signalled its willingness to conduct and participate in stakeholder dialogue and has founded a Nanotechnology Task Force. In its Strategic Research Agenda

for the European Technology Platform “Food for Life”, CIAA gave an outline of its research strategy, including its approach to nanotechnologies:

“Understanding and predicting:

- a) impact of bioactive compounds in food and beneficial micro-organisms on human health,*
- b) effect of food matrix formulation (structure, components) on the activity, delivery and transfer of bioactive compounds and beneficial micro-organisms (2015).”*

[CIAA, 2007, p. 29]

The CIAA also stresses the importance of research on biodegradable, active and intelligent packaging, and of the interface between pharmaceutical and food-related questions of risk assessment [CIAA, 2007, p. 30 & 59].

Despite these recent initiatives, the long time lag before industry offered to participate in dialogue led to increased distrust by many NGOs, especially regarding nanotechnology and food. National dialogue programmes including the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW) and the Consumer Conference Germany 2007, and stakeholder initiatives by leading companies such as L’Oréal in France, indicate that the cosmetics industry in Europe was more attentive to public requests and provided information more readily to regulators, NGOs and the media than the food industry.

In the United States (US), a citizen petition to the Food and Drug Administration (FDA) requested that “FDA amend its regulations for products composed of engineered nanoscaled particles generally and sunscreen drug products composed of engineered nanoscaled particles specifically” and fuelled the debate about nanomaterials in the US cosmetics sector. The FDA experienced even more pressure when the report “Beneath the Skin: Hidden Liabilities, Market Risk and Drivers of Change in the Cosmetics and Personal Care Products Industry” was published. This report, by the Investor Environmental Health Network (IEHN) [Little et al., 2007], was described as a:



Little et al., 2007

“ticking time bomb scenario of a largely self-policed industry in which regulatory action by the U.S. Food and Drug Administration (FDA) typically is triggered only by reporting from the companies themselves.”

[Nanowerk, Cosmetics, 2007]

The authors of this report address this issue again when dealing with the specific regulatory requirements in section 6.

The food industry’s strategy of delayed information came at a price. Its lack of transparency and the ambiguity of its communication strategies led in March 2008 to a powerful call for:

“A moratorium on the further commercial release of food products, food packaging, food contact materials and agrochemicals that contain manufactured nanomaterials until nanotechnology-specific safety laws are established and the public is involved in decision making.”

[Friends of the Earth, 2008, p. 3]

Friends of the Earth requested a targeted regulation of nanomaterials as new substances, an extended definition (up to 300 nm), transparency in safety assessments and labelling, public involvement, and support for sustainable food and farming. It also raised the broader social, economic, and ethical challenges associated with the use of nanomaterials in food.

“To ensure democratic control of these new technologies in the important area of food and agriculture, public involvement in nanotechnology decision making is essential.”

[Friends of the Earth, 2008, p. 37]

Under the European Commission’s 7th Framework Programme for Research, a concerted support action called FRAMINGNano was initiated in May 2008 [FRAMINGNano, 2008]. This project envisions creating an inventory of existing or ongoing regulatory processes, conducting an expert Delphi study of the issues, and providing a governance plan for the EU in this area. An important component of the project is to spread relevant information to a wider public audience. Additionally, a second EU project, the ObservatoryNano, will monitor recent developments in nanotechnology research, risk assessment, risk management and concern assessment. A dynamic website was due to be launched in October 2008, and will include reports and analyses of nanotechnology developments. It is intended to inform the broader public as well as the various stakeholder communities involved in the debate [ObservatoryNano, 2008].

In this context, many actors in the debate have encouraged industry to initiate or endorse dialogues on voluntary codes of best practice for risk management and risk communication, as will be shown in section 8.

Overall conclusions for risk governance

- Nationally and internationally, public authorities are requesting more and better information from producers of food and cosmetic products that could contain nanoscaled materials. They also favour an open exchange of information between academic, industrial, regulatory and civil society actors. This information exchange should take place within the pre-assessment phase of a new product and should be at the pre-regulation level. This will necessitate greater communication efforts amongst scientists, regulators, NGOs and consumers.
- NGOs are calling for more democratic control and more participative approaches to risk regulation. However, they may themselves lack the staff and resources needed to take part in

a range of stakeholder dialogues at national and international levels. It seems advisable to start with a more modest approach and initiate a general framing platform among the major stakeholders, including NGOs, as a means of defining terms of reference and developing a joint understanding of what the focus of the risk assessments should be. This framing exercise could be followed by a joint effort to deal with more concrete risk assessment protocols and to agree on the most suitable risk assessment methods.

- Several industrial players, and many regulatory agencies, are convinced that growing concern about nanotechnology among NGOs and consumers can only be addressed by launching a proactive consultation and communications programme. However, the effects of such a stakeholder dialogue are difficult to predict. If the overall aim of supporting innovation and a powerful new technology is not shared by the respective stakeholders, a dialogue will not produce viable agreement among the actors. If the aim is to create a common platform for a consensual approach to regulation or self-regulation, the prospects for an agreement among the key players may be more realistic. Public dialogue can also clarify the reasons for public opposition or resistance, and identify cultural patterns of risk perception at an early stage of the debate. This could allow them to serve as an early warning system for informing private investment, public regulation, and insurance policies. Past experience, for example during the GMO debate, has

shown that the strategy of “hide, wait and see” transforms the debate into an almost inevitable communications disaster which carries economic and reputation risks for companies and increases the likelihood of litigation. Engaging in proactive dialogue may be difficult, particularly for the food industry and to a lesser degree for the cosmetics industry. Part of the problem is that their non-involvement in past dialogues on nanotechnology has undermined their credibility. However, becoming an active player in the debate – even at a late stage – provides the only opportunity to reduce the potential for distrust, to increase or regain credibility and to provide incentives for positive attitudes to the technology.

- In addition to the assurance of best practice in risk assessment and management, a dialogue programme on these sensitive applications should include a reflection on value systems and cultural visions of food and cosmetics.
- As we discuss later in this report (see Section 8), several proposals have been made that promise to address self-regulation, risk assessment and management activities, as well as communications needs, and the IRGC risk governance framework could be used as guidance for approaching this issue. The framework specifically suggests that physical risk assessment needs to be enhanced by a concern assessment which investigates risk perception, social concerns and socio-economic impacts [IRGC, 2005, p. 23].

Given the heightened attention of NGOs to nanotechnologies and the growing pressure they are putting on regulators and industry, it is important to find out how the media and the public at large respond to the issue of nanoscaled materials in food and cosmetics. The following section will address the public perceptions of nanotechnologies and consumer attitudes to their applications in food and cosmetics.

Risk perception is a general term applied to the processing of physical signs and information about potentially harmful events or activities, and the formation of a judgement about their seriousness, likelihood and acceptability [Slovic et al., 1982; Brehmer, 1987; Rohrmann and Renn, 2000; Renn, 2004; and Breakwell, 2007].

Public perception of technological risks depends on two sets of variables. The first set includes such well-known psychological factors as perceived threat, familiarity, personal control options, and a positive risk-benefit ratio [Slovic, 1992; and Boholm, 1998]. The second set includes political and cultural factors. These include perceived equity and justice, visions about future developments in the area, and effects on one's interests and values [Wynne, 1984; Tait, 2001; and Renn, 2004]. The first set of variables can be predicted, to some degree, on the basis of the properties of the technology and how it is introduced. The second set is almost impossible to predict.

Comparative qualitative and quantitative studies have been conducted on the public perception of nanotechnology [e.g. Gaskell et al., 2004]. Several analyses have also been carried out which approach the issue from a broader science, technology and society perspective. These have looked at social concerns about nanotechnology and the societal impacts of its possible applications [e.g. Bainbridge, 2002; 2004; Fogelberg and Glimell, 2003; Johansson, 2003; Sweeney et al., 2003; Wolfson, 2003; Cobb and Macoubrie, 2004; and Spinardi and Williams, 2005]. Empirical results in North America and Europe thus far show that consumers in these two regions have broadly similar perceptions of nanotechnology applications when they talk about their perceived benefits and risks in general terms. Yet, with regard to food, there are distinct differences in risk perception between the two continents. Unfortunately, no data is yet available on Asian consumer perceptions. This section of the report will therefore focus on the comparison between North America and different EU Member States.

As the GMO debate showed, EU citizens tend to associate food with "naturalness". Any change in food, for example with the help of nanotechnologies, is likely to be perceived as "tampering with nature" [Sjöberg, 2000]. Unlike Europeans, US consumers are more concerned that nanotechnology could be misused to harm people, exacerbating existing social inequalities and conflicts. The following paragraphs give an overview of various studies on the public perception of nanotechnologies in general and, more

specifically, on food or cosmetic applications. Much of the data comes from ordinary survey research, while other insights were generated during the course of participatory processes such as citizen conferences or public engagement groups.

Survey results in chronological order

In 2001, one of the first US surveys on nanotechnologies showed a significant positive attitude from the vast majority of the participants (57.5%), who agreed with the statement that "human beings will benefit greatly from nanotechnology" [Bainbridge, 2002]. Although this internet survey (n=3909) was set up with a sample of email addresses derived from pro-technical and highly educated respondents from universities, or readers of *National Geographic*, similar results were found by Gaskell et al. in a random probability telephone survey conducted in 2002 [Gaskell et al., 2005]. In their survey, 50% of US participants expressed a clear positive attitude that "nanotechnologies will improve life" and only 35% expressed a "wait and see" attitude. The authors compared positions and behavioural patterns towards nanotechnologies in the US and Europe and found some striking similarities. Only 4% in the US and 6% in Europe expected negative effects from nanotechnologies. The authors concluded that the claims that "Old Europe" is culturally anti-technology must be treated with caution. However, differences were apparent in overall attitudes towards the further development and application of nanotechnologies. In Europe, only 29% of the respondents expressed a highly positive position, stating that nanotechnologies should be promoted, as compared to 50% in the US sample. Additionally, the majority (53%) of Europeans chose the "wait and see" option, compared to 35% of the US sample.

In 2004, Michael Cobb and Jane Macoubrie published a random sample telephone survey to examine the knowledge base of respondents in the US [Cobb and Macoubrie, 2004]. They found that 83.6% of the respondents had heard "little" or "nothing" of nanotechnologies and that only 16.4% said they heard "some" or "a lot". Around 40% of all respondents expected more benefits than risks, 38% expressed a neutral or ambivalent attitude and 22% believed that the risks outweighed the benefits. The survey demonstrated a low knowledge base combined with a generally positive technical attitude. These results have been confirmed in several subsequent US surveys. Respondents' knowledge was only minimally related to their attitude to nanotechnology or to their preferred option for regulating it.

The study did not refer specifically to food or cosmetic applications, but it provides an interesting insight into the issue of trust. Although the majority of the respondents were reported to be "somewhat hopeful" or "very hopeful" about nanotechnologies, they had a low level of trust in business leaders to protect consumers from the potential risks. 60.4% said that they had "not much trust" in the

ability or willingness of business leaders to minimise risks; slightly more than 35% had “some trust”; and, less than 5% expressed “a lot of trust”.

During the same year, in the United Kingdom (UK), BMRB Social Research undertook research on behalf of the Nanotechnology Working Group of the Royal Society and the Royal Academy of Engineering. The research comprised quantitative and qualitative studies to explore public attitudes towards nanotechnologies in the UK [BMRB Social Research, 2004]. In the quantitative survey (n=1005) only 29% of the representative sample were aware of the term “nanotechnologies”. The majority (68%) expressed a positive attitude and only 4% expected that nanotechnologies “would make things worse”. 13% selected the middle (ambivalent) category of “it depends”. Benefits were expected foremost in the medical sector and, to a lesser extent, in the cosmetics sector and for environmental applications. Food was not mentioned.

In Germany, the “Komm-passion” study (2004) on “Knowledge and Attitudes towards Nanotechnology” demonstrated that the German public showed a higher level of awareness and knowledge than the samples encountered in the UK and the US [Komm-passion Group, 2004]. Only 48% said that they had never heard of nanotechnologies. 45% had heard something or a lot and 15% of those who had heard about it were able to name specific applications or could provide more detailed information. Concerning the risks, only 10% associated nanotechnologies with significant risks; 34% were “not sure”. A large majority expressed positive expectations for nanotechnologies in medical applications, in environmental protection or to help economic growth. With respect to trust, this survey showed similar results to the US study. Half of the participants stated their distrust of industry, and 64% demanded more regulation. The authors stated that credibility and transparency are the key issues for public acceptance of nanotechnologies and should be the central targets for effective risk communication.

In 2005, Scheufele and Lewenstein confirmed the previous US findings that people form opinions and attitudes in the absence of relevant scientific or policy-related information [Scheufele and Lewenstein, 2005]. Steven Currall et al. conducted a national telephone survey in 2005 (n= 503) and investigated this process of “creative” attitude formation [Currall et al., 2006]. They concluded that people draw analogies from past technologies when assessing new technological candidates such as nanotechnologies. Compared with other familiar technologies, including stem cell research, respondents associated nanotechnologies with “medium risk and moderate benefit”. Attitudes to GMOs and asbestos were significantly more hostile.

Two other studies of random samples, one of 1200 participants in the US and the other of 2000 adults in Canada, were compared by Edna Einsiedel (2005). The two samples had similar results. In the US sample, four out of ten responded that they had heard, read or seen “a little” or “a lot” about nanotechnologies.

Compared with the data from 2004, the number of more or less well-informed people had more than doubled, from 16% to 40%. The Canadian study showed similar results. 38% had heard or read about nanotechnologies. In both samples around half of the respondents (Canada 51%, US 49%) expected substantial benefits and only 16% in the US sample and 13% in the Canadian sample anticipated substantial risks.

In spite of these overall positive attitudes, almost all respondents expressed support for a policy of informed choice. They demanded that industry and governments provide accurate information on the risks and benefits in order to allow consumers to exercise the right to choose which risks were acceptable. Additionally, a large majority (73% in Canada, 63% in the US) agreed with the statement that “until more is known about risks of NT [Nanotechnologies], government should slow the use of NT” [Einsiedel, 2005, p. 6]. As was the case in previous surveys, participants had little trust in governments to regulate the risks in an appropriate way. More than half voiced their scepticism that governments were doing enough to study and monitor the impact of nanotechnology products.

Einsiedel concluded her study with several lessons for the risk governance of nanotechnologies:

- Trust, transparency and accountability are crucial in the shaping of public attitudes and risk perception with respect to nanotechnologies;
- The public expects to be involved in the process of risk governance;
- It is important to disseminate information on risks and benefits through multiple channels to diverse audiences;
- Information material for schools and public education should be developed and implemented; and
- Opportunities for public involvement should be encouraged.

In the autumn of 2005 Jane Macoubrie conducted 12 citizen groups with a total of 177 participants in three different locations in the US (Washington, Texas and Ohio), on behalf of the Wilson Center [Macoubrie, 2005]. Presented with both a pre- and post-meeting questionnaire, 54% of the respondents indicated that they knew almost nothing about nanotechnology and 43% answered they knew something or a little. One of the most interesting results of the comparison between the pre- and the post-responses was that the percentage of participants who expected that the benefits would exceed the risks rose from 16% to 40% after the citizens were informed and had a chance to discuss the consequences and opportunities associated with nanotechnologies. At the same time, however, the opposite assessment also became more popular. The number of respondents who felt that the risks would outweigh the benefits increased from 5% to 15%. The information input during the meeting clearly had the effect of making people less indifferent

about nanotechnology: the number of people who chose the “don’t know” categories fell from 65% to 14%.

A year later, in September 2006, Peter D. Hart Research Associates conducted a US survey among 1014 adults [Hart, 2006]. This survey found that public awareness of nanotechnologies was down from 43% in 2005 to 30%, with more than two thirds (69%) having heard little or nothing about nanotechnology. Hart made a clear association between familiarity with nanotechnology and a positive attitude to it. This interpretation contrasted with previous results which had suggested that a positive attitude to nanotechnology was independent of a low degree of awareness or knowledge. In Hart’s study only 15% of the overall sample base said that the benefits would outweigh the risks. But of those who were more familiar with nanotechnology, 32% expected greater benefits than risks. The Hart Report also showed an unusually negative attitude amongst the US population in general, with 35% of the respondents claiming that the risks would outweigh the benefits and 43% responding that they were “not sure” about it. With 78% displaying negative or ambivalent positions, the optimistic US view on nanotechnology seemed to have faded.

In 2007, the Wilson Report [Kahan et al., 2007] was published and provided a contrast to some of the results of the work by Hart Associates, in particular with respect to public awareness and its relation to attitudes to nanotechnology. Overall, 81% indicated that they “know nothing at all” or “just a little” and 19% that they knew “some” or “a lot”. Kahan et al. reported that 53% estimated that benefits will outweigh risks and only 11% said they were “not sure”. A total of 36% indicated that “risk will outweigh benefits”.

Compared to earlier studies, both the Hart and the Kahan et al. studies confirmed a trend towards an increase in negative attitudes. However, neither a negative nor positive correlation between awareness and knowledge was observed. They concluded that information did not affect attitudes to nanotechnologies in the general population.

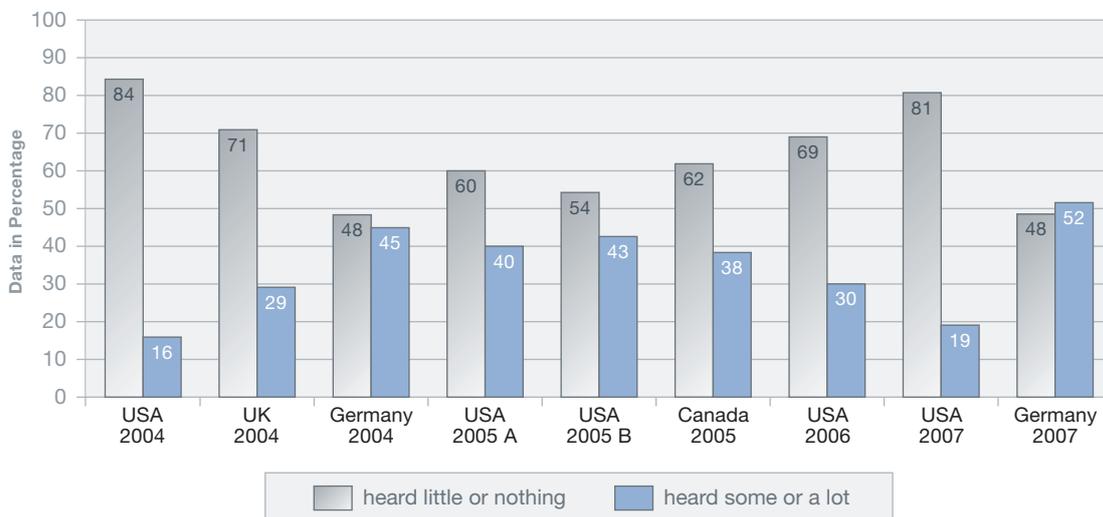
The most recent quantitative results came from Germany’s Federal Institute of Risk Assessment [BfR, 2007] which in December 2007 published initial data from a representative telephone survey (n=1000). In this investigation, public awareness of nanotechnology increased to 52% of participants who had heard about nanotechnologies and were able to name specific applications. A large proportion (66%) believed that nanotechnology as a whole would offer more benefits than risks. However, this overall impression was not true for all applications. Surface treatments or paints were approved by 86%; dirt-repellent textiles, packaging materials (also relevant for food) and sunscreen products also received high acceptance rates. Nanomaterials in cosmetics achieved an approval rate of 53%. However, for food applications the German respondents were far more sceptical: 69% rejected the use of nanoscaled additives in spices and 84% voiced the opinion that they would not like any nanomaterials in foodstuffs.

The BfR survey also included several questions on trust with respect to different actors. The highest level of trust (92%) was enjoyed by consumer organisations and scientific experts. Journalists of consumer magazines were granted high credibility too. At the low end of the trust scale were representatives from industry (32%) and politics (23%).

Although one must exercise caution in interpreting the results of these studies, they collectively seem to convey a rather consistent message, even if stable attitudes have not yet been formed on the subject. It is that respondents are in general in favour of the development of nanotechnologies but do not trust industry or government to act in the public interest when it comes to managing

Key:
 USA 2004: Cobb, M./Macoubrie, J. (2004); UK 2004: BMRB Social Research (2004);
 Germany 2004: Komm-passion (2004); USA 2005 A: Einsiedel, E. (2005);
 USA 2005 B: Macoubrie, J. (2005); Canada 2005: Einsiedel, E. (2005);
 USA 2006: Hart, P. (2006); USA 2007: Kahan et al. (2007);
 Germany 2007: BfR (2007)

Figure 2: Public knowledge base on nanotechnologies in international surveys



or regulating the risks. Most people associate nanotechnology with a series of recent technological innovations, such as genetic engineering, with which they associate a mixture of both risks and benefits. They complain about a lack of commitment from industry and government to ensuring that only applications with a clear positive benefit-to-risk ratio are pursued. Industry is believed to place profits over safety, and governments are seen as being too weak to promote effective regulation.

The overall impression given by these studies is that most people were not familiar with nanotechnologies, and were unable to describe nanoscaled material or nanotechnologies in open questions. Perhaps because these surveys used samples composed of members of the general public rather than people with a higher technical background (except in the first studies), overall awareness of nanotechnologies was reported as having fallen after 2004, although this trend is not supported by the new results from Germany (see Figure 2 on previous page).

With regard to risks and benefits, as Figure 3 (above) shows, only one out of nine surveys indicated that respondents perceive more risks than benefits when making judgments about nanotechnologies. Eight of the surveys support the thesis that most people associate more benefits with nanotechnology than risks. The fact that this ratio can reverse itself in a rather short period of time is another indication of the volatile nature of public perceptions. It can be assumed that the majority of people support nanotechnologies because they believe in public benefits. But this positive attitude is far from being stable and is open for re-consideration if negative information is received and believed.

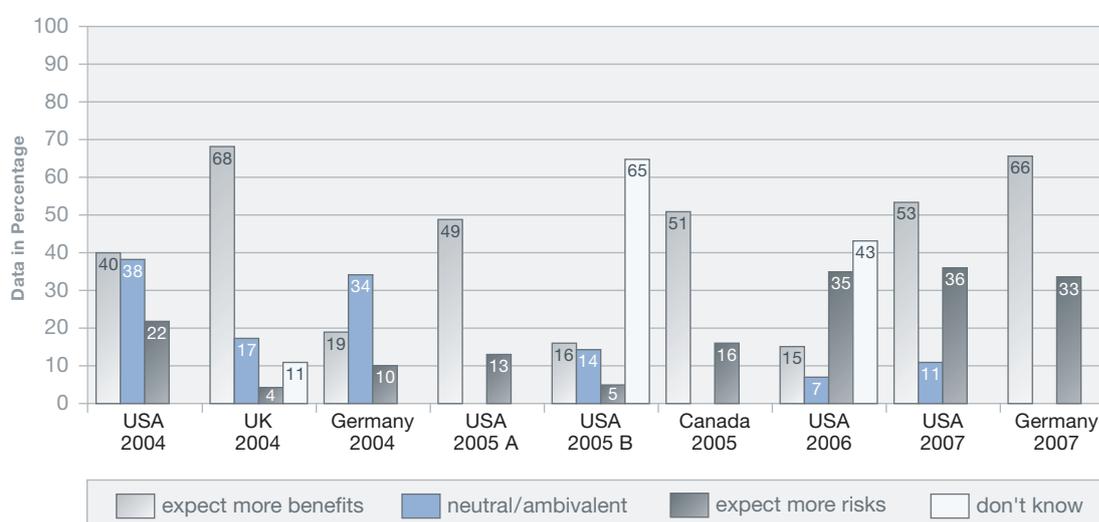
The insights from these different surveys should be interpreted with care. Their results are not directly comparable because of differences in research design and in how questions were articulated. For example, some of the surveys provided respondents with the option to say "I don't know"; others did not, and obliged

respondents to choose one of the proposed options. This was particularly important when people were asked whether they expected the benefits of nanotechnologies to outweigh the risks or vice versa (USA 2005 A, Canada 2005, and Germany 2007). In two of the three surveys that included the "I don't know" option, the majority of respondents chose it (USA 2005 B and USA 2006). In those surveys which did not include it (and so obliged respondents to make a judgement about risk and benefits), participants had a tendency to select the optimistic over the pessimistic option.

Other variables that impact on the still volatile attitudes to nanotechnology include individuals' level of knowledge, their media exposure and their trust in the key actors. In particular, the study by Kahan et al. demonstrated that people with little knowledge of the subject tend to be guided by affective reactions that are highly related to publicly available perceptions or stereotypes. People with a strong interest in and knowledge of nanotechnology had more positive beliefs about it than those with little interest in the subject.

A study by Siegrist et al. showed that public perceptions about nanotechnologies and food are more differentiated than views on nanotechnologies in general [Siegrist et al., 2007]. The researchers investigated the perceptions of 153 ordinary individuals on nanomaterials in food and food packaging. The research showed significant differences in perceptions for the different applications in food and food packaging, and between food and other applications. The study examined the factors that influence consumers' willingness to buy products such as coated tomatoes, bread containing nanoencapsulated fish oil, juice enriched with encapsulated beta-carotene, and meat packaging with antibacterial silver particles. The benefits of packaging using nanotechnology were perceived as being greater than those for foodstuffs containing nanomaterials. Again, social trust was identified as the crucial factor "directly influencing the affect evoked by these new products" [Siegrist et al., 2007, p. 1].

Figure 3: Expectations about benefits and risks of nanotechnologies (Key as for Figure 2)



An international survey with comparable data on individual knowledge, awareness of risks and benefits, the influence of media coverage, and trust in industry and other actors would be helpful to create more reliable and comprehensive results on the perceptions of risk and their drivers.

Results from qualitative studies and public participation exercises

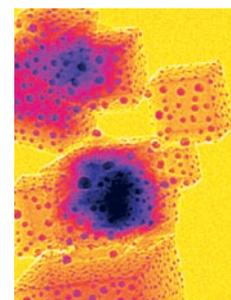
In addition to these quantitative research results, the issue of nanomaterials in food and food packaging has been a major topic of several qualitative studies applying the method of focus groups, citizen panels or consumer conferences. Several focus groups and citizen panels on this subject have been conducted across Europe, for example the UK Nano Jury [Nano Jury UK, 2005] and the Nanotechnology Engagement Group [Gavelin et al., 2007], the Netherlands focus groups [Hanssen and van Est, 2004], the German Consumer Conference [BfR, 2006] and TA Swiss Publifocus [TA Swiss, 2006]. In addition, nanotechnology in food was also included in broader studies in France [Nanosciences, 2007] and Denmark [Danish Board of Technology, 2004]. Similar results were found by the Madison Area Citizen Conferences in the US [Kleinmann and Powell, 2005].

In most of the studies, participants stressed the necessity to define nanotechnologies and to provide more information to citizens. Consumers were positive about the opportunities offered by nanotechnology to fight disease, to clean the environment and to develop ecologically sustainable and economically competitive products. In common with the quantitative studies referred to above, participants in these exercises often expressed scepticism about the effectiveness of public regulation, oversight and control. They were also concerned that there might not be adequate consideration of long-term impacts on the environment and on society at large. Even in citizen panels, participants expressed their support for more deliberation and stakeholder dialogues. Food and cosmetics were specifically addressed in some European focus groups. Participants who mentioned these applications (Switzerland and Germany) came to the conclusion that food and, to a lesser degree, cosmetics are particularly sensitive to people's concerns for the following reasons:

- Direct contact with the body via the skin and through intake;
- Concerns about health detriments because nanoscaled particles may pass through natural barriers (cells, blood-brain border, placenta barrier) leading to unexpected and irreversible effects;
- The lack of information from either industry or academia on the potential risks of nanomaterials in food (for example, food industry representatives refused to attend the German citizens conference), and limited information on cosmetic applications. For both applications there is a perception of secrecy and lack of transparency;

- Lack of perceived competence and trust in public authorities and low knowledge of their activities; and
- Close associations between nanotechnology and recent scandals such as Bovine Spongiform Encephalopathy (BSE) and experiences with the debate on Genetically Modified Organisms (GMOs).

The quantitative results of Jane Macoubrie's study of citizen groups have been explored above. In her qualitative analysis, all participants agreed on the potential benefits of nanotechnologies and nanomaterials for medical applications, environmental protection and lower-cost energy supply. They also identified a number of benefits. "Safer food" (from smart packaging), "more nutritious food", and the ability to "feed the world" were among the ten most frequently named benefits. At the same time, however, the citizens associated their three top-ranking concerns with



Magnesium Oxide Dice

food and food packaging. Their top concern referred to unknown risks and consequences of unintended use. Their second concern was a lack of trust in regulation, and the third was unknown health risks due to unnatural manipulation of the original material. Stated negative associations included "long-term consumption of nano food", "adulterated field crops", negative effects on "natural agriculture and animals", "foods that metabolise to worsen health", "biopharming in the wrong hands" and "using live people for experiments with FDA approval". In light of all these concerns and the low trust in the US Federal regulation system, the citizen groups recommended:

- More testing before products are introduced to the market;
- Providing more information to the public on the risks and benefits of nanomaterials in food items; and
- Reflection of social and ethical concerns at an early stage of research and product development.

Overall conclusions for risk governance

- Most people in the US and Europe are still not aware of the opportunities and risks of nanotechnologies, although the number of people who have started to get interested in this technology and form beliefs about its applications is increasing. The majority of studies suggest that as people become more aware and seek more specific knowledge, consumers tend to become more ambivalent about the risk-benefit ratio rather than becoming universally more positive. This has been confirmed by most of the quantitative and qualitative studies that have investigated this relationship between knowledge and attitude.

- With respect to food and cosmetics, the data clearly indicates that food and, to a lesser degree, cosmetics are highly sensitive application areas that cause heightened concern and require particular vigilance. The direct contact with nanomaterials in food and cosmetics, and the risk debate about the possible migration of nanomaterials from food contact materials, lead to higher risk awareness for food and cosmetic applications compared with any other applications. This awareness is further fuelled by a perception of insufficient oversight by public regulatory agencies, and by distrust of safety provisions in industry. This emphasises the importance for risk governance of a thorough concern assessment to inform risk characterisation and evaluation.
- Public attitudes to nanotechnology are characterised by a high degree of positive expectations, paired with vigilance. Since individuals have little knowledge and are unable to

acknowledge potentially negative side effects on the basis of personal experience or senses, they rely on information from third parties. In this situation trust is crucial. The situation underlies the need for early risk communication and open exchange of information. In several studies, citizens expressed doubts about their trust in industry, public authorities and campaigning NGOs. Scientists and consumer organisations were usually regarded as more credible. Dialogue should not only be the task of industry, but should include these other actors as well. A balanced and concerted dialogue is needed, with bridges between the major actors in the private, civil and public sectors, and at the international as well as the regional and local levels.

The following section will address how the regulatory systems respond to pressures from NGOs and to the increasingly sceptical attitudes of consumers in Europe and the US.

Most of the food and – to a lesser degree – the cosmetics industry appears to be seeking to attenuate discussion of the risks in nanoscaled materials. At the same time, NGOs and several public authorities are pressing for more openness and more proactive risk management. The NGOs in particular are increasing the pressure on regulatory agencies to deal with this issue. NGOs want regulators to provide guidelines, to take legal action to force industry to assess the risks of nanoscaled materials, and to take protective measures if such risks can be detected. Public authorities are calling for more and earlier information about the nanomaterials that are used in research projects and in products, including those in development as well as those already on the market. Furthermore, they want to learn more about the approaches and results of the risk assessments conducted by private industry. Considering these diverse interests and positions, it is important to have a clear understanding of the present state of regulatory activities around the world, which will be given in the following section.

Table 1 (see page 23) demonstrates that nano-specific regulation of risks is currently nowhere in sight around the globe. The table also suggests that, in the countries reviewed, there is a range of existing legislation which indirectly covers nanotechnology applications in the cosmetic and food sectors. Since the situation in different regions and countries varies widely, this section will describe a range of national and supranational (EU) regulatory activities before concluding with an overall assessment. The selection of the countries was governed by the availability of data and information in English. Therefore, this table cannot claim to be complete. Most of the input relies on the results of web-based research, the responses to a written request to national regulatory authorities and several telephone interviews with 15 national regulators from the US, the UK, the Republic of Korea, Japan, Austria and Germany.

United States

An examination of the current state of regulation in the US shows that there are a number of laws that can be linked to the regulation of nanotechnologies. These include The Toxic Substances Control Act (TSCA), The Occupational Safety and Health Act (OSHA) and various product liability laws and environmental laws such as the Clean Air Act (CAA). Focusing on food and cosmetics specifically, the main legal basis is the Food, Drug, and Cosmetic Act (FDCA), which sets out the framework under which the US Food and Drug Administration (FDA) is mandated to oversee and control the safety of food, drugs, and cosmetics.

For food applications, the situation is complex and will be described briefly. The FDCA requires pre-market testing for food and colour additives, independent of their particle size. Accordingly, these



rules apply also to nanomaterials. FDA reviewers can require manufacturers to contribute scientific information on any substances added to food directly or indirectly to support regulatory decisions [FDA, Nanotechnology Task Force, 2007, p. 25]. FDA's requirement for risk assessment in the pre-market authorisation phase regulates all types of food additives unless the substance is "generally recognised as safe" (GRAS) [FDA, 2004]. For food additives that are not previously approved as GRAS, FDA can require information on the identity and properties of the material, including its physical characteristics such as particle size, its physical or chemical effects, and the analytical methods used to determine the quantity of the substance and the safety of the intended use [FDA, Nanotechnology Task Force, 2007, p. 26]. These requirements generally cover food additives regardless of their physical or chemical characteristics. This includes nanomaterials as well as larger particles, and aggregates or agglomerates of nanoscaled objects. Safety data is required for products containing food additives as a whole [FDA, Food Additives, 2006]. This includes products consisting of nanomaterials and agglomerated materials with or without single nanoscaled objects. If there is scientific evidence of a significant risk, FDA can set limits in terms of physical or chemical properties, or the concentration of additive in relation to the mass of the food product. If a substance has not been approved yet, the applicant must provide general information on toxicity that relates to the substance. The FDA also requires applicants to provide information if there is an indication that the structure of the substance (in particular the surface to mass ratio) has an impact on toxicologically relevant features.

For dietary supplements, the Dietary Supplement Health and Education Act of 1994 (DSHEA) has to be applied.

"The dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements."

[FDA, 2008]

Additionally, manufacturers have to make sure that information on product labels is truthful and not misleading.

The FDA's current practice has been generally approved by the food and cosmetics industry and criticised by environmental NGOs. It has had mixed reviews among independent experts. One external review of FDA's performance by the Wilson Center identified several gaps in the "legal tool kit" but, more importantly, argues that the FDA lacks by some distance the resources it needs to fulfil its regulatory task:

"Just to be able to do what it was doing in 1996 and continue the new activities mandated for it since then, FDA's 2006 budget would have to be 49% greater than it is. Under the President's

proposed 2007 budget for FDA, the funding gap between responsibilities and capacity will grow again, to 56%.”

[Taylor, 2006, p. 3 & 30]

According to the Wilson Center, the “harsh budget reality” hinders the FDA’s effective oversight of nanotechnologies in foods in both pre-market and post-market phases.

Sunscreens have a particular regulatory status and require formal approval from the FDA before they can be sold on the market. However, the FDA generally does not require data (including safety data) before cosmetic products are marketed. The submission of reports about adverse effects is voluntary under US legislation [FDA, Nanotechnology Task Force, 2007, p. 14] and the “misbranding” of cosmetics (for example labels which are false or misleading, or do not contain the required information) is prohibited. In such instances, FDA does not have the authority to recall the product or take action against the manufacturer, but it can ask the Justice Department to order the company to have the product removed from the market. The report of the Wilson Center therefore concludes that cosmetics – including those containing nanomaterials – “are essentially unregulated” in the US [Davies, 2006, p. 13].

In summer 2007, the US FDA Nanotechnology Task Force published a report on regulatory requirements for the use of nanoscaled materials in which it responded in part to the criticism of civil society institutions. However, the report also expresses concern about the comparability of nanoscaled materials with conventional chemicals:

“There may be a fundamental difference in the kind of uncertainty associated with nanoscaled materials compared to conventional chemicals, both with respect to knowledge about them and the way that testing is performed”

[FDA, Nanotechnology Task Force, 2007, p. 13].

For these reasons the report recommended that individual hazard studies of specific nanoscaled materials be carried out and that these studies be synthesised if possible into general information on the properties of nanomaterials. The authors also called for physiologically based pharmacokinetic models (PbPk) or quantitative structure activity relationship models (QSAR) for the characterisation of the materials in terms of material type, size, charge, and surface modification. Further, they argued for the development of a comprehensive database using standardised methods, standards and ontologies.

The question of whether the FDCA, and the mandate given to the FDA, are adequate for the issues raised by nanotechnology and its application to food and cosmetics has been raised by, amongst others, the US-based International Center for Technology Assessment:

“Current legislation provides inadequate oversight of nanomaterials. A modified or sui generis, nano-specific

regulatory regime must be an integral aspect of the development of nanotechnologies.”

[ICTA, 2007, p. 3]

European Union

In the European Union (EU) the regulations – whether related to substances such as the European Community Regulation on chemicals and their safe use (EC 1907/2006 – REACH) or to products (i.e. food or cosmetics) – do not refer specifically to nanomaterials. Thus, EU regulation makes no distinction between the risk assessment required for a substance in general and that required for specific forms such as nanostructures.

Probably the most important EU regime for nanotechnologies is REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). Though it does not explicitly regulate nanostructures, the REACH regulation’s section on operational conditions specifies the physical form in which the substance is manufactured (REACH, Annex I, section 5.1.1) and states that the properties of a material have to be described in terms corresponding to the form of the application (Annex IV of Directive 67/548/EEC). Under REACH, manufacturers and importers have to submit a registration dossier for materials at or above one tonne per year. Additionally, a Chemical Safety Report (CSR) is needed if the amount of material is at or above 10 tonnes per year. For nanomaterials, and for the current political debate on possible risks in the food and cosmetics industries, the following passage is of huge importance:

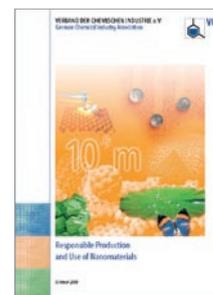
“Furthermore, if deemed necessary for the evaluation of the substance the European Chemicals Agency can require any information on the substance, independent of the minimum information requirements of REACH.”

[EC, Regulatory Aspects of Nanotechnology, 2008, p. 4]

The German Chemical Industry Association (VCI) therefore recommends their members to be proactive and provide information even for materials below one tonne per year, and to communicate their assessment results along the value chain in Safety Data Sheets.

“It should be noted that there are also legal requirements below the threshold of 1 tonne per year for a REACH registration: Obligations for, e.g., risk assessment, classification and labelling, occupational health and safety, as well as the Chemical Agents Directive 98/24/EEC, continue to apply; and there are no volume thresholds for these obligations. This means that manufacturers or importers must classify substances, or even specific products, according to the hazardous properties of the substances or products, label them if necessary, and provide specific safety information.”

[VCI, 2008, p. 9]



VCI, 2008

Table 1: Overview of legislation in regard to the regulation of nanotechnologies in cosmetic and food applications

	USA		UK	
	Regulatory Body	Key Legislation/Code of Practice	Regulatory Body	Key Legislation/Code of Practice
Nano-specific legal prescription	none	none	none	none
Relevant legal prescription for nanotechnology and cosmetics	Food and Drug Administration, Environmental Protection Agency	Food, Drug, and Cosmetic Act, 21. U.S.C. § 301(1938), Toxic Substances Control Act (General Approach to Oversight of Nanoscale Materials)	Department of Health, Department of Trade and Industry	Council Directive 76/768/EEC Cosmetics Directive, 1976 O.J. (L262) 169 EU; Cosmetic Products (Safety) Regulations, 2003, S.I. 2003/835
Relevant legal prescription for nanotechnology and food applications	Food and Drug Administration, Environmental Protection Agency	Food, Drug, and Cosmetic Act, 21. U.S.C. § 301(1938), Toxic Substances Control Act (General Approach to Oversight of Nanoscale Materials)	Food Standards Agency	Regulation (EC) N° 258/97 (Novel Food Regulation); Regulation (EC) No. 882/2004 on Official Feed and Food Controls, 2004 O.J. (L191) 1 (EU); Food Safety Act, 1990, c.16; Food Standards Act, 1999, c.28

	GERMANY		AUSTRIA	
	Regulatory Body	Key Legislation/Code of Practice	Regulatory Body	Key Legislation/Code of Practice
Nano-specific legal prescription	none	none	none	none
Relevant legal prescription for nanotechnology and cosmetics	Federal Ministry for Food, Agriculture and Consumer Protection (BMELV)	German Food and Animal Feed Code (LFGB), § 26 LFGB and § 31 para. 1 – based on Council Directive 76/768/EEC Cosmetic Directive, 1976 O.J. (L262) 169 EU	Federal Ministry for Health, Family and Youth (BMGFJ)	Council Directive 76/768/EEC Cosmetics Directive, 1976 O.J. (L262) 169 EU; Cosmetics Act, Federal Law Gazette BGBl.II.375/1999; Cosmetics Labelling Act
Relevant legal prescription for nanotechnology and food applications	Federal Ministry for Food, Agriculture and Consumer Protection (BMELV)	Regulation (EC) N° 258/97 (Novel Food Regulation); Regulation (EC) No. 882/2004 on Official Feed and Food Controls, 2004 O.J. (L191) 1 (EU)	Federal Ministry for Health, Family and Youth (BMGFJ)	Regulation (EC) N° 258/97 (Novel Food Regulation); Regulation (EC) No. 882/2004 on Official Feed and Food Controls, 2004 O.J. (L191) 1 (EU); Food Safety and Consumer Protection Act (LMSVG)

	JAPAN	
	Regulatory Body	Key Legislation/Code of Practice
Nano-specific legal prescription	none	none
Relevant legal prescription for nanotechnology and cosmetics	Pharmaceutical and Medical Device Agency	Pharmaceutical Affairs Law, Law No. 145 of 1960
Relevant legal prescription for nanotechnology and food applications	Department of Food Safety, Ministry of Health, Labour & Welfare	Food Sanitation Law, Law No. 233 of 1947; The Food Safety Basic Law, Law No. 48 of 2003

In 2007 the European Commission adopted a Proposal for a Regulation on classification, labelling and packaging of substances and mixtures, amending Directive 67/548/EEC and Regulation (EC) No. 1907/2006, in order to align the EU system of classification, labelling and packaging substances and mixtures to the United Nations Globally Harmonised System (GHS). This proposal, again focused on the form and physical state of the substances, implies that nanotechnologies are likely to be regulated under the requirements of REACH [Klauk, 2008].

Analogously to US regulation, other Directives that are obligatory and which concern the use of nanomaterials include the Directives on Worker Protection (89/391/EEC) and the General Product Safety Directive (Directive 2001/95/EC).

Additional legal bases apply in the area of food and cosmetics. Concerning food in particular, Regulation 258/97 on novel foods and novel food ingredients has similar functions to REACH. Nanotechnology applications in the food industry have to be classified as novel foods or novel food ingredients in cases where they result in significant changes in the composition or structure of foods or food ingredients which might affect their nutritional value, metabolism or level of undesirable substances, and which were not consumed within the EU before 15 May 1997. Under Regulation 258/97, pre-market authorisation of nanomaterials is required if they are either a novel ingredient, i.e. a totally new substance that is presented in a nanoparticulate form, or are the product of a novel process, i.e. an existing ingredient marketed in nanoparticulate form that has significantly different biological or chemical properties as compared to the existing material. Regulation 258/97 is binding on all EU Member States and has to be implemented by all national authorities. Although it does not specify that its criteria include particle size, the prescribed assessment procedure includes details of composition, nutritional value, metabolism, intended use and the level of chemical containments, and might require additional studies of toxicology and allergenicity where appropriate.

An important regulation for packaging at the EU level is Regulation (EC) No. 1935/2004. This regulation covers materials and articles that are intended to be, already are, or can reasonably be expected to be brought into contact with food. Like the Novel Food Regulation, this food packaging regulation is articulated in all-encompassing language so that the migration of nanocomponents into food from food contact materials and articles is covered.

These regulations have not been adjusted specifically to cover nanotechnologies. EFSA has recently been asked to prepare a scientific opinion on risks arising from nanoscience and nanotechnologies on food and feed safety, and on the environment. This opinion is expected to be completed in 2009 (see Section 4).

The EU's regime for managing nanoscaled materials in cosmetics is similar to that employed in the US. In both regulatory regimes, pre-

market approval is only required for preservatives, colourants, and the active ingredients of sunscreens. Some nanoscaled materials are used as active ingredients in sunscreens and are considered to be part of the "negative" list of active ingredients, i.e. ingredients that are not to be used unless peer-reviewed safety assessments have been carried out and which clearly demonstrate their safety for consumers [Calster, 2006, p. 242].

Meanwhile, Council Directive 76/768/EEC (the "Cosmetics Directive") states that, as a general principle, only cosmetic products that do not cause damage to human health can be put on the market (Article 2). In addition, the Directive makes it obligatory for the manufacturer to keep information on its cosmetic products readily accessible for the control authorities of the Member States (Article 7a). This information is supposed to contain the physico-chemical and microbiological specifications of the raw materials and the finished product, as well as the assessment of the safety for human health of the finished product. The European Commission Directive which regulates the production, sale and use of cosmetic products is currently being modified to refer specifically to the challenges posed by the use of nanoscaled materials in cosmetics. To date there is no particular requirement for information on particle size [EC, Written Question, 2003].

Gaps in the European regulation of nanomaterials in cosmetics have been identified in a recent study by the European Commission's Scientific Committee on Consumer Products (SCCP). Amongst other issues, hazard identification, exposure assessment, translocation and possible health effects were seen as still lacking scientific testing and examination. As a consequence, further research activities are explicitly recommended and prior assessments of zinc and titanium dioxide are being re-examined [SCCP, 2007, p. 33-37]. In response to the recent opinion of the SCCP, the European cosmetics industry has decided to cooperate with the Commission and will submit a revised and up-to-date dossier to the Commission before the end of 2008.

In the European Commission's Communication on Regulatory Aspects of Nanomaterials, the Commission said:

"Overall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework. However, current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation."

[EC, Regulatory Aspects of Nanotechnology, 2008, p. 3]

The Commission addressed the challenge of the implementation and use of the regulatory instruments in relation to risk assessment, information exchange and pre-market approval. They stressed the need to improve the knowledge base, in particular regarding test methods and risk assessment, and indicated the measures that

should be taken, based on the precautionary principle, in cases of an insufficient data base.

While the EU seems to be content with the flexibility of the current regulatory framework, it has been looking at additional safety efforts. Several scientific committees, groups and agencies are actively engaged in addressing environmental and health risk, food and consumer products, and occupational health. There have been regular conferences at which safety issues have been addressed. A number of research projects have been launched covering the topic and several open consultation sessions were organised such as the consultation on codes of conduct for responsible research (see Section 8). The European Commission's Code of Conduct for Responsible Nanosciences and Nanotechnologies Research complements the existing legislation and provides further guidelines that promote a responsible and transparent approach to conducting and communicating nanoscience research.

The current EU regulations provide the most important framework for activities at the national level of the EU Member States. Perhaps as a result, national regulatory agencies within the EU seem hesitant about implementing national legislation, or do not see the need to do so. However, there have been numerous reviews and initiatives at the national level, such as these in the UK, Germany and Austria.

United Kingdom

Among the countries reviewed for this survey, the UK appears to be the country closest to implementing regulation, particularly for nanotechnology applications [Bowman and Hodge, 2007, p. 19]. Prompted by the reports of the UK Better Regulation Taskforce (2003) and the Royal Society (2004), several reviews of the regulatory situation in the UK have been conducted and published recently. They have come to different conclusions [Royal Society, 2004]. The reports of the Food Standards Agency [FSA, 2006] and the Health and Safety Commission [Health and Safety Executive, 2006] do not see a need to change existing laws or create new ones because of alleged knowledge gaps. The Food Standards Agency considers the process prescribed under the Novel Food Act as adequate to identify potential risks associated with newly designed nanoscaled materials [FSA, 2006, p. 6]. Regulatory gaps may exist for ingredients which have been used in the past above the nanoscale level and might in future be marketed at smaller particle sizes of 100 nm or below. The FSA argues that, regardless of whether or not the final product or the production process is based on nanotechnologies, it has to conform to all the requirements of EU Food Law Regulation (178/2002), which requires that food placed on the market must be safe (this was also the Regulation which established the European Food Safety Authority).

In contrast to the opinions of the FSA and the UK Better Regulation Taskforce, the report of the Department for Business, Enterprise

and Regulatory Reform (BERR) suggests that “free, engineered nanomaterials might be classed as ‘hazardous’ substances unless or until there is sufficient evidence of their safety in a particular context” [BERR, 2006, p. 33]. Independent of the results of these various reviews, the UK agencies are bound to align with the EU bodies. Therefore the Health and Safety Executive UK states that there is:

“almost no scope for changing regulations and supporting elements on a purely national, UK basis; almost all such envisaged changes would need to be negotiated and a position ultimately agreed across the EU.”

[HSE, 2006, p. 15; for food in particular see FSA, 2006, p. 16]

There is currently a regulatory debate in the UK on single and multi-walled carbon nanotubes (CNTs), focusing on possible health risks from their different uses. In Europe there is an intensive debate on the obligation to treat CNTs as hazardous waste, and on questions of occupational health in the context of the need to avoid an inhalation of short, stable, asbestos-like CNT fibres. This debate is mainly aimed at laboratories in companies and universities. In addition to this regulatory debate, many voluntary codes and reporting schemes have been launched. The most notable efforts at present are the “Responsible Nano Code”, a project initiated by the Royal Society, the British Nanotechnology Industries Association and a private investment company, and the DEFRA Voluntary Reporting Scheme, which is designed to provide the UK government with information relevant to regulating nanoscaled materials [DEFRA, 2008].

Germany

German public authorities have also reviewed the legal situation, particularly in a preliminary “Review of the legislative framework of Nanotechnologies” [Führ, M. et al., 2006]. The focus of this report was on environmental aspects and it paid little attention to consumer issues such as food and cosmetics. On the basis of this report, the German government issued a statement about whether changes in the regulatory system were necessary [BMBF, 2007]. It concluded that no changes in the legal framework are necessary at present and that available instruments at the national and European level are sufficiently flexible to include the risks of nanoscaled materials. It added that specific cases might call for changes in the regulatory provisions, but that they should be delayed until common international definitions are in place and appropriate analytical tools for risk assessment have been established. The report also said that, in the case of specific applications, the regulatory bodies are already empowered to act on the basis of their general mandate to minimise risks to the public.

This general power to intervene if public health or safety is at risk might be used to permit rapid regulatory action if a major incident occurred or new scientific information about risks surfaced. German

authorities stated at the NanoCare Conference in November 2007 that, in general, the flexibility of regulatory frameworks at national and EU levels permits appropriate responses to new scientific results or events linked to nanoscaled materials.

In the absence of “hard” legislation, VCI, which represents the German chemical industry, has taken a lead in self-regulation efforts. One example of proactive engagement by producing industries is a series of dialogues with the Swiss-based Risk Dialogue Foundation. This initiative is supported by multinational companies such as BASF, EVONIK (formerly DEGUSSA) and BAYER. Based upon the feedback from the dialogue events, the VCI has developed industrial guidelines for the responsible use of nanoscaled materials in line with the REACH reporting approach and including materials produced in small quantities below the REACH threshold of one tonne per year [VCI, 2008]. Additionally, VCI has promulgated two guidelines for occupational health measures [BAuA and VCI, 2007] and for material safety data sheets [VCI, 2008] as means to improve the responsible use of nanomaterials.

The UK and Germany stand out in their efforts to reflect the need for nanotechnology regulation. Both countries have come to the conclusion that at present, “soft” forms of regulation, in the form of voluntary codes of conduct and public dialogue initiatives, are sufficient to ensure public health, safety and environmental protection.

Austria

Other EU countries have also addressed the challenges posed by the new technology. A good example is Austria. Under the lead of several federal ministries, a Platform on Nanotechnology was established, including representatives from several ministries, NGOs and scientific institutions, with the goal of exchanging information and coordinating risk assessment and communication activities in the field. As knowledge gaps have been internationally recognised as the major hurdle to effective nanotechnology regulation, the Austrian authorities established a clearinghouse for nanotechnology-related information called “NanoTrust”, in 2007, funded by the Federal Ministry for Transport, Innovation and Technology. “NanoTrust” is intended to provide relevant information to stakeholder groups involved in the debate focussing on regulatory institutions.

Japan

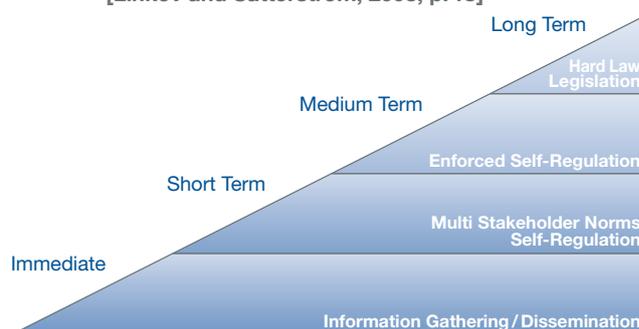
As Table 1 indicates, the regulatory situations are similar in Europe and the US. Even if we turn to Asia, the picture does not change significantly. A good example here is Japan. As in many European countries (such as Austria), at the EU level, and in the US, the arrival of nanotechnology has not led to any revisions of existing legislation. No laws have been changed, amended or initiated. However, efforts to standardise nanotechnologies and nanoscaled

particles were launched in 2004 [Matsuura, 2006, p. 111; Ata et al., 2006]. Several national institutes are now working together in the “Research project on the facilitation of public acceptance of nanotechnology” which published a report in 2006. The report recommends supporting research on the potential risks of nanotechnology and advises the government to establish public forums for dialogue, to prepare a national risk management strategy and to conduct a review of regulations which could be applied to nanotechnologies. In parallel, The Ministry of Economy, Trade and Industry (METI) conducted a survey of industry practices, and asked industry for data on environmental health and safety as an input for the development of national guidelines [Shatkin, 2007, p. 13]. Like other industrial countries, Japan has launched a broad range of initiatives to deal with the challenges of nanotechnology regulation but shies away from any legally prescribed procedure that differs from those already in place for food and cosmetics.

Nanotechnology regulation has become a subject of academic research. Several authors have attempted to conduct a systematic review and assessment of the regulatory situation in different countries [Abbott et al., 2006; Calster, 2006; Hunt and Mehta, 2006; Marchant and Sylvester, 2006; Matsuura, 2006; Bowman and Hodge, 2007; and Linkov and Satterstrom, 2008].

Most of these reviews have echoed the distinction between “hard” (legally prescribed) and “soft” (public incentives) regulatory activities [Bowman and Hodge, 2007]. The preference for soft regulation seems to be the dominant feature of all the regulatory systems that have been studied. To further illustrate these two types of regulation, the most recent contribution of Linkov and Satterstrom combined the two dimensions in what the authors refer to as the incremental regulatory pyramid (see Figure 4, below):

Figure 4: Incremental regulatory pyramid
[Linkov and Satterstrom, 2008, p. 18]



In the case of highly complex technologies such as nanotechnologies, and in the face of extensive knowledge gaps in the area, it seems appropriate to place information gathering and dissemination in first place, making it the foundation of the regulatory pyramid. The second level represents activities such as self-regulation and stakeholder dialogue, both of which can be established by the actors themselves outside a legal framework and without oversight by regulatory agencies. Higher up on the

pyramid, the approach becomes more prescriptive and punitive, with the establishment of hard legislation at the very top.

This report's review of the nanotechnology initiatives and plans of various countries makes it clear that at present there are no hard laws or even self-regulatory instruments in place which are specifically focused on nanotechnologies. The majority of the governmental reviews conducted in single countries such as the US, the UK and Germany conclude that their respective agencies perceive no hard evidence that would require additional legal prescriptions. These perceptions have been criticised by research centres such as the Woodrow Wilson International Center for Scholars and many NGOs, for example by Friends of the Earth. In its 2008 report on nanotechnologies on food, Friends of the Earth suggests classifying nanomaterials as "new substances" and calls for an inclusion of these nanoscaled materials in the "hard" regulatory systems:

"There is an urgent need for regulatory systems capable of managing the many new risks associated with nanofoods and the use of nanotechnology in agriculture. Alongside managing nanotoxicity risks, governments must also respond to nanotechnology's broader social, economic, civil liberties and ethical challenges."

[Friends of the Earth, 2008, p. 37]

One of the projects initiated by the OECD's Working Party on Manufactured Nanomaterials has the objective of establishing whether "existing test guidelines (as for 'traditional chemicals') can be successfully applied to" manufactured nanomaterials. An associated project has been established to select and test a representative set of nanomaterials for their effects on human health and environmental safety. The choice of substances to be tested is "based on materials which are in commerce or close to commercialisation". Another project has involved a comparison of regulatory regimes and the development of a template for identifying components of them that are or are not appropriate for manufactured nanomaterials [IFCS, 2008].

At present it seems unlikely, given the state of research and the position of regulatory agencies around the world, that new laws specific to nanotechnology will be introduced. However, there is ongoing work on different annexes of existing regulations which may lead to specifications for applications using nanomaterials or nanotechnologies.

In the meantime, most stakeholders seem to agree that self-regulatory and reporting activities are appropriate and feasible. These form the base of the Linkov and Satterstrom regulatory pyramid (Figure 4). There have already been several information-based initiatives. Some have been launched by regulatory agencies, some by industrial actors and some by a consortium of different actors, including NGOs. Examples are NanoTrust in Austria and the ongoing survey on industry practices by the Japanese government.

At the second level, self-regulation, several initiatives can be identified such as the DEFRA Voluntary Reporting Scheme [DEFRA, 2008], the US EPA's voluntary Nanoscale Materials Stewardship Program [EPA, 2008] and the VCI guideline programmes for occupational health measures and for material safety data sheets [VCI, 2008]. To complete this short review of the regulatory pyramid, a variety of projects on stakeholder involvement and public participation for information exchange about technologies has taken place in different countries. Examples here are public dialogues in France, in the UK and in the Netherlands, consensus conferences such as the "PubliForums" carried out by the Swiss Centre for Technology Assessment, and a consumer conference on nanotechnologies in food, cosmetics and textiles organised by the German Federal Institute for Risk Assessment (see Section 5).

Overall conclusions for risk governance

- Particularly in the US, Europe and Japan, regulatory agencies have examined the need for regulatory action and have come to the conclusion that existing laws and technical provisions are sufficient to cover nanoscaled materials in general. This confidence in the existing regulation rests on the assumption that testing for substance and product safety is sufficient to cover possible unintended side effects. However, there is less confidence about whether available test methods and protocols are adequate to demonstrate the safe use of nanomaterials in consumer products. A second concern is linked to the capacity of regulatory bodies to monitor and control measurements and risk assessments. The question of how to design and implement an adequate regulatory framework is seen as the main challenge in Europe and the US.
- Current frameworks need flexibility to react to new scientific results emerging from test data. Regulators in the US and in Europe have a mandate to require additional information if new scientific developments or substantiated safety claims demand such a re-appraisal. In terms of risk governance, this issue requires an international multi-stakeholder dialogue on the design of valid, reliable risk assessment conventions and protocols. Once such an agreement is reached, these conventions need to be made common practice for all stakeholders in the field.
- Since nanotechnology is also related to a high degree of ambiguity, it seems prudent to include all major stakeholder groups in its evaluation and the design of risk reduction measures. Since hard facts on risks to human health and the environment are missing, regulatory activities should include measures that build upon precautionary vigilance (strict monitoring and testing) but also on the inclusion of stakeholders in the process of balancing physical evidence with the reasonable concerns and worries of consumers.

The following subsections report on current risk assessment studies that could provide information on the applications of nanoscaled materials in food and cosmetics. These studies focus on exposure via the gastro-intestinal tract for food, or via the skin for cosmetics (see Subsection 7.1). Three sample materials (see Subsections 7.2-7.4) have been chosen for an in-depth analysis based on the following criteria:

- The cases should be central to the current debate on nanotechnology in food and cosmetics. The materials chosen are of high relevance to both fields of application;
- They should be typical of a broad range of applications and products that are already on the market or near to it. The chosen materials are already on the market and show substantial potential for further market growth; and
- Sufficient scientific data from independent sources should be available to characterise the three cases. This is true for this selection of materials.

The selected materials are synthetic amorphous silica (silicon dioxide, SiO₂), titanium dioxide (TiO₂), and encapsulated vitamins.

7.1 General risk assessment studies on nanomaterials

The Wilson Center report “Nanotechnology in Agriculture and Food Production” mentions a wide range of potential applications in the field, for example the efficient and safe release of pesticides, herbicides, and fertilisers in agriculture, and the general improvement of nutrient absorption from food [Kuzma and VerHage, 2006]. However, this report does not mention risk assessment studies of specific materials. The authors considered that, at this early stage in the debate, no public research results were available on the impact of nanomaterials on the gastro-intestinal tract. Other studies, for example the Nanoforum report [Nanoforum.org, 2006], also list many applications such as smart packaging with alert functions, or interactive foods which use nanocapsules containing nutrients, but there are few references to specific risk assessments in these studies.

In 2006 the German Federal Institute of Risk Assessment and the University of Stuttgart conducted an Expert Delphi on Nanotechnologies in food, cosmetics, textiles and surface textures. 100 experts from academia, NGOs, industry and public authorities estimated the economic potential, assessed the toxicity and exposure for selected nanomaterials, and gave their opinion on regulation, risk management and risk communication measures for these consumer-relevant applications [Grobe et al., 2007]. In a general ranking process, in which concrete applications were not specified, experts ranked food as being of greater concern to them than cosmetics. Yet when asked about specific materials

and applications, the cosmetic materials and applications were judged more risky than the food ones. Other applications such as easy-to-clean surfaces or functional textiles were rated as being less problematic, because they involve nanomaterials which are embedded in a matrix.

For cosmetics, the expert panel, consisting of representatives from academia, public authorities and NGOs, considered seven possible uses of nanomaterials. They forecast that four of the product types would have “no toxic potential”. These were hydroxylapatite nanoparticles in toothpaste, zinc oxide and titanium oxides in contact lenses, zinc oxide dispersions for UV protection, and nano-emulsions in the form of avocado or jojoba oil in hair treatment. 33% of the experts rated applications with titanium dioxide (TiO₂) as “having a low toxic potential” caused by the unknown properties of particles below 20 nm in size. Silver particles in soaps were assessed by 29% as “having low toxic potential”, due to their antibacterial properties. Only fullerenes in anti-ageing creams were rated as “having a medium toxic potential”, this time by 41% of the experts. They were associated with the highest potential risk of all the materials assessed in the Delphi process.

By comparison, the different applications in food (encapsulated vitamins and amino acids, multi-walled carbon nanotube membranes for separating proteins, colloidal silica used for flow-regulating agents, titanium dioxide covers for chocolate bars, highly dispersive silicic acid used as a thickening agent, nanoscale micelles as a carrier for antioxidation systems) were in general associated with “no toxic potential”. The only exception was the use of silver in dietary supplements, which were rated as having “low toxic potential” [Grobe et al., 2007, p. 16]. The experts recommended a case-by-case approach and identified 19 criteria for toxicity testing.

In 2007 the FDA Nanotechnology Task Force collected and summarised available knowledge on interactions between nanoscaled material and biological systems [Warheit et al., 2007; Hoshino et al., 2004; and Oberdörster et al., 2005]. Its report states:

“that one should pay particular attention to the composition and surface characteristics of nanoscaled materials that may come in contact with biological systems.”

[FDA, Nanotechnology Task Force, 2007, p. 9]

The authors cite several findings of toxicologically-relevant effects, such as the way in which positively-charged nanoscaled lipid vesicles alter the blood-brain barrier [Lockman et al., 2004]. But they also point to a reduction of toxicity through biocompatible polymers [Derfus et al., 2004]. They emphasise that these findings are material-specific and that there is no knowledge base for extending them to broad classes of materials. They concluded:

“The available information does not suggest that all materials with nanoscale dimensions will be hazardous. Furthermore,

if all nanoscale materials are compared to all non-nanoscale materials, whether larger or smaller, it is not apparent that the nanoscale materials as a group would have more inherent hazard. However, consideration of the basic science of how materials interact with biological systems does indicate that a material's properties can change when size is increased or decreased into, or varied within, the nanoscale range."

[FDA, Nanotechnology Task Force, 2007, p. 11]

Friends of the Earth's 2008 report reached more negative conclusions. FOE analysed toxicity studies from the respiratory exposure pathway [Oberdörster et al., 2005; and Gatti et al., 2004], in-vitro experiments [Ashwood et al., 2007; and Donaldson et al., 1996] and in-vivo experiments demonstrating the possibility of gastro-intestinal uptake of nanoscaled particles [Chen et al., 2006; Wang et al., 2007; and Wang et al., 2007] and concluded that there is sufficient evidence that selected nanomaterials are toxic in commercial use for food [Friends of the Earth, 2008, p. 22 and Table 8 p. 25]. These findings are highly controversial.

In the absence of an adequate methodology for risk assessment studies, and of concrete information about nanomaterials in food, it is difficult to appraise the appropriateness and comparability of existing methods for conducting toxicity tests. But the need for risk assessment studies is uncontested. In a comment to the US Nanoscale Science, Engineering and Technology (NSET) document "Environment, Health and Safety Research Needs for Engineered Nanoscale Material" in January 2007, the Institute of Food Technologists (IFT) emphasised that the widespread possible daily use of nanomaterials, and the exposure that this would mean for consumers, makes research on the possible hazards vital [IFT, 2007]. The IFT pointed to priority areas including the physicochemical properties of nanomaterials, access to federally funded research facilities for characterisation and toxicity testing, the development of a testing framework for FDA approval, screening mechanism to assess safety, research on migration, absorption, and partitioning from packaging, and the need for funding public education programmes to avoid consumer aversion to nanomaterials.

The situation is different for cosmetics since several scientific studies on risk assessments have been completed [Tan et al., 1996; Pfluecker et al., 1999; Lademann et al., 1999; Schulz et al., 2002; Cross et al., 2007; Mavon et al., 2007; and Nohynek et al., 2007] and international research projects such as NanoDerm have been launched. This project investigated the possible penetration of nanomaterials through the stratum corneum and discussed the possibility of critical exposure through the vital dermis [NanoDerm, 2007]. The authors tested concrete properties of defined nanomaterials (titanium dioxide), using a range of methods.

The following section will focus on available risk assessment results for three nanoscaled materials used in the food and cosmetics industries. The main objective of this section is to describe typical

problems of assigning and classifying nanomaterials with respect to selected reference materials used in food and cosmetics today, and to discuss the available risk assessment results. The materials chosen for these case studies were synthetic amorphous silica (silicon dioxide, SiO₂), titanium dioxide (TiO₂) and encapsulated vitamins. They were chosen on the basis of their relevance in the public debate on food and cosmetics and the availability of data from risk assessment studies. Note that the following section is preliminary and cannot predict the EFSA results which were due to be presented at the Safety For Success Dialogue in October 2008.

7.2 Example 1: Synthetic amorphous silica

Synthetic amorphous silica (SAS) is used in large quantities and is one of the most important materials in the present debate on the safety of nanomaterials in food and other sectors. It is also used to create easy-to-clean surfaces, and in composites, coatings, traction technology and in toner applications. Some studies mention synthetic amorphous silica in nanoscaled form as an ingredient in food, cosmetics or food packaging [Friends of the Earth, 2008; BUND (Friends of the Earth Germany), 2008; and IFST, 2006].



BUND, 2008

Synthetic amorphous silica is an approved food additive (E551) but industry argues that it should not be called a "nanomaterial" [BLL, 2008, p. 3]. This refers back to the problem (see Section 2) of ambiguity in the definition and classification of nanomaterials. SAS is used for anti-caking and flow improvement for common salt and food powders, such as spray-dried vegetables, whey, fruits, egg, and coffee creamer, as a thickening or stabilising agent in emulsions (both in foods and cosmetics), to achieve viscosity and transparency in oils for cosmetics, or to improve storage and temperature stability. It is also used to improve free-flowing properties of hair bleaching agents and coating performance in nail polishes, and for distributing pigments in lipsticks and make-up [Evonik, 2008]. The European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) also lists the use of this substance as feed additives and for beer and wine clarification. SAS has been produced since the 1950s in a variety of modifications with different physical and chemical properties; current worldwide production exceeds 1 Mt/y [ECETOC, 2006]. It is therefore at least arguable whether SAS, with its wide history of use, needs to be reassessed from the perspective of nanoscaled particles.

The ECETOC report includes a table [referring to Ferch, 1976] which gives the primary particle sizes for pyrogenic amorphous silica as 5 to 50 nm, for precipitated SAS as 5 to 100 nm, for

gels 1 to 10 nm and for sols 5 to 20 nm. For the pyrogenic and precipitated silicas, ECETOC makes the assertion that “primary particles do not normally exist as individual units”.

In aggregated form, particle sizes cluster above the nanoscale, at between 100 nm and 1 µm, which is 1000 nm. The agglomerate size is given as 1–250 µm. [ECETOC, 2006, p. 12]. In terms of the ISO definition and the description of the production process the material is a nanostructured material consisting of nano-objects.

The German Max Rubner-Institut (Federal Research Institute of Nutrition and Food) has collected scientific studies from the 1950s on the polymerisation and depolymerisation of amorphous silica [Stöber, 1956; Alexander et al., 1954; and Baumann, 1959]. Research has also been conducted on its general functionality [Rutz and Bockhorn, 2005] and on the specific technical processes for spray-dried materials [Ibach and Kind, 2005]. Even today, solubility [Tarutani, 1989; and Özmetin et al., 2004], surface interactions [Barthel, 1995] and particle size [Barthel et al., 1998] remain important issues for risk assessment. The Max Rubner-Institut’s experts reported evidence from a Polish study [Binkowski and Krystafkiewicz, 2002] which showed that the particle sizes of synthetic amorphous silica behave according to a normal distribution of aggregated and agglomerated particles, and that there are only marginal areas with single primary particles in the nanometre scale.

A selection of commercially-available products using SAS from different companies were tested extensively [ECETOC, 2006]. Tests were made of acute and repeated dose toxicity, irritation of the skin, the respiratory tract and of the eyes, sensitisation, genotoxicity, chronic toxicity and carcinogenicity as well as reproductive toxicity. The tests were carried out in animals and in-vitro. Effects on humans and epidemiological studies are also summarised in the report. The authors concluded:

“In humans, SAS (Synthetic Amorphous Silica, ed.) is essentially non-toxic by mouth, skin or eyes, and by inhalation. Epidemiology studies show little evidence of adverse health effects due to SAS. Repeated exposure (without personal protection) may cause mechanical irritation of the eye and drying/cracking of the skin.”

[ECETOC, 2006, p. 2]

The authors also referred to questions of occupational health – potentially relevant to people working in food processing – and the ingestion of silica that may be associated with food intake:

“Analytical data on the kinetics of SAS deposition in the lung of experimental animals during and after prolonged exposure are largely consistent. The initial uptake phase is followed by dissolution in the lung fluid. SASs are rapidly eliminated from the lung tissue, whereas crystalline silicas exhibit a marked tendency to accumulate. Also, after ingestion, there is limited accumulation of SAS in body tissues and rapid elimination

occurs. Intestinal absorption has not been calculated, but appears to be insignificant in animals and humans”. (...)

The authors came to the conclusion that:

“There is no indication of metabolism of SAS in animals or humans based on chemical structure and available data. In contrast to crystalline silica, SAS is soluble in physiological media and the soluble chemical species that are formed are eliminated via the urinary tract without modification.”

[ECETOC, 2006, p. 4]

The results showed no significant effects on human or animal health, or on environmental quality. The study compiled and confirmed former findings, which led to the approval of silicon dioxide as European food additive E551 in 2000 (Commission Directive 2000/63/EC of 5 October 2000 amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners, O.J. L277, 28.10.2000, p. 1). This approval explicitly included pyrogenic and precipitated silica. SAS are therefore excluded from further hazard definition and risk assessment [ECETOC, 2006, p. 5].

In the US, silicon dioxide is FDA-listed as “may be safely used” (21 CFR 172.480). In some fields of application, such as anti-caking and free flow agents in foods such as common salt, it is limited to less than 2.0 % by weight of the food. Other limits are defined for finished food (<1%) and dried egg products (<5%) (US FDA/CFSAN Listing of Food Additive Status 2006, silicon dioxide). It is approved for use as a stabiliser in the production of beer, to be removed by filtration prior to the final process. Generally, silicon dioxide is only permitted in food items for which the anti-caking effect can be demonstrated. If they are used for packaging materials where there is a risk of migration to food from paper and paperboard products, they are listed under 21 CFR § 182.90. A different form of silicon dioxide, so-called silica aerogel (21 CFR § 182.1711) is “generally recognised as safe” (GRAS) [EPA, 2003]. Silicon dioxide may also be used as a component for microcapsules for flavouring substances (complying with 21 CFR § 172.480 as adjuvant). In the US, substances listed as GRAS are not subject to pre-market review and approval requirement by FDA [FDA, 2004].

Besides the GRAS certification, anti-foaming or anti-caking agents have been tested in combination with silicone fluids by the FAO/WHO Expert Committee on Food Additives in 1974 [FAO/WHO, 1974]. The main result was:

“Studies have been carried out on silicone fluids with and without the addition of silica. The presence of silica did not raise any toxicological problems nor did it affect the results of the experiment in a significant way.”

[FAO/WHO, 1974]



Nanostructure of silicon carbide grown from droplets of gallium on a silicon surface

The study explicitly covers dimethylpolysiloxane (anti-foaming agent) that is used today, for example, in McDonalds french fries in the US [McDonalds, 2007]. It concluded that safe use is assured because the material is excreted in an unchanged form:

“The metabolic studies, including those in man, indicate that the orally administered dimethylsiloxanes are mainly excreted unchanged in the faeces.”

[FAO/WHO, 1974]

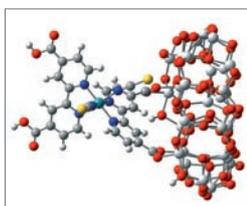
Conclusions for risk governance with respect to synthetic amorphous silica

- The publicly available data on silicon dioxide or synthetic amorphous silica does not permit a final verdict on whether these substances should be regarded as nanomaterials when used in food. Due to their specific particle size distribution, nanoscaled particles may or may not agglomerate in marginal areas. It has been argued that isolated particles could be present but they were not quantified or investigated separately. Representatives of NGOs stress that isolated nanoparticles could cause risks to human health. In terms of risk governance, discussion is needed as to whether the protocols for testing need any changes to accommodate for the special effects of nanostructured materials.
- For the known products that have been investigated, the data collected provides evidence that nanoscaled primary particles occur occasionally but that they tend to aggregate, do not cause harm to humans or animals, and are excreted unchanged. These scientific tests refer to marketed products. But these findings do not exclude the possibility that materials may be developed in future with particle sizes below 100 nm, could be applied in food and could cause some harm to human health. If smaller forms of SAS are going to be marketed in the future they would need to be reassessed as new substances. In line with the precautionary approach for risks with higher degrees of uncertainty, a strict monitoring process and further tests seem to be appropriate.

7.3 Example 2: Titanium dioxide

Industry consumes huge amounts of titanium dioxide. Brian Curvin, a researcher from the US National Institute of Occupational Safety and Health (NIOSH), wrote in his summary of a titanium dioxide exposure study:

“Titanium dioxide (TiO₂), a poorly soluble, low-toxicity (PSLT) white powder, is used extensively in many commercial products, including paint, cosmetics, plastics, paper, and food as an anti-caking or whitening



Nanostructural molecule-TiO₂ interface

agent. Production in the United States was an estimated 1.43 million metric tons per year in 2004 (DOI, 2005).”

[Project on Emerging Nanotechnologies, Inventories, 2008]

This statement was targeted at pigment-grade materials at a micrometre scale. When discussing its use in nanoscaled form, many scientists, journalists and representatives of the cosmetics industry have argued that titanium dioxide has been an approved food additive for many years and is not likely to have a negative impact when also applied in cosmetics. However, this argument may be misleading, since titanium dioxide may be used in a wide variety of particle sizes. The following discussion distinguishes between titanium dioxide in food and in cosmetics.

In food, titanium dioxide is well-known as an approved additive and as an effective white pigment (food colouring E171). The best results for colouring purposes are achieved from particle size distributions between 200 and 350 nm, so that this can hardly be called a nanoscaled material. In this larger form it is applied as a white pigment for surface coatings in confectionery products, as the basis for coloured sugar coatings such as coloured chocolate drops or, for example, in low-fat mayonnaise.

Yet the discussion on nanoscaled titanium dioxide is continuing. In 2006, media articles prominently reported the presence of nanoscaled titanium dioxide in confectionery such as Mars chocolate bars, Twix and M&Ms, in a size between 5 and 20 nm [Chaudhry, 2006]. Indeed, Mars Inc. holds the US Patent on inorganic coatings in a nanoscaled dimension (US5741505). The inorganic nano-coating is directly applied to a food product in order to provide moisture or to establish an oxygen barrier for improved shelf life or flavour impact. But the company denies using this patent for its products at present [Presentation from U. Pollmer at Nano4food, 2008]. One should remember that TiO₂ is not an approved food colourant at a nanoscaled size according to E171. Producers such as Evonik or BASF informed the authors of this report that they do not sell nanoscaled titanium dioxide to food companies.

At present, there is no hard information available about whether nanoscaled TiO₂ is in use in the food industry. The IFST gives some references to TiO₂ in food, but there is no explicit evidence of these materials having a particle distribution in the nanoscale dimension. Like silicon dioxide, which is also mentioned as an aggregated product and not as a separated fraction of nanomaterials, TiO₂ as a food additive has been assessed as safe – independent of size and with even fewer restrictions than silicon dioxide:

“Titanium dioxide is an approved food colour (E171) with a “non specified” Acceptable Daily Intake. ADI is an estimate of the quantity of a particular chemical in food or drinking water, expressed on a body mass basis (usually mg/kg body weight) which, it is believed, can be consumed on a daily basis over a lifetime without appreciable health risk. (...)

“A “non-specified” ADI means there are no toxicological reasons to impose quantitative restrictions on the use of the material.”

[IFST, 2006, p. 6]

In cosmetics, titanium dioxide materials with sizes of 200-350 nm, comparable to those found in food, are used for facial make-up products to produce white colours. Since the purpose is to produce white colour, the materials used for this application must be beyond the nanoscale. Industry associations such as the Personal Care Products Council stated in 2008 that nanoscaled titanium dioxide is used widely in cosmetics, particularly as an effective, transparent UVA-light and UVB-light blocker with a consumer-friendly, smooth texture [The Personal Care Products Council, 2008].

Titanium dioxide in the nanometre range has been tested extensively for applications in cosmetics. Research into the question of whether TiO₂ in its nanoscaled form will penetrate the skin and cause a systemic exposure came to the following conclusion:

“Summing up, we do not expect any health effects for the topical application of sunscreens containing TiO₂ nanoparticles (especially when coated) on healthy skin which are related to the particulate state.”

[NanoDerm, 2007, p. 46]

Other studies came to similar results [Gamer et al., 2006; Mavon et al., 2007; Schulz et al., 2002; Lademann, 1999; and Pflücker et al., 1999]. They were all able to prove that the properties of nanoscaled titanium dioxide mean that penetration through the epidermis or living dermis of human or porcine skin was extremely unlikely, and was only possible where skin injuries were present [Nohynek et al., 2007].

However, in the SCCP opinion on the safety of nanomaterials in cosmetic products (SCCP/1147/07) it is stated that:

“... the SCCP considers it necessary to review the safety of nanosized TiO₂ in the light of recent information and to consider the influence of physiologically abnormal skin and the possible impact of mechanical action on skin penetration.”

[SCCP, 2007, p. 4]

Meanwhile, recent studies carried out in the US [Umbreit et al., 2007], in Europe [Fabian et al., 2008] and in Japan [Sugibayashi et al., 2008] have demonstrated that no adverse effects, no signs of toxicity and no inflammation were observed if nano-sized titanium dioxide were injected subcutaneously, or even directly into the blood stream. These studies were intended to simulate the consequences of systemic exposure to nanomaterials.

In an additional comment on the safety testing of nanoscaled titanium dioxide, the cosmetics industry recently pointed out that:

“In sunscreen lotions, nano titanium dioxide is not present in the form of nanoparticles; it is present in the form of

large clusters that ensure optimal protection of the skin. These clusters form during the manufacturing process and are important in the final SPF (sun protection factor) of the product. The size of the clusters is generally between 300 nm and 10000 nm depending on the manufacturer.”

[Quinn, 2008]

It seems that after lengthy debate on the safety of TiO₂ nanoparticles in sunscreens, no nanoparticles are found in them if they are defined as being below 100 nm in size. But again, it is difficult to determine whether their use in cosmetic products meets the definition of nanostructured materials. Since the international debate on the appropriate definition is not yet resolved, the question remains open.

Nevertheless, the debate on whether there are single nanoparticles or just huge agglomerations of them in sunscreens may miss the point. The crucial issue is safety, not size. It could be helpful to reconsider the SCENIHR recommendation for a systematic characterisation and assessment of nanomaterials in terms of their typical properties such as coalescence, agglomeration, aggregation, degradation and solubility [SCENIHR, 2007]. Safety, health and environmental concerns could then be assessed on the basis of a full set of criteria, including the formulation of the material in question. This would permit a case-by-case approach in which all relevant factors, not just particle size, were considered.

Conclusions for risk governance with respect to titanium dioxide

- At present, no literature from the food industry or from public authorities contains evidence that nanoscaled TiO₂ is used in food products. TiO₂ is an approved food additive, but only in a larger format and not as a nanoscaled material. Producers such as Evonik and BASF do not deliver nanoscaled TiO₂ for food applications. This means that the conventional risk governance cycle based on substance and product safety should be sufficient to regulate its use in food. Additional tests could be necessary if lower temperatures are used in the production processes for the aggregated materials.
- It has been suggested that titanium dioxide as a whitening agent may contain isolated nanoscaled particles as a small part of the overall size distribution, but it is assumed that these nanoscaled particles within larger agglomerates do not cause harm to humans. This would mean that the use of TiO₂ as an agglomerated substance with single nanoscaled particles in the distribution is considered safe by the majority of experts, with an unspecified “Acceptable Daily Intake” (ADI) when the full product is assessed. Again, it may be prudent to monitor its effects more closely and make sure that specifically engineered nanoscaled materials are tested before being used in food or cosmetics.

- For special applications in cosmetics, such as sunscreens, the effects of nanoscaled titanium dioxide particles have been investigated by scientific projects such as NanoDerm. Toxicological studies demonstrate that negative health impacts are not to be expected, because penetration through the vital dermis is extremely unlikely if the particles are greater than 20 nm. According to the cosmetics industry, sunscreen lotions contain titanium dioxide in the form of large clusters bigger than 300 nm. Furthermore, toxicological tests demonstrated no effect even when nanoscaled sized particles were directly injected into the blood stream.

7.4 Example 3: Encapsulated vitamins

Another field of nanotechnology applications in food are “Nano-Delivery-Systems”. These are encapsulation systems for functional ingredients, including food additives, such as vitamins, antioxidants, antimicrobials, flavourings, colourants and preservatives. These functional ingredients are also used in products ranging from agrochemicals, health care products and pharmaceuticals to cosmetics. Nano-Delivery-Systems can provide three services: first, to carry the functional ingredients to a defined target; second, to protect them from chemical or biological degradation including oxidation; and, third, to enable a controlled release [Weiss et al., 2006].

Many health ingredients such as vitamins A, D, E and K, the carotenoids β -carotene, lycopene and lutein, poly-unsaturated fatty acids (PUFAs) and co-enzyme Q₁₀, are insoluble in water. They are therefore formulated as fine emulsions or suspensions and finally encapsulated in microscale powders, using technologies that have been employed for decades. The particle size of the health ingredient is typically 200-400 nm or bigger, despite which these materials have been considered as nanoformulations. Researchers from BASF characterised these encapsulation systems and indicated the requirements for food applications:

“The formulator has a strictly limited choice when developing products for use in food applications. Formulation auxiliaries – chiefly emulsifiers, hydrocolloids – must be wholly acceptable and approved for food use. In addition they have to behave either neutral to the human body or underlie normal metabolism and excretion processes.”

[End et al., 2007, p. 1]

End et al.’s paper demonstrated the influence of particle sizes on the bioavailability of health ingredients. For example, the authors provided evidence for the absence of toxicity for nanoformulated lycopene [Christian et al., 2003; and Mellert et al., 2002]. Comparable formulated lycopene and lutein have been assessed by Shao and Hathcock in 2006, who reviewed 11 clinical trials on

lutein and 16 studies on lycopene. On the basis of this review, they confirmed the absence of any patterns of adverse effects related to consumption in any of the published human trials. This meta-analysis provided support for a high level of confidence in this conclusion, since the “no effect” level was also observed for relatively high dosage, far above the recommended upper level of intake [Shao and Hathcock, 2006].

In another study, synthetic and naturally occurring lycopene (from tomatoes) were compared and tested systematically [McClain and Bausch, 2003]. The authors reported no significant systemic toxicity and no evidence for adverse effects on reproductive parameters.

“Both synthetic lycopene and lycopene in a tomato concentrate accumulate in the liver of rodents upon repeated administration with noticeable birefringent pigment deposits in hepatocytes; however no histopathological changes in the liver have been observed after long-term administration.”

[McClain and Bausch, 2003, p. 284]

The Institute of Food Science and Technology commented on the GRAS approval for synthetic lycopene as follows:

“A synthetic lycopene produced by BASF has undergone toxicity tests and has been GRAS-affirmed (“generally recognised as safe”) under US FDA procedures. The GRAS status would imply that the absorption of synthetic lycopene nanoparticle is considered to be marketed on the basis of a notification by the applicant company without the substance being specifically subject to pre-market review and formal approval by FDA. It is the responsibility of the applicant company to ensure that the food ingredients that it markets are safe and comply with all applicable legal and regulatory requirements.”

[IFST, 2006, p. 6]

The IFST authors emphasised that the use of lycopene as a food colour will require pre-market review and approval by the FDA. Food colours are subject to specific approval procedures.

Recently, the Joint Expert Committee on Food Additives of the WHO and FAO (JECFA) has evaluated lycopene on the basis of safety studies with encapsulated products, and established an acceptable daily intake (ADI) level for its use in foodstuffs.

NGOs are concerned about possible adverse effects from excessive vitamin consumption, e.g. for Vitamin A, B6 and folic acid [Friends of the Earth, 2008, citing Downs, 2003; and US IOM, 1998]. These safety concerns could be valid if the bioavailability of a nutrient is strongly enhanced by a new technology. In this case, a previous risk assessment may no longer be valid. This is especially important for nutrients such as vitamin A, calcium, fluoride or folic acid, where there may be a risk of excessive intake above safe levels. This concern is underlined by other scientific studies [for an overview of negative toxic effects see Rosenbloom, 2007; and

Russell, 2000] and was shared by the majority of experts in the German Delphi Survey on nanotechnologies in food, cosmetics and everyday items [Grobe et al., 2007]. Experts addressed the issue of possible unintended over-dosage for food and cosmetics (Vitamin E, A, Q10) and the necessity for more information and a change in consumer behaviour.

Conclusions for risk governance with respect to encapsulated vitamins

- Encapsulated micronutrients are the most prominent examples of what is considered as nanotechnology in food, and are hugely important in anti-ageing cosmetics. Studies have shown that their oral intake led to the desired effects associated with their nanoscaled properties. Furthermore, the available safety studies on lycopene could not detect any negative health effects in clinical trials, even for high-dose exposures.
- Safety concerns could arise if the bioavailability of a nutrient is strongly enhanced by a new technology. In this case a former risk assessment may not remain relevant. A re-evaluation of the former risk assessment, and additional studies, may be needed to prove the safety of a daily intake of highly bioavailable micro- or nano-nutrients which has not been previously assessed. In this case a precautionary rather than a risk-based approach may be needed. This approach may benefit from parts of the concern assessment, including the investigation of consumption patterns with respect to overdose and inadequate use. If there are indications of inadequate use, risk reduction measures need to be considered. These could include consumer information and labelling, or restricting the use of encapsulated nutrients in food items that tend to stimulate overdose or other forms of inappropriate use.

Overall conclusions for risk governance

In this section on risk assessment, it has been suggested that not all nanomaterials will be dangerous because of their size, even if they have different properties from microscale products of the same composition. The observed effects depend on the specific material, its surface, and the composition or formulation of the material in the final product.

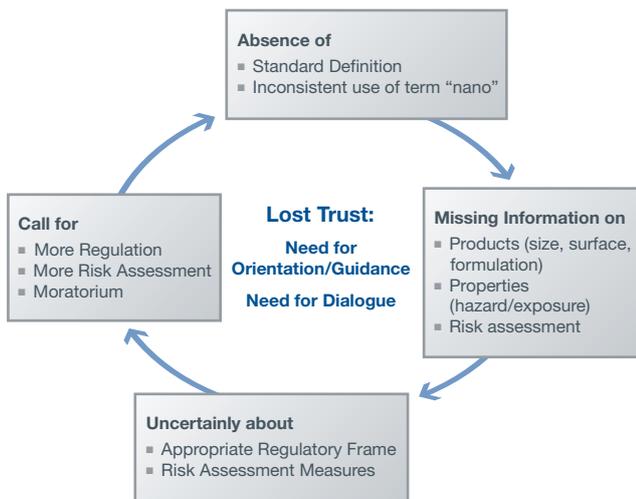
- However, the absence of generalised observations that would apply to all nanosized materials necessitates a case-by-case approach. It is therefore impossible to answer the general question: Are nanomaterials in food or cosmetics dangerous or not? The answer is that it depends. In order to test nano-sized material in a case-by-case approach, a reliable and standardised characterisation, notification and reporting scheme is urgently required. At the very least, consistent communication is needed about whether products contain

nanomaterials or not. Working on these issues should be one of the first steps in any future stakeholder dialogue on nanotechnology.

- Due to the wide scope of possible daily intake or exposure, nanomaterials in food and cosmetics have to be assessed separately from the assessment of the substance as such. Several organisations, particularly NGOs, have asked for the establishment of a new testing framework for FDA approval with a nanotechnology-specific guideline for toxicity testing. This could guarantee a systematic screening and fully-fledged risk assessment of nanomaterials. The NGOs stressed the need for research into migration, absorption and adsorption. Such research cannot be done without actual nanomaterials on which to work and without close cooperation between industry, public authorities and science.
- There is a need for continuous dialogue on the appropriateness of existing regulations as new basic research and risk assessments emerge concerning hazard, exposure and impacts on environment, health and safety. There are regulatory institutions at the national level (US and EU Member States) and supranational level (EU, OECD, ISO Working Groups) that could offer platforms for such a continuous dialogue. However, most of these institutions are struggling with issues of mandate, stakeholder representation, shortage of resources and lack of capacity. A major challenge for risk governance in this field will be to streamline and structure these different and often uncoordinated dialogue activities. The aim should be to create a more adequate, operational and easy-to-implement framework that could help to standardise risk assessment approaches, and which could respond quickly if new scientific results warrant new risk management or regulatory activities. It will not be easy to navigate between the need for the international harmonisation of standards and risk management practices on the one hand, and the need to allow for cultural diversity and different market approaches within the global economy on the other.
- Efforts coordinated by the OECD's Working Party on Manufactured Nanomaterials are a positive step towards resolving a number of the issues raised by the current lack of risk assessment data. These initiatives include projects to develop test guidelines, cooperate on risk assessment schemes, and test a representative set of nanomaterials. Considerable benefits will come from maximising the number of participating countries, maximising the number of materials tested, and making the results of the risk assessments public.

Although this is undoubtedly an idealistic approach, the alternatives run the risk that the main actors become stuck in a vicious cycle, as it is outlined on the next page.

Figure 5: Vicious cycle of the nanotechnology debate



In the absence of an agreed set of international standards, or internationally-coordinated and integrated processes of characterisation, assessment, and regulation, several stakeholders have taken action on their own and have developed proactive voluntary codes of conduct. The goal is to avoid being trapped in a vicious cycle (as illustrated in Figure 5) and to build up trust or, in other words, to earn the “licence to operate”.

The following section will introduce and compare different concepts of voluntary codes.

The following codes and frameworks provide guidelines for risk assessment, management and communication. Their main objectives are:

- to frame the issue in terms of the responsible use and production of nanomaterials in a broad sense;
- to complement rather than replace regulation and industrial directives and guidelines;
- to enhance transparency and demonstrate care for consumer and environmental safety;
- to engage in communication programmes and stakeholder dialogue; and
- to address larger political, social and ethical aspects.

Voluntary codes provide orientation and guidance for entire industry sectors or for single companies. In other industries, codes have been used to set global standards which have largely satisfied the demands of NGOs, removed the need for regulation and provided consumers with a means of recognising products which derive from approved sources and processes. An example is the Forest Stewardship Council's Principles of Forest Stewardship and the standards which derive from them [FSC]. Although many NGOs favour the establishment of such voluntary codes or certification systems, they are more sceptical when they gain the impression that such codes are meant to calm concerns or demonstrate responsiveness without substantive self-regulation in place. In this case, voluntary codes are dismissed as simple window-dressing.

However, compliance with voluntary codes is a useful, and perhaps the most promising, means of overcoming real and perceived deficits in risk governance. Voluntary codes do not replace the necessary regulation processes, but they can make a contribution to clarifying and boosting awareness of issues such as safety assurance, risk control and a targeted approach to risk communication [IRGC, 2006].

For nanomaterials, several codes or frameworks are presently being discussed:

1. Global Core Principles of Responsible Care® – an example of an international Industry Association Code
2. The European Commission's Code of Conduct for Responsible Nanosciences and Nanotechnologies Research – an example of a Regulatory Code
3. The Responsible Nano Code – an international stakeholder initiative
4. The Nano Risk Framework – an example of a company-NGO initiative

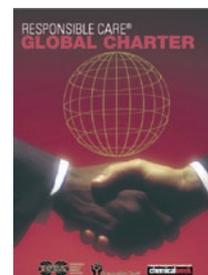
These codes have a number of similarities and points of overlap, although they also contain different emphases and levels of specificity, scope and degree of obligation. This is understandable, given that

they derive from and are intended to complement different regulatory environments and political and social cultures, and have different target audiences. But each is intended to provide a structure for the framing of nanotechnology risks, for risk assessment throughout the life-cycle, and for management and communication strategies. They are all, therefore, intended to offer benchmarks for the responsible research, production and use of nanomaterials.

8.1 Global Core Principles of Responsible Care®

The International Council of Chemical Associations (ICCA) serves as a link between the industry and international health, safety, environment or trade organisations, including the United Nations Environment Programme (UNEP), the World Trade Organization (WTO) and the OECD [ICCA, 2008]. Responsible Care is an overall approach by the chemical industry to demonstrating corporate responsibility. It was originally developed by the ICCA to continuously improve the environmental, health and safety performances of the chemical industry. The Responsible Care Global Charter has been adopted by companies in 53 countries. Its voluntary character, and its commitment to reach beyond regulatory requirements, is highly relevant to nanomaterials and their use, as has been pointed out in a VCI paper on "Responsible Production and Use of Nanomaterials":

"Responsible Care is the global chemical industry's health, safety and environmental initiative to drive continuous improvement in performance. It achieves this objective by meeting and going beyond legislative and regulatory compliance, and by adopting cooperative and voluntary initiatives with government and other stakeholders. Responsible Care is both an ethic and a commitment that seeks to build confidence and trust in an industry that is essential to improving living standards and the quality of life."



Responsible Care – Global Charter

[VCI, 2008, p. 4]

Responsible Care encourages the development of specific codes, including one on nanomaterials. The Responsible Care Global Charter has nine core elements of which the first is a set of six core principles:

1. *Continuously improve the environmental, health and safety knowledge and performance of our technologies, processes and products over their life cycles so as to avoid harm to people and the environment*
2. *Use resources efficiently and minimise waste*
3. *Report openly on performance, achievements and shortcomings*

4. Listen, engage and work with people to understand and address their concerns and expectations
5. Cooperate with governments and organisations in the development and implementation of effective regulations and standards, and to meet or go beyond them
6. Provide help and advice to foster the responsible management of chemicals by all those who manage and use them along the product chain

[ICCA, Status Report, 2007, p. 2 & 4]

The Responsible Care Global Charter is probably one of the most widely adopted, global industrial codes. It has been developed and modified since the mid-1980s. Since 2007 it has been accompanied by the Product Stewardship Guidelines, which together form a comprehensive management system that includes existing codes and best practice guidelines for occupational health, environmental protection and product safety. Nanoscaled materials are not mentioned in specific terms but according to the initiators of the Responsible Care Charter the principles cover them adequately [VCI, 2008].

Companies claim that these guidelines help to advance sustainable development, to improve environment, health and safety performance and to enhance reporting, including verification processes carried out either by associations, government agencies or other external organisations. All industrial members of Responsible Care are obliged to develop and apply systematic procedures for verifying the implementation of all measurable indicators every two years. Companies are also requested to initiate risk-based and cost-effective management measures to prevent negative human health and environmental impacts, in accordance with the precautionary approach. Furthermore, they make a commitment to share best practice through mutual assistance with upstream suppliers and downstream users. This obligation includes education, research and information on testing approaches. The Charter emphasises transparency of information and joint data collection. It also advises participants to communicate with interested parties inside and outside the Charter's membership and to share best practices through information networks [Responsible Care, 2006; ICCA, Product Stewardship Guidelines, 2007].

The Charter imposes a specific degree of obligation on its signatories. It requires a formal commitment by each company to a set of guiding principles, signed, in most cases, by the Chief Executive Officer. The ICCA provides guidance notes, indicators for evaluation, communication strategy recommendations and checklists to help companies meet their commitments. It also defines procedures for verifying that member companies have implemented the measurable and practically observable elements of Responsible Care [Responsible Care, 2008]. An overview of the implementation in each country is provided in a periodic status report.

8.2 European Commission: Code of Conduct for Responsible Nanoscience and Nanotechnologies Research

In July 2007 the European Commission launched a consultation on the "Code of Conduct for Responsible Nanoscience and Nanotechnologies Research" [EC, Responsible Nanoscience, 2007]. Adopted on 7 February 2008, the Commission's Recommendation includes the seven principles of the Code of Conduct. The aim is to promote integrated, safe and responsible nanoscience and nanotechnologies (N&N) for the benefit of European society as a whole [EC, Recommendation, 2008, p. 3]. Target groups are the Member States, employers, research funders, researchers (including private laboratories) and, more generally, all individuals and civil society organisations involved in N&N research.

The following principles are in accordance with the EU Nanotechnologies Action Plan [EC, Action Plan, 2005]:

- **Meaning**

N&N research activities should be comprehensible to the public. They should respect fundamental rights and be conducted in the interest of the well-being of individuals and society in their design, implementation, dissemination and use.

- **Sustainability**

N&N research activities should be safe, ethical and contribute to sustainable development serving the sustainability objectives of the Community as well as contributing to the United Nations' Millennium Development Goals. They should not harm or create a biological, physical or moral threat to people, animals, plants or the environment, at present or in the future.

- **Precaution**

N&N research activities should be conducted in accordance with the precautionary principle, anticipating potential environmental, health and safety impacts of N&N outcomes and taking due precautions, proportional to the level of protection, while encouraging progress for the benefit of society and the environment.

- **Inclusiveness**

Governance of N&N research activities should be guided by the principles of openness to all stakeholders, transparency and respect for the legitimate right of access to information. It should allow participation in the decision-making processes of all stakeholders involved in or concerned by N&N research activities.

- **Excellence**

N&N research activities should meet the best scientific standards, including standards underpinning the integrity of research and standards relating to Good Laboratory Practices.

■ **Innovation**

Governance of N&N research activities should encourage maximum creativity, flexibility and planning ability for innovation and growth.

■ **Accountability**

Researchers and research organisations should remain accountable for the social, environmental and human health impacts that their N&N research may impose on present and future generations.

[EC, Recommendation, 2008, p. 3]

The degree of obligation of the various parties involved is not directly stated. However, it can be expected that research proposals for funding (under the Framework Programme for Research) should be in line with the Code of Conduct. Independent experts are used to evaluate these research proposals, which can contain sensitive ethical issues regarding compliance with EU-level requirements. These experts can use the Code as a basis for their advice on revising such proposals. The Code of Conduct also requires applicants for EU funding to submit a risk assessment for their research project. In addition, it is recommended that the Code be adopted by EU Member States for their national funding programmes. For both Member States and the EU as a whole, the Code is complementary to existing regulations. Since February 2008, compliance with the Code of Conduct is recommended but not mandated.

Compared to the Responsible Care Global Charter, the European Commission Code refers specifically to nanotechnologies. It also stresses some new issues such as respect for fundamental public rights, and the accountability of researchers and research organisations for the social, environmental and human health impacts of their work. The EC's Code also refers specifically to the precautionary principle. In accordance with the core principles of the Code, several recommendations are currently being discussed in the course of the adoption process by Member States. For instance, it has been recommended that Member States follow the Code by integrating its provisions into their national research strategies and by developing sectoral or institutional standards. In addition, Member States should apply the Code for institutional quality assurance mechanisms and funding criteria, and should encourage the voluntary adoption of the Code by relevant research funding bodies and civil society organisations. In terms of communications, the Commission stated:

“That this Recommendation also be used as an instrument to encourage dialogue at all governance levels among policy makers, researchers, industry, ethics committees, civil society organisations and society at large with a view to increasing understanding and involvement by the general public in the development of new technologies.”

[EC, Recommendation, 2008, p. 4]

The dialogue approach is also emphasised in the “Guidelines on action to be taken” in Section 4.1-4.3.3. It says that EU Member States should stimulate a societal debate about concerns and hopes and facilitate the emergence of possible initiatives and solutions. Additionally, they should enhance the accessibility and dissemination of information, intelligible to ordinary citizens as well as to the scientific community. The application of these guidelines aims to improve the exchange of knowledge and data on benefits, risks and uncertainties as well as on relevant standards, references, labels, and the research on impacts, regulations and laws.

The Code obliges Member States to encourage private and public sector laboratories to share their best practices in N&N research, with due respect for the protection of intellectual property, and to foster excellence and integrity of published scientific results. The Code also calls for an ethical review of research projects, the enforcement of transparency, compliance with relevant research project regulations, and the development of methods and tools for risk assessment. In addition, the Code endeavours to protect society, the environment, workers and consumers, with an aim to reducing, refining or replacing animal experimentation [EC, Recommendation, 2008, p. 8]. It also imposes restrictions on funding certain research activities, such as if fundamental rights or ethical principles are violated, if research is aimed at non-therapeutic enhancement of human beings, or of research involving deliberate intrusion of nano-objects into the human body if the results of long-term risk assessment studies are not available. Because of the uncertainty of current knowledge of N&N, Member States are expected to apply the precautionary principle with respect to occupational health, environmental safety and consumer protection [EC, Recommendation, 2008].

Member States should also agree to monitor the implementation of the Code in their countries under a set of criteria (to be developed) and to review the appropriateness of the Code every two years.

The recommendations and guidelines accompanying the core principles of the Commission's Code imply serious changes in the criteria for allocating research funds by Member States. In addition, it gives concrete recommendations for establishing research priorities and for guiding public investment decisions with respect to risk assessment, information activities and public dialogue.

8.3 The Responsible Nano Code

The Project on the “Responsible Nano Code” was initiated in the UK in November 2006. The Royal Society, Insight Investment, and the Nanotechnology Industries Association (NIA) conducted a multi-stakeholder workshop with international organisations to explore the technical, social and commercial uncertainties relating to nanotechnologies. One of the workshop's results was a recommendation to develop voluntary principles for good practice. The aim was to provide guidance on responsible governance:

“It was felt that such a Code should be principles based rather than standards based and would be developed through a process of engagement between a representative group of businesses from various stages of different supply chains and a wide range of stakeholders, including NGOs, government and consumer groups.”

[Responsible Nanocode, 2008]

At the time of writing (in autumn 2008) the seven principles of the Responsible Nano Code had been agreed upon by the multi-stakeholder working group (following an international consultation), and made public, together with a set of examples of good practice. These are in the process of being developed into a Benchmarking Framework by which companies will be independently evaluated on their adherence to good practice and the Principles of the Code. The Benchmarking Framework and its accompanying process were due to be announced in October 2008.

The target groups for this Code are:

- Companies of all sizes which manufacture products using nanotechnologies, regardless of whether their focus is on business-to-business customers or final consumers;
- Retailers of products using nanotechnologies;
- Companies and commercial partnerships researching or manufacturing nanomaterials; and
- Those involved in the disposal or recycling of products using nanotechnologies.

Due to the broad range of these target groups compared to the Responsible Care Code (which is only for the Chemical Industry) or the EC’s Code of Conduct (which is directed towards research communities), the Responsible Nano Code is more general in nature and has only a few prescriptive recommendations. The Code outlines the principles of best practice and responsible behaviour but does not specify any performance standards or indicators of compliance that could be audited. It also shies away from the controversial issues of definitions, characterisation and risk assessment protocols.

“The Code should provide strategic guidance on the governance of nanotechnology, rather than detailed recommendations on required corporate behaviours and performance. The Code is designed to provide clarity on the strategic issues that organisations need to address and offers potential indicators of good practice to guide their responsible behaviour in the most important areas.”

[Responsible Nano Code, 2007, p. 4]

The Code refers to the following seven principles:

Principle One – Board Accountability

Each organisation shall ensure that accountability for guiding and managing its involvement with nanotechnologies resides

with the Board or is delegated to an appropriate senior executive or committee.

Principle Two – Stakeholder Involvement

Each organisation shall identify its nanotechnology stakeholders, proactively engage with them and be responsive to their views.

Principle Three – Worker Health & Safety

Each organisation shall ensure high standards of occupational health and safety for its workers handling nano-materials and nano-enabled products. It shall also consider occupational health and safety issues for workers at other stages of the product lifecycle.

Principle Four – Public Health, Safety & Environmental Risks

Each organisation shall carry out thorough risk assessments and minimise any potential public health, safety or environmental risks relating to its products using nanotechnologies. It shall also consider the public health, safety and environmental risks throughout the product lifecycle.

Principle Five – Wider Social, Environmental, Health and Ethical Implications and Impacts

Each organisation shall consider and contribute to addressing the wider social, environmental, health and ethical implications and impacts of their involvement with nanotechnologies.

Principle Six – Engaging with Business Partners

Each organisation shall engage proactively, openly and cooperatively with business partners to encourage and stimulate their adoption of the Code.

Principle Seven – Transparency and Disclosure

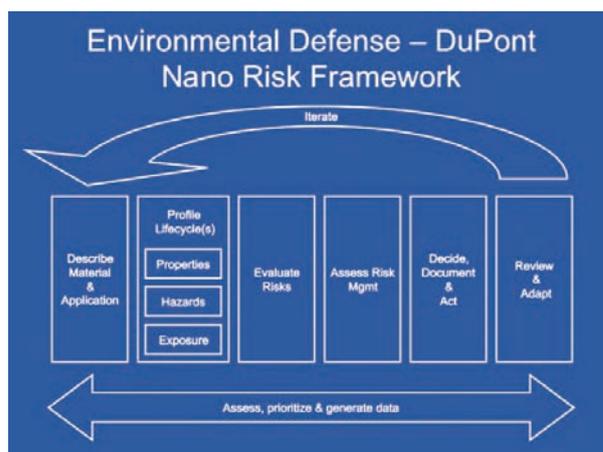
Each organisation shall be open and transparent about its involvement with and management of nanotechnologies and report regularly and clearly on how it implements the Responsible Nano Code.

The Responsible Nano Code has a strong focus on stakeholder relations and the exchange of information. A new and interesting aspect is its demand for responsible practice in marketing products containing nanotechnologies. In particular, the Code advises companies to use the word “nano” for marketing or advertising only if nanoscaled particles are part of the products, or nanotechnologies were used in the manufacturing process.

8.4 The Nano Risk Framework

The Nano Risk Framework is the result of a two-year stakeholder dialogue project on nanotechnologies between DuPont and the Environmental Defense Fund (EDF), a US-based NGO [Environmental Defense Fund and DuPont, 2007].

Figure 6: The Nano Risk Framework [Environmental Defense Fund and DuPont, 2007, p. 1]



The Framework assembles a process for describing materials and applications, for exploring properties, hazards and exposure, and for evaluating risks. Furthermore, it gives orientation to both risk assessment and management, and provides guidance on how to implement and document decisions and to review the entire risk governance process. Most of the components of the Framework are in line with the risk assessment paradigm from the EPA's New Chemicals Program [EPA New Chemicals Program, 2008] and they are similar to classic Health, Safety and Environment programmes and product stewardship concepts. However, DuPont and the Environmental Defense Fund have expanded the information profiles to include nanotechnology-specific recommendations for risk characterisation, toxicity, and ecotoxicity testing and life-cycle assessment.

The six steps of the Nano Risk Framework provide more concrete advice to those who subscribe to them than the other codes mentioned in this document. They are also compatible with the technical guidelines of NIOSH, the German Chemical Associations Guidelines and the Swiss Accident Insurance Fund (SUVA) Guidelines on Occupational Health. The Framework includes data sets for physical and chemical properties, hazard characterisation and human and ecological risk assessments. They require information on safety data such as flammability, explosiveness, incompatibility, reactivity, corrosiveness, stability, decomposition, polymerisation and photoactivity. They also define a Life-Cycle Exposure Profile with a checklist of required exposure data.

The Nano Risk Framework is probably the most detailed and, at the same time, practical code available. General principles that are included in the previously described codes of conduct are integrated into it. In addition, the Framework offers recommendations that come close to technical guidance documents:

- It addresses general principles of good risk communication such as stakeholder engagement, transparency and accountability;

- It includes concrete technical guidance and process requirements that resemble best practice and provide assurances that the best methods and techniques for risk assessment and management are being applied;
- It covers almost the full risk governance cycle including the evaluation stage. Less developed are the stages of framing and concern assessment, which constitute an integral part of the IRGC risk governance framework;
- Like other voluntary codes, it has the major advantages of low transaction costs and a low administrative burden;
- It finds a compromise between evidence-based risk management and the application of the precautionary principle for cases of high uncertainty or ambiguity; and
- It includes concrete checklists with added tools for evaluation such as output worksheets.

The Nano Risk Framework provides ample opportunities for reporting, improving current practice, and risk communication. This makes the Framework very attractive but is also a cause for some criticism within industry. Some companies think that the Framework demands excessive resources and therefore they stated that the Framework would be more suitable for big global players.

If applied in the food and cosmetics sector, the Framework's requirement for data for characterisation and risk assessment could be a serious burden, particularly for smaller companies facing obvious gaps in knowledge [Environmental Defense Fund and DuPont, 2007, p. 24, 25, 33, 38, 43, 47, 50, 53, 58 and 59]. However, the Environmental Defense Fund described the base set of information as "a bare minimum for the conduct of a thorough risk assessment", if fully completed. The Fund also stressed that the Framework incorporates flexibility and makes allowances for precautionary risk management and transparency measures in the face of incomplete testing, especially at early stages of product development. This helps its suitability for smaller companies.

8.5 Summary: Overview of Codes and Framework

This overview of the different codes and of the Nano Risk Framework shows that there are a number of core criteria which are shared by all approaches (see Table 2).

Table 2: Overview of Codes of Conduct and Framework

Criteria to regard	Responsible Care®	EU Code of Conduct Research	Responsible Nano Code	Nano Risk Framework
Signed Commitment (on CEO-level)	directly mentioned	directly mentioned (national)	directly mentioned	directly mentioned
Support Regulatory Frame	directly mentioned	directly mentioned	directly mentioned	directly mentioned
Life-Cycle Approach	directly mentioned	directly mentioned	directly mentioned	directly mentioned
Fundamental Rights (ethical standards)		directly mentioned		
Sustainability	directly mentioned	directly mentioned	indirectly mentioned	directly mentioned
Precautionary Principle	directly mentioned	directly mentioned		directly mentioned
Occupational Health	directly mentioned	directly mentioned	directly mentioned	directly mentioned
Reflection of Social and Ethical Concerns	directly mentioned	directly mentioned	directly mentioned	
Transparency/ Access to Information	directly mentioned	directly mentioned	directly mentioned (indicators)	directly mentioned
Stakeholder Engagement	directly mentioned	directly mentioned	directly mentioned	directly mentioned
Continuous Improvement/ Best Science Standards	directly mentioned	directly mentioned	indirectly mentioned	directly mentioned
Innovation and Growth	directly mentioned	directly mentioned	directly mentioned	directly mentioned
Accountability	directly mentioned	directly mentioned		directly mentioned
Cooperation with Governments on Regulation and Standardisation	directly mentioned	directly mentioned	directly mentioned	directly mentioned
Responsible Sales/ Marketing	indirectly mentioned		directly mentioned	
Support to adopt the Code along the Value Chain	directly mentioned	indirectly mentioned	directly mentioned	directly mentioned
Guidelines for Characterisation, Risk Assessment, Risk Management, Risk Evaluation, Documentation and Communication	directly mentioned (in the Product Stewardship Guidelines)			directly mentioned
Concern Assessment	indirectly mentioned	directly mentioned	indirectly mentioned	indirectly mentioned
Framing of the Issue	indirectly mentioned	directly mentioned	indirectly mentioned	indirectly mentioned

The different voluntary codes reflect diverse regulatory and cultural backgrounds. To be effective throughout an entire industry, these codes need to allow for the restricted resources of Small and Medium Sized Enterprises (SMEs) as well as be suitable for the multinational companies which tend to be more active in their development. For nanotechnology applications in food, there is also the need to acknowledge the special history of stakeholder relations that has developed as a result of the GMO debate. At this point there is no mutual commitment to any one of these codes and it is questionable whether it is possible to have a “one-size-fits-all” solution. However, there is growing interest among international companies, international public authorities and regulatory agencies in promoting and adopting one or more of these codes as a means of avoiding costly regulation, assuring best practice and ensuring consumer confidence.

Voluntary codes offer an alternative to regulation. As we explained earlier, regulation is extremely difficult to design because of the problems of defining novel nanoscaled materials. Although new regulations specific to nanotechnology, whether in food and cosmetics or in other sectors such as medicine, appear unlikely at the present time, industry would be well advised to establish an enforceable, transparent and inclusive process of self-regulation through a voluntary code. However, this step may not satisfy concerned NGOs: “Voluntary initiatives are wholly inadequate to oversee nanotechnology... the public overwhelmingly prefers mandatory governmental oversight to voluntary initiatives” [IUF, 2007].

Overall conclusions for risk governance

- In an ideal world, there should be only one such code. The existence of a multitude of codes is confusing to the consumer and may lead to unfair competition if different codes have different degrees of commitment and rules. Moreover, having a number of codes may not satisfy NGOs as the respective industrial player might have the choice to opt for the code with the most lenient provisions. At the same time, however, the objective situation varies for large and small companies, regulatory requirements vary from one country to another, and responsiveness to public concerns is contingent on political culture and the communication climate. If a comprehensive and universally valid code were to be developed it should reflect regional differences and regulatory styles.
- SMEs would probably need support to conduct the necessary measurements and tests. However, each code refers to the overall requirement of promoting the responsible and sustainable use of nanotechnologies. A step-by-step approach that begins with a variety of parallel codes might be more viable than attempting to impose a single code. They could each focus on different sectors, branches, company sizes or domains. This might be more effective and simpler than seeking a minimum one-size-fits-all solution.
- Once these codes have been established it would be of value, in a second step, to make sure that the requirements and standards of each is harmonised so that performance can be based on a single set of benchmarks. This also has legal implications since courts tend to relate claims of negligence or compensations to the common performance criteria of existing codes. In the long run, it is in the interest of all players to reduce the variability of codes or at least the heterogeneity of performance standards in order to avoid being arbitrarily held responsible by courts or other actors. Even if there is no other choice than to live with a variety of codes of conduct, this might still be better than living with no codes at all. At least such codes raise the awareness of potential risks and encourage questions about the impacts of nanotechnology and its various uses.
- It would be wise for the food and cosmetics industry to become proactive players and trusted partners in this global debate.
- Voluntary codes have the potential to assist companies which wish to demonstrate their openness and responsibility for product safety in a situation where regulation allows a broad scope of industrial applications. Several NGOs have started active campaigns, and consumer attitudes have become more critical towards the use of nanomaterials in food and cosmetics. These codes may facilitate the process of building trust and credibility and lead to meaningful and constructive dialogues among the key players in the debate. Within the risk governance framework, the decision to establish a voluntary code lies within the realm of risk management and is one of the few immediately available options to reduce risks and respond to public concerns.
- If these codes have no provisions to enforce action or compliance, or in other words have “no teeth”, and merely reflect public relation concerns, they will fail and may even be more devastating to public opinion than doing nothing. Adopting best practices and a transparent process of risk assessment and management, over the entire life-cycle, are the conditions under which dialogue with moderate critics and consumer organisations can lead to the best and most widely acceptable results. Awareness of these conditions is particularly important for the food and, perhaps to a lesser degree, the cosmetics industry. Both need to overcome the increasingly sceptical view of many NGOs and attentive consumers. Both industries should make a concerted effort to reflect on critical comments and use them constructively, as an incentive to assure the responsible production and use of nanomaterials.

Notwithstanding the potential economic value (described in Section 1 of this report) and the prospective direct and indirect consumer benefits, the introduction of nanotechnologies in food and cosmetics is accompanied by concerns about human health and environmental safety. For the pathways of ingestion and dermal application, studies so far do not allow conclusive judgements about the potential health and environmental risks.

The potential impacts of nanomaterials on people and the environment are complex, uncertain and ambiguous. Public authorities, industry, academia and NGOs all recommend occupational protection measures to avoid undue exposure, and suggest closed systems for work environments in which nanoscaled material is processed [NIOSH, 2007; VCI, 2007]. In this context different voluntary codes of conduct (Responsible Care, the European Commission Code of Conduct for Research, the Responsible Nano Code and the Nano Risk Framework) have been introduced as a means to facilitate best practice in risk assessment, management, evaluation and communication, to initiate a constructive dialogue with stakeholders, and to combine evidence-based risk assessment with a precautionary approach for cases in which high uncertainty and ambiguity prevail. Many of these codes are directed towards self-regulation in occupational settings and towards limiting exposure to the inhalation of nanoscaled particles.

The picture is different for the gastro-intestinal and dermal pathways. The debate relating to these applications has to reflect the fact that, in food and cosmetics, the whole idea is to expose the user to the nanomaterials. Packaging is the obvious exception here. In these areas:

- There is very limited public scientific knowledge available on the nanomaterials which are in use, and even less on the results of risk assessment studies including those of different exposure routes. This is explicitly the case for gastro-intestinal studies with nanomaterials; and
- The lag and lack of information has led to a loss of trust between public authorities, industry and NGOs. Even if public perception of nanotechnologies is still positive in general, new survey data and the findings of citizen conferences show that society is highly concerned about safety and health when nanomaterials are used in food and, to a lesser extent, in cosmetics.

Definition and classification

Currently there is no mutually accepted definition of what is meant by “nanotechnologies” or “nanomaterials” in food or cosmetics. The definitions that are used refer either to the size (<100 nm) of human made materials or to their novel size-related properties. Defining and characterising nanoscaled materials in food and cosmetics pose specific problems for industry as well as for the regulatory bodies. In this regard, reaction to and (particularly by industry) acceptance of the ISO’s proposed technical specification (ISO TS

27687) is crucial. Its inclusion of aggregates and agglomerates of nanoscaled objects has the effect of defining as nanomaterials many materials that would not be defined as such on the basis of only a limited size range of between 1 and 100 nm.

Second, there is ambiguity about the inclusion of naturally-occurring nanomaterials. Many novel engineered nanosystems for food and cosmetics are based on naturally-occurring nanomaterials (lipids, sugar and proteins) or imitate naturally-occurring nanosystems. This ambiguity must also be removed. Thirdly, and due to these definitional problems, there is no agreement on issues such as labelling, protocols for testing, or risk management strategies. For example, the labelling or reporting of nanotechnology or nanomaterials is currently voluntary and there is no common approach by industries or countries.

Available data and risk assessment

Two approaches to risk assessment are being discussed. One is to focus on the safety of nanoscaled particles and their special properties, and the other is to concentrate on the safety of the whole product to which consumers are exposed. The lack of a clear definition impedes the availability of reliable data for both approaches. Information is missing about what material is used and at what size. Difficulties in characterising risks are exacerbated by a lag in the availability of scientific knowledge on the gastro-intestinal-uptake of nanomaterials in general.

In addition, some frequently-mentioned “nanomaterials” consist of nanoscaled primary particles which aggregate and agglomerate as a result of industrial processing. Several of them have been in use for as much as 50 years and have been submitted to extensive risk assessment in the past. It is a point of debate among experts whether these materials need to be re-assessed with a special focus on nanoscaled particles and their impacts on human health. However, information about which nanomaterials are presently used in food and cosmetic products is difficult to obtain. Only a few proactive companies in the food and cosmetics business voluntarily report on encapsulated vitamins, titanium dioxide or silicon dioxide. Only those which use the term “nano” proactively are mentioned in the most recent publications by NGOs.

The European food and drink industry (CIAA) and the European Cosmetics Association (COLIPA) have both recently initiated their own Nanotechnology Task Force, so as to become more involved and active in the current debate on nanotechnology. Such an exchange of information is urgently requested by both EU and FDA regulators. In spite of this pressure the dominant response by the food and – to a lesser degree – the cosmetics industry appears to be to wait and see, perhaps in the hope that sceptical attitudes will vanish over time. Such a “Strategy of Silence” has never worked in the past and it is unlikely it will work this time. The recent activities of leading NGOs in the debate, and the results of the most recent

surveys and consumer conferences, demonstrate that public concern is on the rise and that attitudes to nanotechnology have become more sceptical over the past five years. This is particularly true for nanotechnology applications in food.

For cosmetics the situation is slightly different: there are some nanomaterials openly and publicly documented such as titanium dioxide and zinc oxide for sunscreens, as well as different systems of nanoemulsions and encapsulations. However, there is a scientific dispute between experts from NGOs and industry about the possible side effects from the increased intake of substances (for example vitamins) through encapsulated systems and from unintended carrier functions.

Regulation

The definition of what constitutes nanoscaled material and the question of whether natural and manufactured nanoscaled particles should receive separate treatment have direct repercussions on regulatory provisions in the US and Europe. Under US regulations, no specific risk assessment is needed for GRAS (Generally Recognised As Safe) approved materials, including naturally-occurring, non-toxic materials. The legal situation is different for food additives and colour additives. These need FDA approval based on scientific evidence that they do not cause any hazardous effects in the long run with a specified or unspecified daily intake.

In Europe, the Novel Food Directive covers food items and food ingredients with a new or intentionally modified primary molecular structure. Additionally, REACH prescribes a specific framework for documenting and reporting safety data on nanoscaled materials.

Both of these regulatory systems have enough flexibility to cover nanomaterials. However, there are concerns about the appropriateness of the existing risk assessment protocols to cover nanoparticles and about their capacity for monitoring and controlling environmental, health and safety impacts in the absence of internationally harmonised standards. Additionally, problems of identifying nanomaterials in products, and the restricted information policies of certain industry stakeholders, have created a climate of distrust that may have led to the request from critical NGOs to tighten regulatory constraints for nanomaterials in food and cosmetics.

Regulators in both the US and Europe have addressed the issue of health risks to the consumer by referring to the product as a whole. There is clearly logic behind this approach, as consumers are exposed to a whole product, and never to only the particles that are included in the product. However, the focus of this approach on product safety, rather than on the particle size of ingredients, had been criticised by many NGOs as missing the point. They are demanding special testing protocols and methods for analysing and assessing the risks of nanoscaled materials, independent of their use in larger aggregates or clusters.

Several empirical studies on specific nanoscaled material could not substantiate claims of significant health impairments due to ingestion or skin application of nanoscaled particles, and demonstrated ill effects only through inhalation. Although only a limited number of nano-sized materials have been tested for ingestion and skin application, the list does include titanium dioxide, a substance widely used in cosmetics and sunscreens. Several studies including the EU-funded NanoDerm project concluded that nano-sized titanium dioxide is unlikely to cross the barrier of the vital dermis.

The main question is how to proceed from here. In terms of risk governance a proactive initiative could be initiated by industry and other interested parties to develop and implement a voluntary agreement based on best practice. This may be the best route to assure product safety and gain credibility and trust.

Voluntary codes

In response to the rising concerns of NGOs, regulators, attentive consumers and the media, several voluntary codes have been developed or are in the consultation process in the US and Europe. Each of the four summarised in this report have been developed by significant and reputable organisations (ICCA, the European Commission, The Royal Society, and DuPont and the Environmental Defense Fund). There are others, such as those put forward by individual countries as voluntary schemes or stewardship programmes. These have been the subject of analysis by several OECD projects [IFCS, 2008]. The different voluntary codes reflect diverse regulatory and cultural backgrounds and are targeted towards different actors such as industry, researchers or mixed stakeholder groups. At this point there is no mutual commitment to any one of these codes and it is questionable if it is possible to have a “one-size-fits-all” solution.

Voluntary codes have the potential to guide companies and research organisations which wish to transparently demonstrate their responsibility for workplace and product safety. Several NGOs have started active campaigns on nanotechnology, and consumer attitudes have become more critical towards the use of nanomaterials in food and cosmetics. In this context, such codes may also facilitate the process of building trust and credibility and so lead to meaningful and constructive dialogues among the key players in the debate. However, if these codes remain vague and unrelated to actual performance, and merely reflect public relations activities, this approach is likely to fail and may exacerbate negative public opinion. A constructive dialogue with critics and consumer organisations which can lead to mutually agreed results requires the establishment and implementation of best practices and a transparent process of risk assessment and management over the entire life-cycle. Being aware of these conditions is particularly important for the food and the cosmetics industries. They are confronted with growing concerns and critical questions raised by many civil society groups.

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For its project on the risk governance of nanotechnology applications in food and cosmetics, IRGC invited a number of experts in the field to a workshop in Geneva in April 2008. All participants were provided with a workshop briefing paper prepared by Antje Grobe, Ortwin Renn and Alexander Jaeger of Dialogik gemeinnuetzige GmbH. At the workshop's conclusion, participants were invited to provide feedback to the authors on the briefing paper. This feedback and other comments received have been of significant assistance to the authors in revising the paper and compiling this report, on which it is based.

Although all comments were considered and the vast majority incorporated, this report reflects the views of the authors and does not represent a consensual statement by the workshop participants.

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The International Risk Governance Council (IRGC) is an independent organisation based in Switzerland whose purpose is to help the understanding and governance of emerging, systemic global risks. It does this by identifying and drawing on scientific knowledge and the understanding of experts in the public and private sectors to develop fact-based recommendations on risk governance for policymakers.

IRGC's goal is to facilitate a better understanding of risks; of their scientific, political, social, and economic contexts; and of how to manage them. IRGC believes that improvements in risk governance are essential if we are to develop policies that minimise risks and maximise public trust in the processes and structures of risk-related decision-making. A particular concern of IRGC is that important societal opportunities resulting from new technologies are not lost through inadequate risk governance.

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