Policy Brief

# Appropriate Risk Governance Strategies for Nanotechnology Applications in Food and Cosmetics

international risk governance council

## Abbreviations used in the text:

| | |
|---|---|
| EC | European Commission |
| EHS | Environment, Health and Safety |
| ELSI | Ethical, Legal and Social Issues |
| EPA | Environmental Protection Agency |
| EU | European Union |
| FDA | US Food and Drug Administration |
| FSC | Forest Stewardship Council |
| GMO | Genetically Modified Organisms |
| IUF | International Union of Food Workers |
| IRGC | International Risk Governance Council |
| ISO/TC | International Organization for Standardization / Technical Committee |
| ISO/TS | International Organization for Standardization / Technical Specification |
| NGO | Non-Governmental Organisation |
| nm | Nanometre |
| NSF | National Science Foundation |
| OECD | Organisation for Economic Co-operation and Development |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| SMEs | Small and Medium-Sized Enterprises |
| $TiO_2$ | Titanium Dioxide |
| TSCA | Toxic Substances Control Act |
| UNESCO | United Nations Educational, Scientific and Cultural Organization |
| US | United States |
| WTO | World Trade Organization |


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# Foreword



This policy brief addresses the risk governance of nanotechnology applications in food and cosmetics, provides a commentary on current developments which highlights some of the associated opportunities and risks, and presents the International Risk Governance Council's recommendations for the improved risk governance of nanotechnology in food and cosmetics.

The International Risk Governance Council (IRGC) is an independent foundation based in Switzerland whose purpose is to identify and propose recommendations for the governance of emerging global risks. To ensure the objectivity of its governance recommendations, IRGC draws upon international scientific knowledge and expertise from both the public and private sectors in order to develop fact-based risk governance recommendations for policymakers, untainted by vested interests or political considerations.

Because many emerging risks are associated with new technologies and usually accompany significant economic and public benefits, different governance approaches and policy instruments must often be developed to maximise those benefits while minimising the identified risks. Important opportunities for social and economic development can be foregone where the public perceives inadequate risk governance measures.

This policy brief on the risk governance of nanotechnology applications in food and cosmetics is an example of such fact-based analysis. It is the result of an IRGC project which has been led by Ortwin Renn, Professor and Chair of the Department of Environmental Sociology at the University of Stuttgart in Germany. Project work has involved research and, in April 2008, an expert workshop held in Geneva, Switzerland, at which many of the issues raised in this policy brief were discussed. The workshop was attended by 36 experts from Canada, the United States (US), Korea, Japan and many European countries.

Workshop participants were provided with a detailed technical briefing paper and that paper, considerably revised and updated since the workshop, has been published separately by IRGC in late 2008. The report, "Risk Governance of Nanotechnology Applications in Food and Cosmetics", will provide readers of this policy brief with further information on the issues raised as well as full references for source materials.

Report: "Risk Governance of Nanotechnology Applications in Food and Cosmetics"

Nanotechnology is a rapidly developing technology which offers potentially enormous benefits that include enhanced medical diagnostics and drug delivery, environmental monitoring, water and waste treatment systems, and many others. It also presents significant challenges to government, industry and society at large. In the case of food and cosmetic products containing nanoscaled materials, there

have been forecasts of dramatic market growth but there is also increasing concern about the potential risks of these materials and there remains a lack of published risk assessment data.

There are significant uncertainties which can only be resolved through the design and implementation of adequate risk governance structures and processes. Their resolution is essential if nanotechnology is to achieve its full, long-term potential. IRGC recognises that governments, industry and many other sectors of society are seeking ways to resolve these uncertainties, and IRGC's risk governance recommendations are offered as a means of helping to achieve this goal.

IRGC is extremely grateful to the Korean National Program for Tera-Level Nanodevices and the Austrian Federal Ministry for Transport, Technology and Innovation, whose financial support has enabled us to conduct this project.

Donald Johnston
Chairman
International Risk Governance Council

Geneva, April 2009

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# I Introduction

This policy brief is primarily addressed to policymakers in governments as well as regulators and risk managers in industry concerned with and responsible for the decisions that are needed to resolve the current debate over the use of nanotechnology applications in food and cosmetics. Both the policy brief and the IRGC report "Risk Governance of Nanotechnology Applications in Food and Cosmetics" are intended to help improve the risk governance of nanotechnology applications used in food and cosmetic products.

**Product development is moving faster than risk assessors can appraise new risks**

This document is the final deliverable of IRGC's second project focussing on nanotechnology risk governance. In the first project, IRGC addressed nanotechnology risk governance in general and the project's conclusions included the recommendation that decision-makers should distinguish between two frames when designing appropriate risk governance approaches. For the first frame, passive nanostructures exhibiting stable behaviour, IRGC recommended, inter alia, that "risk assessment is paramount, as product development is moving faster than risk assessors can appraise new risks" [IRGC, 2007].

Current applications of nanotechnology in food and cosmetics fall within IRGC's first frame, and the lack of risk assessment data is one of the reasons that there have been several calls for moratoria. In 2006, Friends of the Earth 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].[1] In 2007, the International Union of Food Workers (IUF) called for a moratorium on 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" of which the first principle calls for "regulations underpinned by a precautionary approach" [IUF, 2007]. 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]

There are forecasts of dramatic market growth for both cosmetic and food products using nanotechnology applications. As cosmetics are applied directly to the skin and foods are ingested, both products involve exposure pathways in which contaminants, or any hazardous contents, can present a risk to human health. In the opinion of IRGC, a failure in the risk governance of nanotechnology applications

[1] All references cited in this policy brief are included in the separately published IRGC report "Risk Governance of Nanotechnology Applications in Food and Cosmetics", which contains a full reference section as an appendix.

in food and cosmetics could have serious adverse consequences for the field of nanotechnology in general.

For nanotechnology to achieve its short-term market potential, consumers need to have confidence in the safety and efficacy of both nanotechnologies and products containing nanomaterials. If this confidence is not gained, or is achieved and then lost, neither the short-term potential in consumer products nor the longer-term opportunities offered by nanotechnologies in other fields, such as medical diagnostics and environmental remediation, will be realised.

In the following sections of this policy brief, IRGC examines the need for the improved risk governance of nanotechnology applications in food and cosmetics in both the private and public sectors. In offering risk governance recommendations, IRGC is fully aware that simple solutions will not work since the governance issues raised by nanoscaled materials in food and cosmetics are very complex, for reasons which include the following:

- Exposure to nanoscaled materials, or systems consisting of nanoscaled materials, in food and cosmetics is deliberate and intentional. This is also true for food packaging materials in some applications. Thus, the potential for risk is the unavoidable by-product of the desired benefits.
- The high exposure of the human body to nanostructures in food has given rise to special concerns. Because of this, investigations into the risks of nanomaterials in food should be addressed as a matter of high priority.
- There is very limited publicly-known scientific knowledge available on the type and nature of nanoscaled materials in use in food and even less on the results of risk assessment studies, including different exposure routes. This is especially the case for gastro-intestinal studies, which measure the impact of ingested nanoscaled materials.
- The delay and lack of reliable risk-related information have led to a loss of trust between public authorities, industry and non-governmental organisations (NGOs). Even if public perception of nanotechnologies remains positive in general, new survey data and the findings of citizen conferences show that society is highly concerned about safety and health when nanoscaled materials are used in food and – to a lesser extent – in cosmetics.

There is a loss of trust between public authorities, industry and NGOs

## Key recommendations

In this policy brief IRGC offers a number of recommendations for improving the risk governance of nanotechnology applications in food and cosmetics at all stages of the risk governance process. In IRGC's opinion, the most urgently required actions are:

- Development of a commonly-accepted definition of nanotechnology and nanomaterials in food and cosmetics. In order to achieve this objective, it is important to:
  - clarify what is meant by manufactured, as opposed to naturally-occurring, nanomaterials;
  - refer to limitations in size, approximately 1-100 nanometres (nm);
  - refer to aggregates and agglomerates that may be larger than 100 nm in diameter but consist of nanoscaled particles;
  - specify what is meant by "specific properties", which are provided by nanomaterials or nanotechnologies; and,
  - use examples to illustrate the scope and meaning of the definition.

  IRGC recommends using the Working Definition of the International Organization for Standardization Technical Committee (ISO/TC) 229 and the Technical Specification ISO/TS 27687:2008 as a basis for defining nanotechnologies and nanomaterials used in food and cosmetics.

**There is a need for greater cooperation among and between major stakeholder groups**

- Design of standards, testing strategies, protocols and methodologies, including pre-market testing and life-cycle analyses, for assessing toxicity.
- Greater cooperation and exchange of information among and between major stakeholder groups. All stakeholders could benefit from access to such information and could use it as the basis for discussing and finding agreement on a set of screening criteria and scientific conventions to collect, assess and evaluate data on the use of nanoscaled materials in food and cosmetics.
- Continuous dialogue on the appropriateness of existing regulatory provisions, which take into account new results in research as well as risk assessments concerning hazard, exposure and impacts on environment, health and safety (EHS).
- Modification of those regulatory provisions if they are found to be inadequate.
- Improved communication and education concerning both EHS risks and ethical, legal and social issues (ELSI). Such communication should involve full disclosure and transparency. For this purpose, better training opportunities

and professional risk communication practices should be initiated for all stakeholders involved in the governance of nanotechnology risks.

- In addition, research on ELSI needs to be intensified. The results of this research can assist risk managers and risk communicators to better address and manage those public concerns that correspond with empirically proven deficits or problems.

IRGC believes that these actions will best be implemented if coordinated and managed by an internationally-recognised, competent and trusted organisation. In this respect IRGC welcomes the initiatives of the Organisation for Economic Co-operation and Development's (OECD) Working Party on Manufactured Nanomaterials and Working Party on Nanotechnology and the many projects that these two working parties are coordinating. IRGC hopes that these activities will provide a solid foundation for improving the risk governance of nanotechnology. Further steps will be needed, and IRGC believes that certain key international organisations constitute the most effective platforms for taking these. In this regard, there appears to be a particular role for the World Trade Organization (WTO) in establishing and monitoring the effectiveness of standards for the international trade of nanomaterials and products which contain them.

Certain key international organisations constitute the most effective platforms for taking the further steps needed to improve the risk governance of nanotechnology

# II Nanotechnology in food and cosmetics – an overview using the IRGC risk governance framework

Nanotechnology is an important and rapidly growing field of scientific and practical innovation that is fundamentally transforming our understanding of how materials and mechanisms interact with human and natural environments. Both governments and industry are investing heavily in nanotechnology research and product development. Hailed by some as a major driver of the next post-industrial revolution, the US National Science Foundation (NSF) estimated in 2000 that, by 2015, US$1 trillion worth of products will use some form of nanotechnology [Roco and Bainbridge, 2001]. Current leaders in this highly competitive field include the US, Japan, the European Union (EU), Korea and China, and government-led nanotechnology initiatives are already underway in more than 30 countries [OECD, 2008].

**Current approaches for managing the introduction of new technologies may be inadequate for the issues raised by nanotechnology**

Nanotechnology raises many complex and far-reaching issues, for which current approaches to managing the introduction of new technologies may be inadequate. Decision-makers worldwide need to work towards a system of risk governance for nanotechnology that is global, coordinated, and involves the participation of all stakeholders, including civil society. IRGC has previously addressed the risk governance of nanotechnology in general [IRGC, 2006; IRGC, 2007]. Here, IRGC focuses on two specific applications of nanotechnology: food and cosmetics. These applications present a high level of potential risk because the human body is deliberately exposed to them and also because they involve comparably higher perceptions of risk than other nanotechnology applications.

Nanotechnologies use techniques, processes and materials at the supramolecular level, approximately in the range between 1-100 nm, to create new properties and to stimulate particular desired functionalities. Applications in the food sector which are mentioned in publicly available literature refer to, for example: release systems for pesticides or fertilisers in agriculture; antibacterial or easy-to-clean surfaces in food-processing machines; food additives such as anti-caking agents; colour additives for many soft drinks; encapsulated vitamins for dietary supplements; and, micelle systems for low-fat products [IFST, 2006; Nanoforum.org, 2006; Friends of the Earth, 2008]. The number of products described as containing or presumed to contain nanotechnologies or nanomaterials is growing with every new publication on the topic. However, estimates should be considered with caution as only limited information has been provided directly by industry. There is both a considerable time delay before information is made public and, in the absence of definitive communication by manufacturers, no real evidence of the extent to which nanomaterials have been used or nanotechnologies applied.

Given this lack of hard data, estimates that the worldwide market for food using nanotechnology applications will reach US$20.4 billion in 2010 [Kaiser, 2004] seem

remarkable, particularly if one considers that the food industry maintains that "there is hardly any use of nanotechnologies in food and drink manufacture in Europe at present" [O´Hagan, 2007].

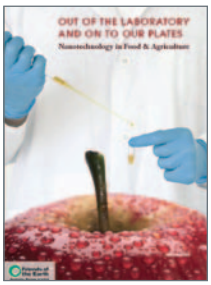
In cosmetics, nanotechnology applications can be found in: sunscreens with efficient UV protection; long-lasting make-up; anti-ageing creams with an increased intake of vitamins or enzymes; toothpaste; and hair care or colouring products [SCCP, 2007; Friends of the Earth, 2006; Grobe et al., 2007]. Again, it is unclear whether certain companies really use nanomaterials in their products. In spite of this uncertainty, the company BCC Research has forecast the global market for cosmetics using nanotechnology applications to reach US$155.8 million in 2012 [BCC, 2007].

Given the absence of a clear, internationally accepted and approved definition of nanomaterials and the lack of accurate information about the extent to which these materials are used in food and cosmetics, it is difficult to discern how the predictions of dramatic market growth have been reached. The same uncertainties also weaken the basis for some of the strong concerns voiced by several stakeholders. However, these concerns have become central to the increasingly polarised public debate on nanotechnologies, for which IRGC offers four possible explanations:

**Concerns raised by several stakeholders have become central to the public debate on nanotechnologies**

- Concerns about health risks may have given rise to the impression that there is a ubiquitous presence of nanotechnologies in food and cosmetics. In turn, and in the absence of contradictory evidence, this impression may have led to an escalation of both expectations (of benefits) and concerns (about risk).
- The food industry, having initially promoted the use of nanotechnology in advertising and marketing, refrained from doing so after realising that the public and, in particular, specific stakeholders, were expressing increased scepticism about nanotechnology in food. The public responses to cosmetics were less pronounced, with the effect that some cosmetic companies still advertise their products as enriched with nanomaterials. Industry's initial promotion efforts raised public expectations of high market potential. However, the subsequent lack of communication by industry was, possibly, then perceived by some as an indication of secrecy and strategic denial rather than honesty.
- The debate on nanotechnology fed into the ongoing polarisation of public attitudes towards industrial food processing. This debate, based on values rather than evidence, has been particularly enduring in Europe due to the association of food products with genetically modified organisms (GMOs), and extends to organic food and nature in general. It is also the result of different levels of trust in certain key actors such as industry, public authorities, the science community and NGOs.

- Last, but not least, it remains possible that purchasers of food and cosmetic products may in fact have experienced an increase of exposure to nanomaterials, despite assurances by the food and cosmetics industries that nanoparticles are hardly used in any of their products. However, independent reports confirm that manufactured nanoparticles are rarely found in contemporary food and cosmetic products.



Friends of the Earth, 2008

Whatever their basis, concerns of many NGOs and consumer associations are increasing about the potential risks to human health and the environment of nanomaterials in food and cosmetics. There remains a lack of published results from relevant scientific studies which address the characterisation and safety of nanoscaled materials used in food and cosmetics. This lack of data has been one of the reasons for several calls for moratoria on the subject [Friends of the Earth, 2006; Friends of the Earth, 2008; Soil Association, 2008; ETC, 2004].

These calls for moratoria are just one facet of the public, and at times fierce, debate about the need to impose stricter regulation on nanoscaled materials in food and cosmetics. Some agencies have opted to extend existing regulatory pathways for cosmetic and food products, substances and production processes to nanoscaled materials. In addition, several voluntary codes of conduct have been introduced as a means to facilitate and encourage best practice for research, risk assessment, management, evaluation and communication. It is hoped that these voluntary codes will initiate a much-needed and constructive dialogue among stakeholders and will combine evidence-based risk assessments with a precautionary approach for cases in which high uncertainty and ambiguity prevail.

## IRGC's approach to risk governance

IRGC defines risk as an uncertain (generally adverse) consequence of an event or an activity with respect to something that humans value. Risks are normally taken by society in order to realise opportunities, and any decision on risk also implies a decision on benefits. This is why risk governance always involves the integration of factual knowledge with societal values and the balancing of competing trade-offs, often in a complex environment and under time constraints.

Governance refers to the actions, processes, traditions and institutions by which authority is exercised and decisions are taken and implemented [IRGC, 2008]. Risk governance deals with the identification, assessment, management and communication of risks in a broad context. It includes the totality of actors, rules, conventions, processes and mechanisms and is concerned with how relevant risk

information is collected, analysed and communicated, and how management decisions are taken. It applies the principles of good governance to the handling of risk.

The willingness and capacity to take and accept risk is crucial for achieving economic development and introducing new technologies. Many risks, and in particular those arising from emerging technologies, are accompanied by potential benefits and opportunities. The challenge of better risk governance lies in enabling societies to benefit from change while minimising the negative consequences of the associated risks.

**The challenge is to enable societies to benefit from change while minimising the associated risks**

IRGC has developed a risk governance framework (illustrated in Figure 1) that has as its purpose to help decision-makers both understand the concept of risk governance and apply it to their handling of risks [IRGC, 2005]. It comprises five linked phases: pre-assessment, appraisal, characterisation and evaluation, management, and communication.

Figure 1: **The IRGC risk governance framework**

The following sections describe and analyse the key issues and problems for the risk governance of nanotechnology applications in food and cosmetics, using as a structure the five phases of the IRGC risk governance framework.

This policy brief and the previously published IRGC report are the result of desk research, interviews with leading experts in research institutions, industry and civil society groups and discussion at a workshop held in Geneva in April 2008, attended by 36 experts and representatives of major stakeholder groups. Both documents include comments and suggestions that were provided to IRGC before, during and after the workshop. However, all opinions and recommendations expressed in this document are the sole responsibility of IRGC.

## 2.1 Pre-assessment

IRGC's approach begins with risk pre-assessment, which has the purpose of providing a structured definition of the problem and how it may be handled. Pre-assessment forms the baseline for how a risk is assessed, evaluated and managed.

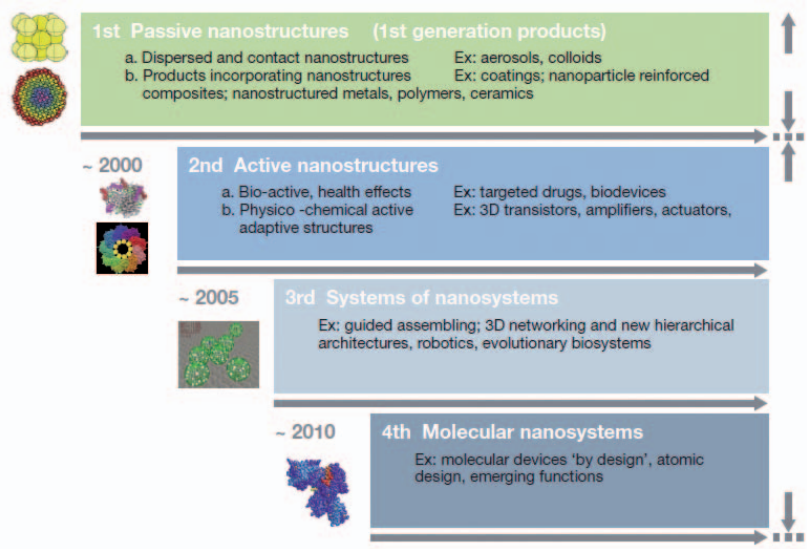
For risks associated with technology developments, pre-assessment requires decision-makers to outline the scientific characteristics of the technology and its potential applications, and to research and identify hopes and concerns that may be raised by major societal groups (governments, industry, the scientific community, NGOs and the general public). In its first project on nanotechnology risk governance, IRGC identified two major frames of nanotechnology products and production processes [IRGC, 2006]:

Pre-assessment requires decision-makers to outline the scientific characteristics of a technology and its potential applications

- *Frame 1, "passive" nanostructures*: here, the opportunities and risks derive from the application of nanoparticles and other relatively simple, passive, or merely reactive nanostructured materials with steady behaviour in different areas of application (e.g. paint, cosmetics, food, and coatings). The property or behaviour of some passive nanostructures may be complex – typically for system components – and, depending on their application, there may also be more or less uncertainty when predicting positive or negative impacts for the economy, the environment and society.
- *Frame 2, "active" nanostructures*: in frame 2, the benefits and risks are related to more complex and/or evolving nanostructures and nanosystems, some of which may utilise fundamental molecular elements or nanobiostructures as their building blocks. The behaviour of active nanostructures and systems typically changes over time and is therefore less predictable by scientific analyses (high complexity). This frame includes taking into account the social desirability of

innovations with far-reaching consequences, such as changes in the interface between humans and machines/products, and addressing ethical issues raised by technologies which interact with the environment and the human body.

Figure 2: Four generations of products and production processes



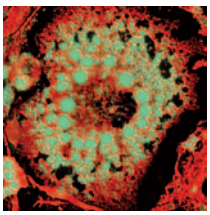

The distinction between the two frames is important. The frame 2 "active" nanotechnology applications will require a far greater level of knowledge and ability to control nanostructure behaviours. Frame 2 applications also demand a more rigorous assessment of the potential risks due to the expectations that their social, economic, and political consequences will be more transformative, although many will be in areas already subject to extensive regulatory oversight such as medical developments. However, "passive" nanostructures are already commercially available, and addressing risk-related concerns requires immediate action. The nanotechnology applications in food and cosmetics that are addressed in this policy brief are both, in IRGC's view, "passive" frame 1 nanostructures.

Passive nanostructures are already commercially available; addressing risk-related concerns requires immediate action

IRGC has previously recommended that more research is conducted into both hazard and exposure characterisation for frame 1 nanostructures. In IRGC's opinion, this is urgently needed for nanotechnology applications in food and cosmetics because of their manner of use and because of growing public concerns about their impact on human health. Since people are, generally, sensitive to materials that they ingest, absorb or apply onto their skin, concerns about the potential health impacts of nanotechnology applications in food and cosmetics are particularly high. The section on concern assessment (see p.20) provides some empirical evidence for this observation.

However, the situation is made especially complicated by three controversial questions, each of which relates to the definition of nanoscaled materials:

1. How and where should the line be drawn between nanoscaled and larger-scaled particles? Many of the materials described as nanoscaled that are used in food and cosmetics do not meet a strictly quantitative definition because the nanoscaled particles aggregate or agglomerate at a size greater than 100 nm. Thus, a definition based solely on size would lead to the exclusion of structures that expand beyond the 100 nm level and could lead to significant knowledge gaps in identifying materials, properties and safety data.



Fat stored in droplets a few micrometres in size in a cell

2. What is the distinction between naturally-occurring and manufactured nanomaterials? Some materials are based, for example, on lipids, proteins or sugar. They are the result of processing conventional materials such as lipid droplets, which could form nano-emulsions, or micelle systems [Weiss et al., 2006]. Many experts do not characterise these as "nanomaterials" in the narrow sense of the term.
3. Do the nanomaterials provide "new" or "novel" properties? Some of the clustered, manufactured nanoscaled materials have been in use for over 50 years and their properties have been known for a long time [ECETOC, 2006]. Thus, any definition based on novel properties also leads to problems of what to include and exclude with respect to the materials used.

Without a valid characterisation of the properties associated with nanoscaled materials, it is impossible to develop adequate risk assessment protocols and appropriate measurement scales. Equally, an imprecise definition of nanomaterials as anything that is small – as is sometimes done for marketing reasons – could give the impression that there is a huge number and volume of nanotechnology applications on the market and that immediate action is necessary. The issue of definition has major implications for risk governance, particularly for risk appraisal and risk communication. At present (November 2008), ISO/TC 229 is working hard to accomplish an internationally accepted definition.

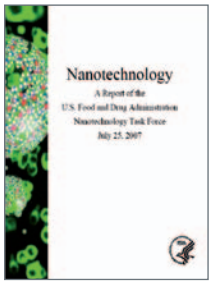
**The issue of how nanotechnology and nanomaterials are defined has major implications for risk governance**

Even when agreement is reached on how to define "nanoscaled", "nanoparticles" and "nanomaterials", the need to understand and recognise potential health and environmental risks will remain. The lack of information about specific materials already in use and the absence of results from scientific risk assessments have been significant factors in the public debate about how much precaution is necessary when using nanoscaled materials in food and cosmetics. Several NGOs advocate a rigorous application of the precautionary principle, which would restrict commercial availability only to products using nanomaterials that had been demonstrated as safe as a result of

a scientific risk assessment [Friends of the Earth, 2006; Friends of the Earth, 2008; IUF, 2007]. Against this background, the European Commission (EC) has recommended:

> *"As long as risk assessment studies on long-term safety is not available, research involving deliberate intrusion of nano-objects into the human body, their inclusion in food (especially in food for babies), feed, toys, cosmetics and other products that may lead to exposure to humans and the environment, should be avoided".*
>
> [EC, Recommendation, 2008]

This tension between rigidly applying the precautionary principle and relying on risk-based evidence of harm is typical of the stakeholder debate on nanoscaled materials in food and cosmetics. The main topic of debate is the potential health impacts of passive nanostructures and at what levels of exposure they may have unintended negative effects. The pre-assessment phase of the IRGC framework also involves selecting the procedural rules for the appropriate scientific assessment of risks. The traditional protocols for risk assessments, such as examining dose-response relationships, may lack effectiveness when used to assess the effects of exposure to nanoscaled materials, due to their increased surface-to-mass ratio [FDA, Nanotechnology Task Force, 2007]. Substances that are non-toxic or considered not detrimental in the quantities to which humans are exposed may become more hazardous, or even toxic, when applied in a nanoscaled format.



FDA, Nanotechnology Task Force, 2007

## 2.2 Appraisal

Risk appraisal develops the knowledge on whether or not a risk should be taken and, if so, how the risk can best be managed. Risk appraisal comprises both a risk assessment – a scientific assessment of the risk's factual, physical and measurable characteristics including the probability of it happening – and a concern assessment – a systematic analysis of the associations and perceived consequences (benefits and risks) that stakeholders, individuals, groups or different cultures may associate with it. The concern assessment is a particular innovation of the IRGC framework, ensuring that decision-makers account for how the risk is viewed when values and emotions come into play [IRGC, 2005].

**Traditional protocols for risk assessment may lack effectiveness when used to assess exposure to nanoscaled materials**

### Risk assessment

Risk assessment asks questions such as: What are the potential damages or adverse effects? What is the probability of occurrence? How clearly can cause-effect relationships be established? What are the primary as well as secondary benefits, opportunities and potential adverse effects?

The principal problem with conducting risk assessments of nanoscaled materials in food and cosmetics derives from the lack of a clear definition, as described above. This has had immediate repercussions on the scientific and public debate on this issue. Several materials are claimed to be "nanoscaled" but often without scientific evidence to support this claim. There are probably many products that contain nanoscaled materials but no one individual or institution is in a position to confirm how many. However, it should be noted that 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 has established an online inventory of nanotechnology goods identified by manufacturers. The inventory indicates that the number of consumer products using nanotechnology has expanded to more than 600; 95 of which are used in cosmetics and an additional 29 examples are listed for sunscreens. Regarding food and beverage applications, 68 products are mentioned, most of them within dietary supplements or as surface treatments for refrigerators or packages. Only three applications are listed as actual food ingredients [Woodrow Wilson International Center for Scholars, 2008]. But even the validity of these assessments is under debate as most companies provide very little data on the scientific characterisation of their materials.

Regarding the scientific knowledge about the health effects of nanoscaled materials in food and cosmetics, there is consensus among experts that, first, in the absence of data that would apply to all nanoscaled materials, a case-by-case approach is necessary. Secondly, it is also generally agreed that new protocols are urgently required for testing toxicity and other impacts influenced by surface-to-mass ratio or other specific characteristics of the nanomaterial under investigation [SCENIHR, 2007; SCCP, 2007]. Without generalised observations that can be applied to all nanoscaled materials or specific studies on individual nanomaterials, it is impossible to answer the more general question: Are nanoscaled materials in food or cosmetics dangerous? The answer is that it depends.

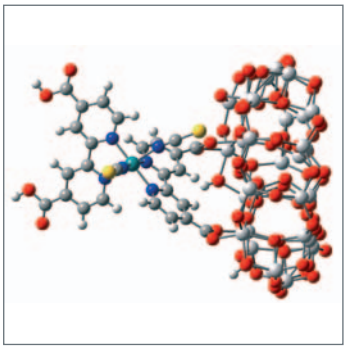
**It is generally agreed that new protocols are needed to test toxicity and other impacts influenced by surface-to-mass ratio**

With no answer to the question of danger to human health, several organisations, particularly NGOs, have asked for the establishment of a new testing framework for approval by the US Food and Drug Administration (FDA). This framework would include a nanotechnology-specific guideline for toxicity testing, which could guarantee a systematic screening and fully-fledged risk assessment for nanoscaled materials. These NGOs have stressed the need for research into migration, absorption and adsorption. Such research cannot be done without actual nanoscaled materials on which to work and without close cooperation between industry, public authorities and scientists. Without knowledge of the materials used, their characterisation and

properties, it is possible neither to develop a suitable protocol for measuring the effects of size in food (ingestion pathway) or cosmetics (dermal pathway) nor to initiate a meaningful risk assessment.

It should be noted that there is not a complete absence of toxicological data. The IRGC report summarises risk assessment results for three major substances that are used in food and cosmetics: synthetic amorphous silica, titanium dioxide ($TiO_2$) and encapsulated vitamins. With respect to silica used in food, the authors reported that typical sizes range far beyond the nanometre scale. The materials have been tested frequently, including over the full size distribution, and have been assessed as safe [ECETOC, 2006]. However, no information was available about possible future applications of silica within the nanometre scale.

Titanium dioxide is an approved food additive and is (as E171) a commonly-used colouring agent in most parts of the world. At the time when the FDA approved $TiO_2$ as a colouring agent in food (1966) [FDA, Food Ingredients and Packaging, 2007], manufactured nanotechnologies had not been developed to the extent that they could be used in industrial production. Furthermore, there were no reliable diagnostic tools to detect nanoparticles among larger particles. The same material applied on the microscale level is used as a white pigment in some make-up products such as eye-shadow in cosmetic products or in facade paints. Given the progress in manufacturing nanoscaled particles, nanoscaled $TiO_2$ can now be produced at a scale more than a hundred times smaller than the conventional material. The properties vary as a function of size. For example, at sizes in the order of 20 nm, $TiO_2$ becomes transparent [SCCP, 2007] and can be used as a very effective UV protector in sunscreens. Several risk assessments have been made of these materials and they came to the conclusion that there was no health risk to the consumer if properly applied [NanoDerm, 2007]. However, nanoscaled $TiO_2$ is not an approved food additive [NanoCare, 2008] and it is not marketed in nanoscaled proportions for application in food products.



Nanostructural molecule-$TiO_2$ interface

**The properties of $TiO_2$ vary as a function of size**

The main conclusion on encapsulated systems for delivering nutrition or vitamins in food and cosmetics was that an overdose of certain encapsulated vitamins might create health problems if consumers were unaware of the correct dosage or they believed that “more is better”. The encapsulated systems were not described in the literature as being hazardous for human health or the environment [End et al., 2007; McClain and Bausch, 2003]. If there are indications of potential health threats caused by the overdose of certain encapsulated vitamins, then risk reduction measures need to be considered. These measures may range from providing consumer information and improving labelling to restricting the use of encapsulated nutrients in food items

that tend to stimulate overdose or other forms of excessive or inappropriate use [Rosenbloom, 2007; Russell, 2000; Grobe et al., 2007]. Even these measures require a consistent line of communication about whether products contain nanoscaled materials or not. Working on these issues should be given the highest priority.

It is noted that there are initiatives in progress by the OECD and its members which should address many of the problems that affect the risk assessment of nanomaterials [IFCS, 2008]. The OECD's Working Party on Manufactured Nanomaterials has established eight projects, one of which involves safety testing a representative set of manufactured nanomaterials which are in, or close to, commercialisation. Another includes sharing data on manufactured nanomaterials between member countries. The OECD's Working Party on Nanotechnology has a programme of six projects, one of which seeks to develop a framework for the international comparison and validation of statistics according to agreed definitions and classifications. These initiatives are indications that efforts are being made to increase the availability of risk assessment data. However, until such data becomes publicly available, concerns and credibility gaps are likely to continue to increase.

## Concern assessment

Concern assessment seeks to establish the public's concerns and perceptions, the likely social response to the risk (and to how it is managed) and whether or not risk managers are likely to face controversial responses from disaffected groups or those who feel that there are inequities in the distribution of benefits and risks. Many observers of the nanotechnology debate have come to the conclusion that public perceptions in this field show similar patterns to the perception of GMOs and other controversial technologies [Hanssen and van Est, 2004].

**People are more sceptical about nanomaterials in food than in cosmetics**

Analysis of a number of studies in North America and Europe has shown that people have, in general, favourable expectations of nanotechnologies, at least amongst those who were familiar with the term. The range of surveyed participants to have heard of nanotechnology and to have some knowledge or idea of what it is varied from between 20% in the US to around 50% in some European countries. In contrast to the overall positive perception of nanotechnology in general, all participation exercises in the US and Europe have found similarly negative views of nanotechnology in food and more ambivalent views of nanotechnology in cosmetics [Nano Jury UK, 2005; Gavelin et al., 2007; Hanssen and van Est, 2004; BfR, 2006; TA Swiss, 2006; Kleinmann and Powell, 2005]. Consumers tend to be more sceptical, sometimes even negative, about nanomaterials in food than in cosmetics. This may be connected to a wider loss of trust in the food industry as compared to the cosmetics industry.

Furthermore, the inconsistent use of the term "nanotechnology" in industry (partly advertising, partly denying) has created a disposition for mistrust, as the responses in different consumer conferences and qualitative surveys suggest. The full IRGC report describes a number of international risk perception studies and provides an overview of consumer attitudes (see Section 5). The main insights from the analysis can be summarised as follows:

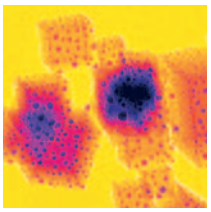
- Most people in the US and Europe are still unaware of the opportunities and risks of nanotechnologies.
- With respect to food and cosmetics, the data clearly indicates that food and, to a lesser extent, cosmetics are socially and politically sensitive application areas that cause heightened concern and require particular vigilance.

Since individuals have little factual knowledge or personal experience with nanotechnologies, they rely almost solely on information from third parties. In this situation, trust is critical and, when this has been studied, people have indicated greater confidence in statements by scientific and consumer organisations than those made by industry, public authorities and campaigning NGOs.

**Survey data indicates that food and cosmetics are sensitive applications requiring particular vigilance**

## 2.3 Characterisation and evaluation

IRGC's inclusion as a separate phase of characterisation and evaluation is to ensure that the evidence based on scientific facts is combined with a thorough understanding of societal values. This is crucial when judging whether or not a risk is acceptable (risk reduction is considered unnecessary), tolerable (to be pursued because of its benefits and if subject to appropriate risk reduction measures) or, in extreme cases, intolerable (to be avoided). There are three major steps [IRGC, 2005]:



Magnesium Oxide Dice

1. Scientific (evidence-based) 'risk profile' focused on risk assessment and concern assessment.
2. Societal (value-based) balancing of benefits and risks (including societal needs, contribution to quality of life, contribution to sustainability, potential for substitution and compensation, policy imperatives, choice of technology, and overall risk-benefits balance).
3. Conclusion on whether risk is acceptable, tolerable or unacceptable.

Risk decision-makers and regulators have the task of collecting all the information from the appraisal process and making a judgement about the balance between the potential negative and positive impacts. Nanotechnology is an enabling technology, influential in chemistry, biology and physics. There are an enormous number of

existing and anticipated nanomaterials and nanostructures as well as uses for them. It is therefore not possible to make a single judgement for nanotechnology as a whole, although some advocates would like governments to do so. Instead, it is necessary to look at each application, to collect what is known about the impacts and then to make a judgement of acceptability or tolerability on a case-by-case basis.

Judgements may also vary according to who makes them. Governments, regulators, industry and members of the public are likely to view and weigh opportunities and risks differently, leading them to make different judgements. Another reason for the current debate on nanotechnology applications in food and cosmetics is that different sectors of society appear to be reaching different conclusions. For example, the call for moratoria by Friends of the Earth and others [Friends of the Earth, 2006] implies a judgement of the risks as being intolerable (until risk assessment data can be made available to demonstrate otherwise). Conversely, the inclusion of nanomaterials in some products now on the market implies that the manufacturers have judged the additional risks of including nanomaterials as tolerable.

**Without data from risk assessments, the risks associated with nanotechnology will be primarily informed by what people think and feel**

For so long as there is very little scientific data available from risk assessments, an evaluation of the risks associated with nanotechnology in food and cosmetics will be informed primarily by the evidence derived from concern assessments (e.g. what people think and feel) and by the values that influence the decision-maker (or decision-making organisation).

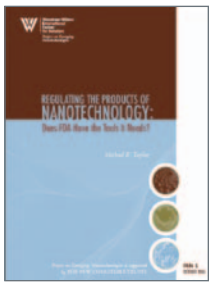
In the conclusions to IRGC's first project on nanotechnology risk governance it was recommended that, because of their many and far-reaching implications for society, the risk governance of frame 2 "active" nanomaterials and nanostructures should include an inclusive societal debate concerning the acceptability of certain applications. IRGC's opinion remains that such a dialogue is best suited to frame 2. However, the focus of the current debate on nanotechnology in food and cosmetics, combined with the lack of scientific evidence to support many of the opinions expressed, suggests to IRGC that some of the associated uncertainty may be best reduced by involving a broad group of stakeholders. This group should be representative of all major interests (governments, regulators, industry, academia and consumer organisations) and should be tasked with reaching a collective judgement that reflects a socially acceptable balance between benefits and risks.

## 2.4 Risk management, regulation and self-regulation

Risk management includes the generation, assessment, evaluation and selection of appropriate risk reduction options as well as implementing the selected measures, monitoring their effectiveness and reviewing the decision if necessary [IRGC, 2005].

Notwithstanding the public debate on the benefits and risks of nanoscaled materials in food and cosmetics, companies are legally obliged to guarantee that their products are safe and that they do not cause any harm to humans, animals or the environment. For food and cosmetics, this often requires a comprehensive risk assessment prior to a product receiving approval for market release. However, the question of whether or not this regulatory framework is sufficient to assure the responsible production, distribution and use of nanoscaled materials has found diverse responses among different stakeholders.

**There is no obligation to undertake a new risk assessment when a large-scale compound in a product is replaced by the same compound at the nanoscale**



Taylor, 2006

While most industrial actors and regulatory agencies believe that current levels of regulation are adequate, representatives of a number of NGOs and several scientific groups have expressed their doubts [Friends of the Earth, 2006; Friends of the Earth, 2008; Soil Association, 2008; Woodrow Wilson International Center for Scholars, 2008; Davies, 2006; Taylor, 2006]. These doubts are due to the fact that most of the pertinent regulations are based on testing products or substances irrespective of substance size. This means that there is no legal obligation to undertake a new risk assessment when a large-scale compound in a product is replaced with the same compound at the nanoscale.

The research conducted during this project included an investigation into whether or not national governments were introducing regulations specific to the risks presented by nanotechnology. Although the research was not exhaustive, the results (see Table 1 below) clearly demonstrate that, in the reviewed countries, there is a range of existing legislation which indirectly covers nanotechnology applications in the cosmetics and food sectors although, as at November 2008, there were no legal prescriptions that relate exclusively to nanoparticles. This indirect regulation creates a legal framework under which companies are obliged to produce or trade materials and products only if they are safe in a comprehensive understanding. In addition, the European **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH) regulation asks for full documentation of risk assessment procedures.

Table 1: Regulations specific to nanotechnology in five selected countries

| | UNITED STATES | | UNITED KINGDOM | |
|---|---|---|---|---|
| | 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 |

Many national regulatory agencies have assessed whether or not there is a need for greater regulatory action and have concluded that existing laws and technical provisions sufficiently cover the potential risks associated with nanoscaled materials [FDA, Nanotechnology Task Force, 2007; EC, Regulatory Aspects of Nanotechnology, 2008; FSA, 2006; BMBF, 2007]. This conclusion assumes that current approaches for testing substance and product safety are adequate to cover possible toxicological or behavioural changes due to size-effects. However, such assurances from national regulatory agencies have not been sufficient to allay some of the concerns expressed by various experts and NGOs that available testing methods and protocols may not be adequate for demonstrating the safety of nanoscaled materials in consumer products to a satisfactory degree. Additionally, concerns have been raised about the capacity of public authorities to deal with a case-by-case approach. More critical reviews from governmental bodies have stressed the impact of knowledge gaps [BERR, 2006] and have recently demanded stricter regulation at the EU level, and the labelling of food products containing nanotechnologies [FSAI, 2008].

In the EU, regulatory provisions do not address nanoscaled materials per se but do require testing for all products covered by REACH, independent of size (EC Regulation 258/97). In the US, the FDA does have the authority to request additional information if it believes that it is required [FDA, Nanotechnology Task Force, 2007]. The need for such information can even be triggered by public perception and/or stakeholder pressure.

Also in the US, the Environmental Protection Agency (EPA) launched, after a period of consultation with stakeholders, the Nanoscale Materials Stewardship Program, in January 2008. The Program's development arose from EPA's conclusion that there was a need to develop a means to provide oversight of nanoscaled materials that fall within the scope of the US Toxic Substances Control Act (TSCA). The Program has the objective of helping to "provide a firmer scientific foundation for regulatory decisions" and each participant is invited to voluntarily "submit available data on risk management practices for nanoscale materials it manufactures, imports, processes or uses"; as at 23 October 2008, 25 companies had made submissions covering 113 nanoscale materials and a further nine companies had committed to making submissions [EPA, 2008]. The Program is primarily aimed at existing materials that are already on the TSCA Chemical Substance Inventory; for new materials not on the inventory (including nanoscale materials), TSCA's normal approval process applies.

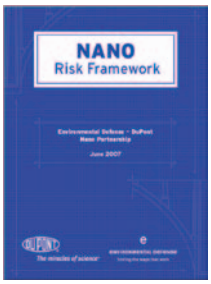
**Hard regulatory options are limited, which is one reason for the interest in voluntary codes**

Overall, IRGC is of the opinion that hard regulatory options are limited and highly dependent on the regulatory style and culture of each country, which is one of the main reasons for the considerable interest of governments, regulators and industry in the use of voluntary codes and proactive risk governance.

Voluntary codes must be sufficiently substantive to avoid being viewed as window-dressing

Voluntary codes have the potential to assist companies and research institutions to transparently demonstrate responsibility for workplace and product safety. They can provide orientation and guidance for entire industry sectors or for single companies. At the same time, however, such codes are difficult to formulate and to align between different countries and industries. The main reason for these difficulties is that the main terms are not always defined or conceptualised in the same way by various international actors. In several industries, it has been possible to introduce and use voluntary codes and 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. This is the case with the Forest Stewardship Council's (FSC) Principles of Forest Stewardship and the standards which derive from them. However, some scepticism remains, particularly if such codes are used only to calm fears or to demonstrate responsiveness and are not matched by substantive self-regulation and sanctions for non-compliance. In such cases, voluntary codes are viewed as simple window-dressing since they contain no specific obligations to the producer beyond those already legally prescribed.

For nanoscaled materials several codes or frameworks are presently being discussed [ICCA, 2008; EC, Responsible Nanoscience, 2007; Responsible Nano Code, 2008; Environmental Defense Fund and DuPont, 2007]:



Environmental Defense Fund and Dupont, 2007

- Global Core Principles of Responsible Care®
- European Commission's 'Code of Conduct for Responsible Nanosciences and Nanotechnologies Research'
- The Responsible Nano Code
- The Nano Risk Framework

These codes share a number of similarities and points of overlap but also contain different emphases and levels of specificity, scope and degree of obligation (see Table 2). Each has a different target audience but all are written with the purpose of providing a structure for framing nanotechnology risks, for risk assessment throughout the life-cycle, and for management and communication strategies. All, therefore, intend to offer benchmarks for the responsible research, production and use of nanoscaled materials.

Table 2: Overview of voluntary codes and frameworks

| Criteria | Responsible Care® | EC Code of Conduct | 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 |

Communication should have the principal aim of enabling all stakeholders to make their own judgments of the risk

To be effective throughout an industry, voluntary codes need to reflect the particular needs and resources of Small and Medium-Sized Enterprises (SMEs) as well as the multinational companies who tend to be more active in their development and for whom compliance may be easier. There is also, for nanotechnology applications in food, the need to acknowledge the particular history of stakeholder relations that has developed as a result of the controversial GMO debate. Currently there is no industry-wide commitment to any of the codes summarised in Table 2 and it remains uncertain whether a "one-size-fits-all" solution is feasible for nanotechnology applications in general, let alone for applications in food and cosmetics.

## 2.5 Communication

Communication, which is at the centre and touches upon all phases of the IRGC risk governance framework, is of the utmost importance. It enables risk decision-makers to ask the right questions of risk assessors. It allows stakeholders and the public to understand the risk itself as well as their role in the risk governance process and, through being deliberately two-way, gives them a voice in it [Renn, 2008]. Once the risk management decision is made, communication should explain the rationale for the decision and allow people to make informed choices about the nature and severity of the risk, its management and their own responsibilities. Effective communication throughout the risk-handling process is the key to creating trust in risk governance.

The first task of risk communication, facilitating an exchange of information among risk professionals and affected stakeholders, has often been underestimated. Close communication between risk/concern assessors, private and public risk managers and risk regulators, particularly in the phases of pre-assessment and tolerability/acceptability judgement, is crucial. Similarly, cooperation among natural and social scientists, close teamwork between legal and technical staff and continuous communication between policymakers and scientists are all important prerequisites for enhancing risk governance and management. This is particularly important for emerging risks such as nanotechnology that tend to have impacts far beyond their immediate physical effects.

The process of risk communication should not aim at convincing the "other side" that a risk is either tolerable or intolerable. Communication should have the principal function of enabling all stakeholders to make their own, balanced and informed judgements of the risk in question.

In order to give stakeholders the required tools to make their own informed and balanced risk judgements, they need to be aware of and knowledgeable about the potential risks and benefits of nanoscaled materials in food and cosmetics. However, there is little publicly-known scientific knowledge available on the type and nature of nanoscaled materials in use and even less on the results of risk assessment studies, including different exposure routes. Thus, consumers are receiving most of the knowledge on which they act from the media and from active NGOs.

IRGC considers that the food industry in particular lacks a proactive communication strategy to deal with the need for more information. Without proactive communication of what they do and what they know, food companies are likely to be exposed to growing concerns, rumours and distrust. In the cosmetics industry one can find more products than in the food sector that claim or even advertise the use of nanoscaled materials. However, there is no information on whether these applications use nanoscaled materials in the strict sense of the term or just use the reference to "nano" for advertising purposes. Moreover, there is no information regarding how they behave and what kind of risk assessment has been conducted.

The present situation requires urgent change. Successful communication starts with transparency about what is at stake and what risks and benefits one can expect from the activity. For this reason, special attention must be paid to the methods that are used to clearly convey the principles of risk assessment and how they need to be adapted to the special features of nanoscaled materials. Furthermore, it should be ensured that the necessary inclusion of value judgements is made transparent and is politically and/or ethically legitimised. This is particularly important for nanoscaled materials which provide only minor benefits to the consumer at the expense of uncertain risks.

**Currently, consumers are receiving most of the knowledge on which they act from the media and NGOs**

Friends of the Earth, 2006

# III Recommendations for the risk governance of nanotechnology applications in food and cosmetics

## 3.1 Recommendations for pre-assessment

- IRGC recommends using the Working Definition of the ISO/TC 229 and the ISO/TS 27687:2008 as a basis for the ongoing task of defining nanotechnologies and nanomaterials used in food and cosmetics. This definition should combine a functional and size-related approach and confine nanomaterials to products that are manufactured or engineered for specific purposes.

IRGC recommends that the food and cosmetics industries explain which nanoscaled materials they are using

- At present, in the absence of a harmonised, internationally accepted definition, IRGC recommends that the food and cosmetics industries explain, in public, which nanoscaled materials they are using, in which size, what kind of risk assessment studies have been carried out, and what the results were of those assessments. Additionally, companies should elaborate a scientifically-based characterisation of nanomaterials, including definitions to adequately describe a material as “nanoscaled”.
- With respect to definition and characterisation, IRGC is also convinced that current and future attempts at communicating benefits and risks to stakeholders and the public need to be scrutinised at all stages of the risk governance cycle in order to avoid misunderstandings and inconsistencies. This is not only a task for companies but also for NGOs, public authorities and politicians when they discuss nanotechnologies, either in general or with regard to specific applications such as food or cosmetics.

## 3.2 Recommendations for risk assessment

- Since basic issues of definition are not yet resolved, IRGC would recommend starting with a participatory framing exercise and, as a sign of goodwill, to have industry reveal the results of its own risk assessments in advance. The framing exercise could then be followed by joint efforts to deal with risk assessment protocols and to agree on the most suitable risk assessment methods.
- The data (described more fully in the separate IRGC report) does not support the hypothesis of increased health risks strictly due to the nanostructure of the material. One should be careful, however, in generalising these results, not least because IRGC’s study covered only three specific materials. There is a significant uncertainty about other materials, especially those which are not biodegradable. However, based on this limited study, there is no compelling reason to ask for a moratorium or other drastic measures to ban or restrict the use of nanoscaled materials in food and cosmetics in general. Nevertheless, restrictions for certain materials with a confirmed risk potential are still feasible.

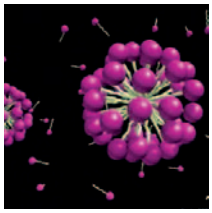
IRGC recommends the establishment of reliable and accurate testing strategies, protocols and methodologies for risk assessment, and the application of these risk assessments to all materials that meet the working definition of the ISO/TC 229.

- Greater cooperation and exchange of information amongst all major stakeholder groups is needed. All stakeholders could benefit from accessing dependable information and using it as the basis for discussing and finding agreement on a set of screening criteria and scientific conventions to collect, assess and evaluate data on the use of nanoscaled materials in food and cosmetics.
- Governments can proactively take the initiative of undertaking risk assessments for an appropriate selection of nanomaterials. Through their research budgets and institutions, many governments have the resources to do this and IRGC recommends that as many countries as possible participate in the OECD's project "Safety Testing of a Representative Set of Manufactured Nanomaterials" in order to maximise the number of assessed materials in as short a time as possible.

**Governments have the resources to take the initiative of undertaking risk assessments for an appropriate selection of nanomaterials**

## 3.3 Recommendations for concern assessment

- Information about potential physical risks needs to be complemented by a concern assessment that investigates risk perception, social concerns and socio-economic impacts. IRGC recommends monitoring public perception on a continual basis and using public fora, citizen or consumer panels and other forms of participatory measures to help risk managers understand public concerns and to incorporate that understanding into appropriate risk management and communication actions.
- Growing concerns by NGOs and consumers can only be addressed by launching a proactive consultation and communication programme. However, the effects of such a stakeholder dialogue are difficult to predict. If the overall aim of supporting innovation and new technologies is not shared by the respective stakeholders, a dialogue will not produce any form of viable agreement among the actors involved. On the other hand, 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. In any case, dialogues have the potential to clarify reasons for public opposition or resistance, as well as to identify cultural patterns of risk perception at an early stage of the debate. Such a dialogue, and the issues raised within it, could act as an early warning system for informing private investment, public regulation and insurance policies.



Micelle models

## 3.4 Recommendations for risk characterisation and evaluation

Label of a product containing nanomaterials

- Given the current lack of scientific evidence from risk assessments of most nanomaterials and even of the products that contain them, judgements of the acceptability or tolerability of the associated risks are mostly, at the present time, founded on values and not facts. Because of the concerns held by some NGOs and the lack of real knowledge of nanotechnology and its uses in food and cosmetic products, IRGC recommends that the reasons for both approval decisions, and for decisions that nothing different should be done, are made public. IRGC also recommends that as much information as possible is communicated, particularly through the labelling of products containing manufactured nanomaterials, in order to enable all stakeholders, particularly consumers, to make their own informed value judgements.
- All stakeholders could benefit from an international and inclusive debate, with the purpose of collecting, assessing and evaluating all available data on the use of nanoscaled materials in food and cosmetics. It will be important to determine which set of existing risk assessment strategies are sufficient to detect these materials and to assess their safety. This process could form a common knowledge base, as well as a trust-building foundation, for a larger effort that includes industry, NGOs and public authorities in evaluating the risk-benefit balance of different applications of nanoscaled materials in food and cosmetics. Currently, there is no international platform for doing so and IRGC would suggest that such a platform be established and organised by an international, scientifically competent and widely-respected institution.

## 3.5 Recommendations for regulation and self-regulation

**Regulators should be open to amending regulatory protocols to account for new knowledge about nanomaterials used in food and cosmetics**

- A number of regulators have concluded that there is, to date, no justification for revising regulatory protocols to account for the use of nanomaterials in food and cosmetics. Given the scepticism of some NGOs regarding the potential health risks, regulators should publicly state the reasons for this conclusion.
- Regulators should also remain open to rapidly amending approval pathways in the event of new knowledge emerging which could challenge the decision not to change regulatory protocols. To ensure that this can be done as rapidly as possible if necessary, regulators should take the leading role in a continuous dialogue with experts from academia and industry on the appropriateness and

adaptability of existing regulatory provisions. This dialogue should take into account new results of basic research, risk assessments concerning hazard, exposure and impacts on environment, and health and safety. The dialogue should also design, on a contingency basis, alternative regulatory provisions for immediate implementation should the need arise.

- Most experts on the risks of nanoscaled materials in food and cosmetics agree that negative effects are unlikely but cannot be excluded (e.g. for particles <20 nm). For many products that are labelled, or even advertised, as containing nanomaterials (sometimes labelled as "Nano"), no risk assessments have been conducted, partially because it is not known if or what nanoscaled material is used. With such high uncertainty, IRGC recommends a risk management strategy of precautionary vigilance, which includes strict monitoring of effects, informed consent by the users of these materials, containment of effects in terms of space and time (to make sure that nanoscaled materials can be removed from the food processing stream if more severe risks become visible) and a negotiation between food producers and food consumers about the level of uncertainty that both sides are willing to accept.
- Since nanotechnology is related to a relatively high degree of controversy, it seems prudent to include major stakeholder groups in the phase of risk evaluation (see Section 3.4) and in the design of risk reduction measures. As recommended before, this would necessitate a neutral platform which could be used as a foundation for this dialogue between regulators, industry and civil society. On the global scale, organisations such as the United Nations Educational, Scientific and Cultural Organization (UNESCO) could provide such a platform.
- Because food and cosmetic products are manufactured and sold on a truly international basis, there is a need for regulatory processes to be harmonised between countries. In particular, regulators worldwide should work together to streamline and structure their different and often uncoordinated activities with a view to standardising risk assessment approaches and responding internationally if new scientific results warrant new risk assessments, management or regulatory activities. The work of the ISO (particularly of Technical Committee 229) and of the OECD Working Parties (on Manufactured Nanomaterials and Nanotechnology) are important steps in achieving the international coordination of risk assessment protocols, risk management strategies and risk communication campaigns.

**There is a need for international coordination of risk assessment protocols and risk management strategies**

Industry should use a voluntary code to establish an enforceable and transparent process of self-regulation

- Policy implementation remains the responsibility of national governments. It is therefore for national governments, whether or not members of the OECD, to work together to agree and implement an internationally harmonised approach to risk assessment and management. In effect, national laws and regulatory processes should be aligned through the voluntary action of separate governments. This may best be achieved, as a first step, by the OECD taking steps to include within the work of its working parties representatives of all governments with an interest in nanotechnology.
- There is no international structure to monitor policy implementation and its effectiveness. However, as has been the case with GMOs, the WTO's arbitration process offers a process of "last resort" to resolve trade disputes between governments. A briefing paper published by Duke University School of Law [Duke L. & Tech. Rev. 0015, 2005] suggests that the WTO Agreement on Sanitary and Phytosanitary Measures, in requiring that such measures must be based on scientific measures, would "objectively balance the benefits and risks of trading in nanotechnology". Attention has also been given to whether or not the WTO's Trade-Related Intellectual Property Agreement "could act as a global regulatory device for nanotechnology" [Bowman, 2007]. This attention prompts IRGC to recommend that governments should collaborate within the WTO process in order to develop appropriately harmonised approaches before the lack of them leads to disputes requiring arbitration.
- Although new regulations specific to nanotechnology 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. Consequently, IRGC welcomes all activities that could lead to one or more codes. Such codes are not a substitute for regulation but an additional, and important, initial step to assure transparency and to facilitate safety and public health by private corporations.
- In an ideal world, there should be only one such code since 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 to choose from offers industry the option of adopting the code with the most lenient provisions. At the same time, however, the objectives between large and small companies are considerably different, regulatory requirements vary from one country to another and the responsiveness to public concerns is contingent on political cultures and communication. If a comprehensive and universal code were to be developed and applied worldwide, it should reflect

regional differences and regulatory styles. IRGC supports the idea of a single but flexible code but also acknowledges the immense difficulties in drafting, implementing and enforcing such a code.

- Even if a single voluntary code can be developed at some future date it may be prudent, as a first step, to work with a variety of competing codes even if the situation is unsatisfactory and may cause certain problems of legal liability. IRGC therefore recommends a step-by-step approach that begins with a variety of parallel codes each focussing on different industry sectors and product areas. Such an approach may be more effective and easier to implement than seeking a minimum consensus for a one-size-fits-all solution. Once these codes have been established it would be of value, in a second step, to harmonise the requirements and standards within each code, so that their effectiveness can be benchmarked. This may also have serious legal implications for business: in some jurisdictions compensation claims for negligence or false advertising may be granted if it can be shown that a company failed to adopt best practice when signing up to a voluntary code. So, 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 for failing to adopt best practice.
- Voluntary codes should not only address the physical risks of nanomaterials in food and cosmetics, but should also include ELSI that often form the basis for public perceptions and concerns. To include ELSI in voluntary codes requires an intensified research programme for characterising and, where possible, quantifying such impacts and measuring public concerns and attitudes. These investigations are essential for designing the most appropriate risk management and communication measures.
- Voluntary codes with no provisions to enforce action or compliance, in other words with “no teeth”, would risk being branded as mere window-dressing for public relations purposes. Such codes are likely to fail and may even be more devastating to public opinion than having done nothing at all. Adopting best practice and a transparent process of risk assessment and management, over the entire life-cycle, are necessary conditions to the use of voluntary codes of conduct as a credible means of assuring consumer and workplace safety.

**Voluntary codes should address both physical risks and ethical, legal and social issues that often form the basis of public concerns**

## 3.6 Recommendations for risk communication

- Past experience has shown that the "hide, wait and see" strategy transforms the debate into an almost inevitable communication disaster and can both aggravate economic and reputation risks and increase the likelihood of litigation. Engaging in a proactive dialogue may be challenging, particularly for the food industry, due to their extended non-involvement in the nanotechnology debate and because of past experience of the GMO debate. IRGC is convinced, however, that becoming an active player in the debate provides the sole opportunity to reduce distrust, increase credibility and provide the necessary incentives for a positive outlook on nanotechnology.

As a first step, industry and NGOs could engage in a dialogue to jointly develop a blueprint for defining and characterising nanomaterials

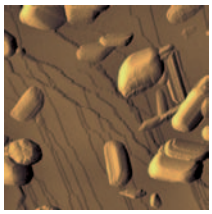
- As a prerequisite for successful communication there is a need for all stakeholders to collectively agree on a definition and characterisation of nanoscaled materials. As a first step, industry and NGOs could engage in a dialogue to jointly develop a blueprint for defining and characterising nanomaterials. Success in doing so will allow both of these key stakeholder groups to communicate their perceptions of nanotechnology and its uses in the same way – the foundation for a genuine dialogue. If there is no agreement on the basic "facts" (including uncertainties and ambiguities) there will be no chance of improving public understanding or resolving conflicts.
- Communication and education concerning environment, health and safety risks and ethical, legal and social issues should be improved. Such communication should involve full disclosure and take place in an inclusive and transparent environment. For this purpose, better training opportunities and professional risk communication practices should be initiated for all stakeholders involved in the governance of nanotechnology risks.
- IRGC sees a particular need for more training and practice in risk communication. Many problems of losing trust or public credibility in the food and cosmetics industries derive from unnecessary secrecy, behaviour that is not transparent and unprofessional attempts at risk communication.

The objective of this policy brief has been to draw some major lessons for policy-making and risk governance by applying the IRGC risk governance framework to the field of nanoscaled materials in food and cosmetics.

The IRGC framework provides a viable and productive tool, both for identifying problems and deficits in the risk governance process and for developing actions to improve the process. IRGC's analysis has shown that there are problems at all phases of the risk governance of nanotechnology in food and cosmetics. These include the lack of a clear, internationally accepted and approved definition of nanomaterials, almost no hard data regarding which nanomaterials are found in which specific products, and very limited scientific knowledge of the risks associated with the nanoscale ingredients or the products that contain them. As a result, the general public, with only limited knowledge of nanotechnology, is being influenced by communications which are based more on societal values than scientific evidence. Consequently, concerns about health risks are growing, even though there is, as yet, no substantive evidence to justify these concerns.

Without a harmonised definition of nanomaterials that satisfies the needs of regulators, progress will be difficult to achieve. Agreeing upon and adopting such a definition is therefore a necessary first step. This will make it easier for companies to state the inclusion – or absence – of such materials in their products and will also provide the principal criteria for what should, and what should not, be subject to a full risk assessment. Risk assessments themselves will remain problematic until appropriate methodologies have been developed and approved, and even this will be insufficient unless these methodologies are internationally harmonised. Without this harmonisation, it will not be possible for countries to accept the results of tests conducted elsewhere. Given the speed with which nanotechnology is developing, and the huge number of possible applications for it, such an international approach is essential if scientific knowledge of risk is going to keep pace with the speed of product development and commercialisation. It is also essential if the technologies – and their benefits – are going to be transferred to developing countries. Harmonisation will require the collaborative efforts of many national governments, coordinated by the OECD and the WTO.

In the absence of hard facts about the uses of nanomaterials and their risks, many of the decisions being made now are based on value judgements. Notwithstanding the potential economic value, as well as the direct and indirect consumer benefits, the introduction of nanotechnology in food and cosmetics is also accompanied by concerns about human health and environmental safety as well as ethical, legal and social concerns. For the pathways of ingestion and dermal applications,



Nanoparticle of titanium silicide embedded in silicon

**Harmonisation of risk assessment methodologies will require the collaborative efforts of governments, coordinated by the OECD and the WTO**

studies so far do not allow for a conclusive judgement about the potential health and environmental risks. However, due to the complexity, uncertainty and ambiguity of the knowledge surrounding the impacts of nanoscaled materials on human health and the environment, public authorities, industry, academia and NGOs recommend occupational protection measures as a means to avoid undue exposure and suggest closed systems for working environments in which nanoscaled materials are processed.

**Proposals for voluntary codes are evidence of efforts by industry and others to facilitate best practice in risk governance**

The various proposals for voluntary codes of conduct are evidence of the efforts being made by industry and others to facilitate best practice in risk assessment, management, evaluation and communication. They also illustrate a general willingness to initiate a constructive dialogue with and between stakeholders. Such codes aim to combine evidence-based risk assessment with a precautionary approach for cases in which high uncertainty and ambiguity prevail. Due to the global nature of this issue, IRGC repeats its recommendation that such multi-stakeholder dialogues should be conducted under the auspices of respected international organisations.

IRGC hopes that the recommendations contained in this policy brief will provide decision-makers with further ideas for actions to improve the risk governance of nanotechnology applications in food and cosmetics.

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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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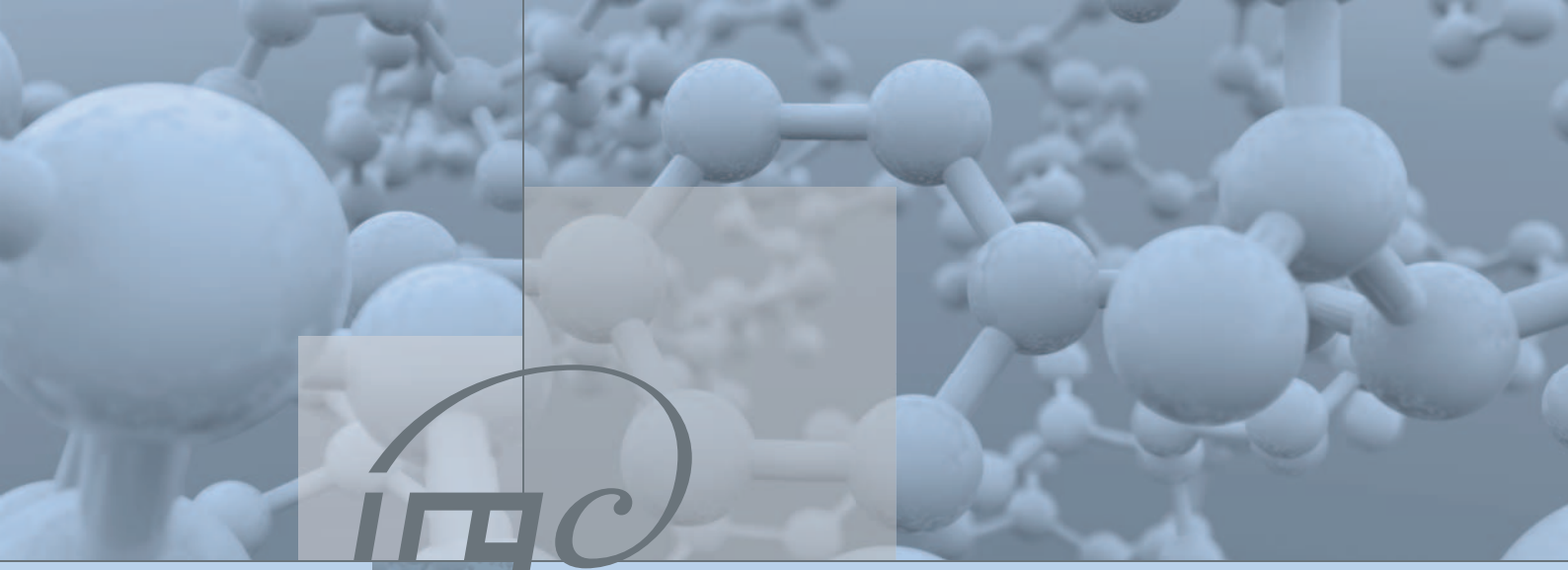


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