### Overview of Current Development in Manufactured Nanomaterials (France)

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<tr>
<th>Date</th>
<th>Major Development</th>
<th>Participants of WPMN meeting</th>
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<td>July 2010</td>
<td>(N/A)</td>
<td>Mr. Philippe CHEMIN etc (total 7)</td>
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<td>Oct 2009</td>
<td>(N/A)</td>
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<td>March 2009</td>
<td><strong>Action at European level</strong></td>
<td>Mr. Philippe CHEMIN etc (total 7)</td>
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<td>- Support by the French Presidency for the workshop held by DG SANCO in Brussels on 2-3 October 2008 on productive dialogue on nanotechnology safety: this workshop brought together all stakeholders in the field. A status report was presented on European and international work, including that of the OECD. Some ten actions emerged from this discussion and have been placed online. (<a href="http://ec.europa.eu/health/ph_risk/ev_20081002_en.htm">http://ec.europa.eu/health/ph_risk/ev_20081002_en.htm</a>)</td>
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<td>- At the initiative of the French Presidency, in 2009 the European Public Health Programme includes a joint action (EC/Member States) on nanomaterial safety. France will co-ordinate this action with the interested Member States. The studies, which will be prioritised, will take into account European and international work (ISO and OECD).</td>
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<td><strong>Action at national level</strong></td>
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<td>- Drafting of legislative provisions contained in Article 37 of the draft programme act concerning the implementation of the Grenelle Environmental Round Table (Grenelle I), introducing an obligation to report any nanomaterials released on the market; <a href="http://www.senat.fr">www.senat.fr</a>.</td>
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<td>- Holding of a national public debate in 2009 on general options for developing and regulating nanotechnologies.</td>
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<td>- On 10 July 2008, the National Consumer Council (<em>Conseil National du Consommateur</em>) was mandated to create a working group to discuss the means of providing simple and understandable consumer information on nanotechnologies, their benefits and potential risks and the precautionary measures required. It should issue its opinion by the end of the first quarter of 2009.</td>
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<td>- The CNRS programme bringing together the Centres of Competence in Nanoscience and the CNRS Department of Human and Social Sciences (SHS) invited the scientific community to an interdisciplinary residential workshop on the legal regulation of nanosciences and nanotechnologies hosted by the Centre of Competence in Nanoscience of Île-de-France (<em>C’Nano IdF</em>). The workshop was held on 27-30 January 2009 and revolved around three broad themes in response to the proposals of the Grenelle Environmental Round Table</td>
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These three themes are as follows:

1. Incorporating the risks involved in nanoparticles and nanomaterials
2. Sources and techniques for setting standards in the field of nanosciences and nanotechnologies.
3. Patents in the field of nanosciences and nanotechnologies.

REPORTS AND OPINIONS:

- **Opinion of the High Public Health Council** (*Haut Conseil de Santé Publique*) of 9 January 2009 on the safety of workers exposed to carbon nanotubes in which it recommends – pending a registration, evaluation and possible authorisation procedure and in line with the precautionary principle – that the production of carbon nanotubes and their use in manufacturing intermediate products and consumer and health products be carried out under conditions of strict containment in order to protect workers from being exposed when these activities involve a risk of aerosolisation and/or dispersion. This recommendation also applies to research laboratories. The HCSP also made recommendations on the identification of potential exposure situations and nanosafety, along with recommendations on metrology research and risks.
  

- **Report by the French Agency for Environmental and Occupational Health and Safety** (*Agence française de sécurité sanitaire de l’environnement et du travail*, AFSSET) on nanomaterials and occupational safety published in July 2008. It shows the need to establish good production practices in order to protect workers from exposure to nanomaterials, the dangers of which are largely unknown.
  
  [http://www.afsset.fr/upload/bibliotheque/308470480642484657342914409116/18_nanomateriaux_avis_afsset.pdf](http://www.afsset.fr/upload/bibliotheque/308470480642484657342914409116/18_nanomateriaux_avis_afsset.pdf)

The Agency is currently exploring nanomaterials-related risks to the general population and in the environment.

- **Recommendations for assessing the toxicity of medicinal products containing nanoparticles** have been finalised by the French Agency for the Safety of Health Products (*Agence Française de Sécurité Sanitaire des produits de santé*, AFSSAPS):
  

- The issue of cosmetics is currently being investigated, since the AFSSAPS is hampered by the failure of manufacturers to provide information and by assessment difficulties due to the lack of suitable metrological and toxicological methods.

AFSSA highlights the need to implement a system for detecting and regulating the marketing of any product containing nanoparticles. In addition, given the still-fragmentary knowledge of what happens to free nanoparticles in porous environments, it also recommends measures to ban any use of nanoparticles that would involve direct injection into the water table. Furthermore, a number of avenues for research are suggested in order to supplement the information available.

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<th>June 2008</th>
<th>(N/A)</th>
<th>Mr. Philippe CHEMIN etc (total 6)</th>
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<td>Nov 2007</td>
<td>The NanoForum being held at the Conservatoire National des Arts et Métiers (CNAM):</td>
<td>Mr. Philippe CHEMIN etc (total 8)</td>
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<td>At the government’s request, the CNAM has organised a series of regular meetings between the various players concerned (researchers, manufacturers, associations, journalists, government administrations, etc.) focusing on the health, environmental and social aspects of the industrial development of nanotechnologies.</td>
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<td>Following the opening session in June 2007, a concrete case – the use of nanoparticle TiO2 in cements – was discussed by a group of scientists, government officials, citizens, manufacturers and NGOs. The conference held on 6 December 2007 addressed the use of nanomaterials in cosmetic products. The session to be held on 7 February 2008 will deal with nanomaterials in food.</td>
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<td>• Proposals developed during the French government’s environmental forum (Grenelle de l’environnement):</td>
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<td>The summary of conclusions of the second roundtable – “Health-environment” Programmes: C) Emerging risks: Anticipating the risks of nanomaterials – formulated the following proposals:</td>
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<td>• To hold a public debate on this issue organised by the Commission Nationale du Débat Public (National Commission for Public Debate) in 2008</td>
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<td>• To implement mandatory labelling on the presence of nanoparticles in consumer products by 2008</td>
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<td>• To require that cost/benefit analysis be conducted systematically before marketing products containing nanoparticles or nanomaterials by 2008</td>
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<td>• To develop a regulatory framework for products containing nanomaterials</td>
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<td>• To ensure that action is taken to inform and protect employees on the basis of the findings of studies currently being conducted (in particular, by the Agence Française de Sécurité Sanitaire de l’Environnement et du Travail, the agency responsible for environmental and occupational health and safety)</td>
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| April 2007 | - Government support for further research on risks [call for research projects by the National Research Agency (ANR), in the wake of work financed in 2005 and 2006].  
- Initial approaches to evaluating risks to the general population and consumers.  
- Feasibility study for a prospective follow-up of a cohort of exposed workers (including researchers).  
- Ongoing establishment of an independent scientific observatory to monitor and issue warnings on health and social risks, and to guide the ANR’s calls for projects.  
- Under preparation: a standing public forum on health and social risks.  
- Opinion of the CNRS Committee on Ethics for the Sciences (COMETS) on the ethical issues relating to nanoscience and nanotechnology.  
- Opinion of the National Consultative Ethics Committee for Health and Life Sciences (CCNE) on the ethical issues raised by nanosciences, nanotechnologies and health.  
- Communication on “The Development of Nanotechnologies” released by the Council of Ministers of 14 March 2007. |
| Oct 2006 | **Current developments in France regarding the safety of manufactured nanomaterials**  
It is worth recalling first that France does not view manufactured nanomaterials in isolation but considers it essential to link their development, promotion and worldwide dissemination to the development, promotion and dissemination of nanotechnologies and the various products of such technologies. Consequently, it is essential not to lose sight of impacts other than those relating to health and the environment, namely the ethical aspects of nanotechnologies, in the broad sense of the term, and of course the issue of social utility. It is for this reason that France would like the OECD Committee for Scientific and Technological Policy (CSTP) to adopt this more general vision of nanotechnologies and would like the two bodies to conduct their work in close collaboration.  
In 2005, the Ministry responsible for industry (Directorate-General for Enterprises – GDE), conducted a strategic study of nanomaterials, from a sustainable development perspective, which subsequently served as a basis for an action plan covering not only research and development (through support for collaborative projects) but also the international presence of France in this sector of activity. At the same time, the recommendation by the Ministry of Industry that industrialists think about their practices in terms of development and safety was followed up through the creation of a working party overseen by the ECRIN Association. While the work on standardisation now in hand within AFNOR’s Technical Committee on Nanotechnologies will help to clarify the metrological aspects, the Ministries responsible for health (Directorate-General for Health), Labour (Directorate-General for Labour) |

Mr. Philippe CHEMIN etc  
Mr. Marc-Henri BOUHIER
and Ecology (Directorate for Pollution and Risk Prevention) advocate the need to examine the health and environmental risks that nanomaterials/nanotechnologies may pose within the general framework outlined above, obviously in a spirit of prevention and precaution. It is for this reason that by as early as 2005 they asked AFSSET to draw up a summary report on the current state of technical and scientific knowledge regarding the:

- Typology, chemical and physical properties, biological and health effects of nanomaterials;
- current and future field of application for such nanomaterials;
- metrological tools currently available or under development;
- data relating to (current or potential) exposure of the general public and workers, and in particular the relevant parameters for characterising such exposure;
- impacts on human health.

The seminar organised on 19 October 2006 at the initiative of the Minister for Health will bring the representatives of the Ministries and public health and safety agencies and institutes working in the field up to the same level of information.

1. Developments in the regulatory field

Strictly speaking, there have been no developments to date. However, recommendations have been issued by both the Prevention and Precaution Committee (CPP) and the French Agency for Labour and Environmental Health Safety (AFSSET) regarding the need to take precautionary measures in the workplace and the general environmental, to list the nanomaterials produced or imported and to ensure that they are taken into account in the REACH Regulation. The reports referred to above were not sufficient, however, and on 29 June 2006 AFSSET was asked to draw up an additional report covering, in particular, the assessment of professional risks; the results of this additional study are expected in June 2007.

The Ministry responsible for health also sent submissions to the French Health Products Safety Agency - AFSSAPS (for drugs, medical devices, cosmetics), and to the French Food Safety Agency - AFSSA (for food products and drinking water). Work is currently in progress.

The aim of the inter-ministerial seminar of 19 October (see below) is to outline lines of action for government in the short, medium and long terms and, possibly, to propose some short-term measures.

2. Voluntary approaches or schemes

France intends to ask industry to provide information on the nature of the nanomaterials sold on the domestic market, as well as information regarding risks, exposure and types of use.

Some industries have developed and introduced their own systems to prevent worker exposure or releases to the environment.

The question needs to be asked whether it should be made mandatory for industry to provide information. How such an obligation could be
introduced and applied needs to be studied.

3. Risk assessment decisions

At this stage in the development of nanomaterials, there are no particular requirements in force in France regarding the risk assessment of nanomaterials. In theory, however, regulations regarding the sale of chemical substances currently in force in France and the EU could be used to gather information on the risks posed by manufactured nanomaterials.

However, the ECRIN association, whose founder members are the National Centre for Scientific Research (CNRS) and the Atomic Energy Commission (CEA) and whose aim is to promote relations between research laboratories and industry, currently oversees a working party on industrial practices in the manufacture, packaging and processing of nanomaterials. This association has created a “nanomaterials safety” site and set up four working parties. The Association is also active in standardisation groups.

The co-ordinator of the European NANOSAFE programme is a member of the CEA.

4. Developing good practice guides

On 23 August 2006 the INRS was approached and asked to draw up a good practice guide for the protection of workers (operators) exposed to nanomaterials, as proposed by AFSSET in its July 2006 report (proposal X.6).

5. Research programmes or strategies developed in response to the safety issues raised by nanomaterials for man and the environment

“Few public bodies in France are currently working on the issue of „nanoparticles – health”. Although a number of laboratories are investigating the biological effects of ultrafine particles in air pollution, very few of them are currently addressing the impacts of man-made nanoparticles.”

Two research projects were accepted from call for tender 2005 PNSE/PST issued by the National Research Agency (ANR):

- In situ characterisation of the surface of ultra-fine aerosols;
- Toxicology of nanoparticles: influence of size, composition, and surface reactivity on lung and kidney effects.

In 2006, the ANR will endorse new projects on these same subjects and AFSSET will launch a project in 2006 to develop metrology.

A European project, NANOSAFE2s, co-ordinated in France by the CEA, is designed to develop technological solutions to the problem of nanomaterials safety. NANOSAFE2 is divided into four separate components. The aim is to develop technologies to detect and track nanomaterials in the environment, since at present nanoparticles can be counted but cannot be readily identified. Two other goals are to develop methods for determining toxicity and limiting exposure to nanoparticles and their dispersal in the environment. Lastly, international standards must be proposed and information given to the public.
6. Public information/consultation and the parties concerned

6.1 Public debate

_The Prime Minister has launched a national debate in which the views of experts will be set against the expectations of the public. The organisation of this debate has been entrusted to the Ministries of Research and Industry, and will also involve other Ministries._

In terms of exchanges and dialogue, mention should also be made of the work of the ECRIN Association, even though the public is not directly involved. A number of theme groups (clubs) have been set up, two of which, the Nanomaterials Club and the Risk Club, have organised two one-day workshops on the integrated approach to risk management (9 November 2004 and 23 March 2005).

Lastly, as part of public communications, the Cité des Sciences et de l’Industrie is currently organising a travelling exhibition entitled “Nanotechnologies and Society”. This exhibition sets out to explaining nanotechnologies to the public, to present its applications and potential and to inform discussions and research regarding the risks relating to its use.

There have also been several initiatives in France aimed at stimulating or organising debate. In 2005, following selection of the “Minalogic” project proposed by the city of Grenoble as part of the Poles of French Competitiveness programme, the Communal Community of the Grenoble conglomeration (“La Métro”) sought to bring together a group of experts to analyse procedures for consulting the inhabitants of Grenoble about technological choices involving their city and to secure their active participation in decisions taken by local authorities. The mission report was published in September 20057. We understand there is nearly no possibility for debating the validity of these technologies.

Other ideas about how the public debate might be enhanced will very probably emerge from the inter-ministerial seminar due to be held on 19 October.

6.2 Associations concerned with nanotechnologies

Since 2002 in Grenoble, Pièces et Mains d’Oeuvre (PMO) has been gathering critical information on nanotechnologies, which it publishes on its Internet site8, and organising public debates. It has recently published an introduction to nanotechnologies as well as an opuscule stating “that the nanotechnologies (and beyond the "converging technologies"), are not a scientific project, but a political and philosophical. A project of eugenics and of artificialisation of life”.

Furthermore, Vivagora10, an association founded in 2003 by two science journalists, organises an annual series of debates to which scientists (from both the hard and human sciences), industrialists, political leaders, associations and the public are invited. In 2006, the third series of debates is devoted to nanotechnologies (who are the players, what promises do nanotechnologies hold, what are the challenges?). The recommendations to emerge from these exchanges of points of view will be presented at the concluding conference in September 2006.
In addition, the RISE association (Réseau International Santé Environnement)\textsuperscript{11}, created in 1995, holds annual meetings aimed at promoting public debate on environmental health issues. In 2006, these meetings are to be devoted to the challenges of nanotechnologies.

The Entreprises pour l’Environnement (EpE) association\textsuperscript{12} is holding a “public consultation” on nanotechnologies at the end of October.

**Other information**

**Benefits**

The Prevention and Precaution Committee (CPP) recalls that the direct and indirect benefits of developing nanotechnologies for society and individuals are currently unpredictable. Once it is possible to identify these benefits, they must be systematically examined in relation to the risks they potentially pose.

**Ethical and societal issues**

The Dupuy-Roure report\textsuperscript{13} provides a robust presentation of these issues and the report by Roure, Gorichon and Sartorius\textsuperscript{14} discusses one specific aspect of nanotechnologies, namely radio labels.

The CNRS Committee on Ethics for the Sciences (COMETS) is also preparing, in collaboration with the National Consulting Committee on Ethics (CCNE) for health and the life sciences, an opinion on the ethical issues relating to the development of nanotechnologies, which are addressed to the research community.

Under the heading “Taking account of societal aspects”, the Prevention and Precaution Committee (PPC) recommends that:

- research bodies should be encouraged to develop programmes on the social and ethical implications of nanotechnologies;
- the awareness of researchers and laboratory workers should be raised with regard to the ethical implications of nanotechnologies and the challenges it poses to society. In this respect, it is important to support “partnerships” (or to create a forum for discussion) between researchers and actors from civil society (both directly and through trade unions, associations, etc.).

**Synergy and co-operation**

We feel that it is essential to pool knowledge at the international level to prevent risks arising from nanomaterials: this effort must be conducted at the international level in order to go beyond issues relating solely to intellectual property, industrial confidentiality and patents, and to work together in the general interest. The OECD can play a role in this respect.