A multi-stakeholder dialogue providing inputs to implement the European Code of Conduct for Nanosciences & Nanotechnologies Research

Synthesis report on codes of conduct, voluntary measures and practices towards a responsible development of N&N

Published under the NanoCode project as deliverable D1.3 for WP1

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SYNTHESIS REPORT ON CODES OF CONDUCT, VOLUNTARY MEASURES AND PRACTICES TOWARDS A RESPONSIBLE DEVELOPMENT OF N&N

Published under the NanoCode project as deliverable D1.3 for Work Package 1 (WP1).

NanoCode is a support action (SA) funded under the 7th Framework Programme (FP7) in the Science in Society (SiS) area

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The main sources of the information contained in this report are the individual Country Reports prepared by each of the Consortium partners that covered the situation in their own country.

September 2010

The Commission Recommendation of 07/02/2008 on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research is available at:

http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf

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Table of Contents

1. The NanoCode Project

The objective of NanoCode is to define and develop a framework aimed at supporting the successful integration and implementation, at European level and beyond, of the Code of Conduct (CoC) for nanosciences and nanotechnologies (N&N) research [1] as proposed by the European Commission.

The unique characteristics and properties of materials at the nanoscale can lead to a huge range of valuable new applications and benefits, but they may also pose novel challenges to manage the technological and societal implications associated with them.

The CoC tackles most of the issues emerged in recent years from the debate on the governance of nanotechnologies, and is an important reference point and guide for the principles that should underpin research activities, the interaction amongst key stakeholders and, in general, the "good" governance for the responsible development of nanotechnologies.

The NanoCode project aims to facilitate a multistakeholder dialogue on the CoC at European level and in selected Associated Countries, to improve and strengthen the awareness about the CoC, promote trust-building among stakeholders and, as an ultimate goal, develop the above mentioned framework to favour the wider application of the CoC.

Based on the opinions of stakeholders and on the experience with other voluntary codes, measures and practices aimed at the responsible development of N&N, this framework will:

- Identify those practices that support the compliance with the principles and actions characterising the EC's CoC and help its implementation;
- Propose criteria and indicators to assess the level of application of the CoC;
- Suggest and evaluate incentives and disincentives to make more attractive the use of the CoC;
- Propose possible integrations and changes to the CoC to facilitate its adoption.

The development of a practical tool (the CodeMeter) to help stakeholders to assess their performance in complying with the CoC's principles will form a key element of the framework.
The project activity is geared around 4 pillars:

- Analysis of existing/proposed Codes of Conduct, voluntary measures and practices for a responsible R&D in N&N and identification of the relevant stakeholders *(condensed in Country Reports for each of the Consortium countries, funneled in a publishable Synthesis Report)*;
- Consultation of stakeholders to assess attitudes, expectations, needs and objections regarding the EC CoC *(survey through an electronic questionnaire to selected stakeholders and structured interviews to a restricted number of them)*;
- Design and development of a CoC MasterPlan (*the framework*) enabling the implementation and articulation of the CoC, including future changes, criteria and indicators of the level of application, best practices, incentives/disincentives and a performance scheme (CodeMeter) for the adoption of the CoC *(a series of National Workshops to discuss the draft MasterPlan and the testing of the CodeMeter with selected stakeholders are foreseen)*.
- Communicate in a suitable form and to the widest possible audience project objectives, findings and outcomes *(among the instruments planned to this end there are the project website, a series of booklet on the application of the EC CoC, a series of National Conferences and an International Conference)*.

The project brings together 10 partners representing 8 European countries, plus Argentina and South Africa.

[1] http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf

2 National activities on the governance of Nanotechnologies

This section provides a synthetic assessment of the regulatory and policy situation with reference to the activities in the field of nanotechnology, as it results from (mainly) the Country Reports prepared by the partners of the NanoCode Project. The objective is to point out awareness and attitudes of the various stakeholders in the different countries toward the responsible development of nanotechnologies and to identify the level of application of the EC CoC, or the compliance of their activities with its indication/principles.

2.1 General overview

The need to govern the development of nanotechnologies with the aim of avoiding the potential risks associated with them is getting an increasing attention from governments, regulatory agencies, industry and other stakeholders that are taking position in defining adequate regulations and risk management structures with reference to both Environment, Health and Safety (EHS) issues and Ethical Legal Social Aspects (ELSA). The debate refers in particular to sectors such as chemicals and materials, cosmetics, foods, occupational health and worker safety, environmental safety, medical devices and pharmaceuticals.

So far, nano-specific regulation is still rare. The general attitude of the authorities is to apply existing regulations to nanomaterials and nanoproducts and to support their implementation, guidance and standards are developed. In a few cases, specific amendments are under evaluation. Till now, the only case of approved regulation including specific requirements for nanotechnology-related products is the new EU cosmetic regulation [European Union 2009], while a discussion on this topic is on going about the EU novel foods regulation [2].

The adoption of voluntary self-regulation measures, as well as the sharing of information, dissemination of best practices and common principles, is generally recognized as a short/medium term option that could complement existing regulatory schemes.

A milestone on the matter is expected in 2011, when the European Commission will respond to the European Parliament about the adequacy of existing regulations with respect to N&N [European Parliament 2009].

In Europe, several of the activities in terms of nanoregulation are promoted and supported by the European Commission and a large part of regulatory provisions at national level mirror the framework defined at the European level.

Generally speaking, the level of engagement in nanotechnology governance in all countries considered in this report is closely related to their level of activity in N&N (considered in terms of parameters such as the level of research, extent of public funding, number of organizations involved, activity).

Countries with a very strong commitment in nanotechnologies, like **Germany**, **UK**, **France**, **The Netherlands** or **Switzerland**, in some case, with the help of specific national initiatives, are particularly active in

[2] The new Regulation on Novel Foods (repealing Regulation (EC) No 258/97) is still in consultation at the European Parliament. More information on the legislative procedure is available at http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=COD/2008/0002

providing support to the development of N&N. In this setting the initiatives that address issues related to nanotechnology governance are also flourishing, basing on their tradition and culture.

Interestingly, these initiatives follow many of the principles guiding the EC CoC, sometimes proposing quite similar actions, but the Code itself is generally not adopted or recommended and only sporadically mentioned. As an example can be cited the Netherlands that are planning to introduce the compliance with the EC CoC as specific condition for funding projects in this field.

In the other European countries considered in the report (i.e. **Spain**, **Italy** and the **Czech Republic**) there are also, promoted by different kinds of stakeholders, initiatives referring to EHS issues and ELSA associated with nanotechnologies, but they are more limited in terms of scope and extent and often tackle just single cases.

With respect to the former Countries, the level of activity in nanotechnologies is lower (though increasing), and even if N&N are included among the priorities of the government R&D programs, do not have a consolidated National initiative to support this effort. This fact may determine a certain lack of coordination among public governing bodies, industry and academia on the matter, which is identified as a bottleneck to address effectively the governance of nanotechnologies.

Activity in nanotechnologies in the remaining two countries of the Consortium, **South Africa** and **Argentina,** is lower than that in the European Countries. However, the role of N&N in their national R&D programmes is increasing and there are relevant initiatives within the public research sector. The involvement of industry is, on the contrary, still limited. A particular mention is needed for South Africa where a specific national nanotechnology programme has been established in 2006 to boost the development of the sector. Particular attention is given to applications relevant for social development (water, energy and health).

In both countries specific agencies have been set up to deal with the governance of N&N and in particular in relation to EHS issue and ELSA. A responsible approach to the development of N&N is seen as an opportunity to underline their societal and economic impact and to improve the coordination among the national actors interested in the N&N development. Both South Africa and Argentina (the latter also in cooperation with Brazil) have started actions towards developing their own code of conduct for nanotechnologies, that has several points of contact with the EC CoC.

To complete the picture, initiatives and policies toward nanoregulation/governance have been briefly investigated also in a number of countries not belonging to the Project Consortium. In Europe, have been considered **Austria**, **Norway** and **Finland,** which are rather active in nanotechnologies. It has been found that in these countries EHS issues, and, to a lesser extent, ELSA, are generally taken into account with funding for R&D projects and that they actively participate to European networks and projects. A particular attention is given to the safety aspects related to the handling of nanomaterials. Most of the National Occupational Health Institutes have activities in this area.

These Countries are characterized by a well-established national strategy for N&N and these strategies explicitly mention the need for actions to address safety and, in some cases, also ethical and societal aspects of N&N [OECD, 2010].

In terms of nanoregulation, they are closely following the development of REACH and other regulation on this matter at EU level and also participate to the work of ISO[3] and OECD[4] on nanotechnologies.

As it resulted from this analysis, the EC CoC has not been recommended or adopted in any of these countries. However, it is worth to mention the recent Austrian Nanotechnology Action Plan, were the need for compliance with the precautionary principle as a prerequisite for the marketing of nanorelated products is explicitly recommended [Lebensministerium, 2009].

Outside Europe, the most active countries in nanotechnology governance are USA, Canada and Australia.

In the **USA**, EHS issues are among the priorities of the National Nanotechnology Initiative (NNI). Funding for research in this field has steadily increased in the last years, involving several of the agencies coordinated by the NNI. The main regulatory agencies have set up specific task forces and published several documents on the matter. In particular, the Environmental Protection Agency (EPA) launched in 2008 the NanoMaterial Stewardship Program (detail are reported in chapter 3) and may introduce in the near future specific regulatory amendments for nanomaterials.

As for ELSA, in the NNI there is a particular focus on the societal dimension of N&N, with programmes devoted to education and public communication (including outreach and engagement). Some centres are dedicated to these themes (such as the National Science Foundation Center for Nanotechnology and Society).

Canada and **Australia**, within their respective national strategies for N&N, have launched important programmes on EHS issue and ELSA and have published in-depth reviews devoted to the governance of N&N. In these documents they explicitly identify the need to adopt a precautionary approach in the development of N&N.

These countries are also currently discussing, through stakeholders and public consultation, possible reform of their regulatory system to include specific requirements for nanomaterials and nano-related products (in particular in the case of chemicals). Canada is planning to introduce a mandatory reporting scheme for nanomaterials, while in Australia a voluntary scheme was recently concluded.

When considering the Asian countries, in particular **China**, **Japan**, **Korea**, **India**, **Taiwan**, which are deeply involved in nanotechnology, it turns out that the responsible development of nanotechnology is getting an increasing attention.

Research initiatives dealing with EHS issues are underway in these countries and specific working groups on nanomaterials have been established at institutional level with reference, in first place, to the occupational and health safety aspects. In Korea**,** for instance, the Ministry of Education, Science and Technology (MEST) has recently launched a project to define possible actions to deal with the societal implication of

[3] See for reference the website of the International Standard Organisation, Technical Committee TC 229 (ISO TC 229) : Nanotechnologies at http://www.iso.org/iso/iso_technical_committee?commid=381983

[4] See for reference the website of the OECD – Working Party on Manufactured Nanomaterials (WPMN) and Working Party on Nanotechnology (WPN) at http://www.oecd.org/site/0,3407,en_21571361_41212117_1_1_1_1_1,00.html

nanomaterials, including both safety and ethical aspects. The definition of a code similar to the EC CoC has also been considered[5].

These countries actively participate, mainly through the OECD and ISO working groups, to the debate underway worldwide on governance and standardisation of N&N. In particular, Japan is chairing the ISO 229 Working Group dealing with "Measurement and Characterization" (WG2) and China the WG devoted to "Material Specification" (WG4).

None of the Asian countries indicated above is planning specific regulatory actions for N&N, though they are watching with particular attention (also because of the possible impact on trade) the regulatory developments in this area in Europe and USA.

In conclusion, considering, in a very qualitative way all the initiatives referring to nanotechnology governance under development in the countries surveyed, in can be said that in all of them the responsible development of nanotechnologies is considered with (increasing) attention though the level of action can vary quite considerably from country to country. In terms of initiatives envisaged, all them reflect some of the guidelines of the EC CoC. In particular promotion of good governance (foster stakeholder awareness, favour an inclusive approach, establish key priorities - guidelines 4.1), and due respect to precaution (guideline 4.2).

At the same time, some of the key actions proposed by the EC CoC, such as prohibition, restrictions and limitations regarding ethical and safety aspects (guidelines 4.1.15, 4.1.16, 4.1.17) and actions towards wide dissemination and monitoring of the CoC (guidelines 4.3) are generally not explicitly taken into account and this is certainly a gap the EC CoC could fill.

The following chapters synthetically describe in detail approaches and actions taken with respect to N&N governance in the countries referring to the Project Consortium (listed in alphabetical order). The objective is to point out the differences and similarities with the EC CoC, useful to address its implementation and further articulation.

2.2 National strategies

2.2.1 Argentina

During the last decade, there has been an important growth in research and development in N&N in Argentina. Considering that it promises to have a positive impact on the economic and social development of the country, nanotechnologies have been explicitly defined as a priority by the Ministry of Science and Technology and Productive Innovation, which is the main funding institution of N&N, with several programmes in this area. Among them are some specific "Strategic Area Projects (PAE)". In particular, the Interdisciplinary Centre of Nanoscience and Nanotechnology (CINN), the Network for the design, fabrication and characterization of micro and nanodevices for application in space, safety and health, and FONARSEC a programme to promote the development of new products based on N&N.

Among the other governmental institutions involved in N&N can be mentioned:

[5] International Nanomaterials Ethics Workshops: good practices, training and dialogue for governance of nanomaterials (INEW 2010), 25 March 2010, Seoul, Korea - http://cnmt.kist.re.kr:8080/Symposium/workshop/workshop2.htm

- The Argentine Foundation for Nanotechnology (FAN) that promotes innovation in N&N, providing risk funds for the production of concrete innovative products and to foster the increase of added value to local products
- The Argentine Technological Centre (FONTAR) also financing some projects in the N&N fields.
- The Argentine-Brazilian Centre for NN (CABNN) that have been established in 2005 to promote bilateral agreement on scientific and technological cooperation and training
- The National Committee on Ethics of Science and Technology (CECTE), dependent of the Ministry for Science and Technology (since 2001), including among its objectives to promote a socially responsible development of N&N.

In terms of public research institutions a relevant role is played by the Institute of Nanoscience and Nanotechnology (INN), within the National Commission of Atomic Energy (CNEA), whose mission is the development of NN within CNEA for peaceful nuclear and non nuclear applications.

Several other research centres and universities, as well as a dozen of private companies are active in nanotechnologies in the country [MINCyT, 2009].

All of the institutions monitored by the Argentina Country Report, though complying with general regulations regarding safety and regulatory procedures, do not have specific procedures for handling nanotechnology-related products. Concerning ethical principles, a few institutions have ethical codes or committees such as the Argentine Physical Association (Code of Ethics for physicists[6]), the National Council for Science and Technology (CONICET), the Asociación Argentina de Biología y Medicina Nuclear, and others, but none of them mention N&N explicitly.

However, there is a growing consciousness among the scientific and technological community in this region about the importance of paying attention to social and environmental aspects of N&N, as emerged during an important bilateral meeting organized by CECTE in 2008, the *Argentine-Brazilian Conference for Responsible Nanoscience and Nanotechnology Research [CECTE, 2008]*. During the event was agreed upon that Argentina and Brazil must seriously consider adopting a CoC in N&N following similar lines as the European CoC.

Among some of the (other) actions proposed during the meeting were:

- creation of public databases with information about new nanomaterials, nano-related products, nomenclature and metrology, including negatives results
- creation of databases of possible evaluators, local and foreign for the evaluation of projects related to N&N
- evaluation of quality conditions, procedures and safety in private and public laboratories
- definition of norms and measures related to N&N
- evaluation of risks and the implementation of the precautionary principle.

Also topics concerning intellectual property rights, financing, social benefits of N&N applications were underlined, but, nevertheless, there is still considerable work to do with respect to implementing concrete measures for a safe and responsible N&N R&D and the discussion on the EC CoC could be an instrument to this end.

[6] www.fisica.org.ar

2.2.2 Czech Republic

The Czech Republic is characterized by a broad landscape in terms of R&D in N&N, with the main activities carried on at the institutes of the Academy of Sciences of the Czech Republic (ASCR), some of the major Czech Universities and other public and private research institutes. Several successful companies with productions based on N&N have grown up in the last years. They are generally SMEs having N&N as core activity, and some of them are playing a relevant role also at international level (in their specific market sector) [Prnka, 2008].

The Country has not yet elaborated a specific strategy or cooperation plan on N&N research, nevertheless some funding programmes have N&N among their objectives. In particular, structural funds including N&N R&D are provided within the programme "Research and Development for Innovation", managed by the Ministry of Education, Youth and Sports[7], and the programme "Enterprise and Innovation", managed by the Ministry of Industry and Trade.

Despite of a lack of coordination at institutional level, some interesting bottom-up initiatives were created with the aim to ensure cooperation in N&N among different organizations (university, research centers, industry). These virtual centres have been working quite successfully. Among them: the Czech Nano-Team, CABIOM–Carbon-based Biomaterials and Biointerfaces, Centre of Nanotechnology and Materials for Nanoelectronics, Nanomedic Cluster, NANOPIN Centre.

In March 2010 the "Czech Roadmap for Research Infrastructures" was approved by the Government and this document includes also structural funds for the development of 5 centres devoted to N&N, including the project for the "CEITEC – Central European Institute of Technology" in Brno devoted to R&D for life sciences and advanced materials.

Other two funding mechanism are managed by the Grant Agency of the Czech Republic and the Grant Agency of the Academy of Sciences of the Czech Republic (ASCR).

In particular, ASCR is managing the specific action *Nanotechnology for Society*, active for the years 2006-2012, supports N&N R&D in the following areas: nanoparticles, nanofibres, nanocomposites, nanobiology, nanomedicine, nano/macro interfaces, new effects and materials for nanoelectronics [8]. The other (several) projects on N&N funded by these agencies are within general programmes (not specific for N&N).

Funding of N&N research from international sources plays also an important role, especially the European Commission Seventh Framework Programme (FP7).

The possibility to develop a Czech Nanotechnology Initiative is under evaluation, and a first draft has been discussed during the Conference "Roundtable II Nanotechnologies in the Czech Republic" organized on June 3rd, 2010 in Prague.

[7] http://www.msmt.cz/

[8] http://www.czechinvest.org/data/files/nanotechnologies-preview-1232-en.pdf

Despite of the large number of research projects on N&N carried out in the country, none of them addressed specifically EHS issues or ELSA, though the attention on these matters is growing, as shown by the series of conferences, seminars, and short courses devoted organized in the last years[9].

At institutional level, the National Institute of Public Health, in cooperation with the Occupational Safety Research Institute and Regional Hygiene Stations, organized a national monitoring of workplaces using nanomaterials and compiled a list of 104 workplaces. Government delegates are also closely following OECD, ISO and EFSA (European Food Safety Authority) activities on N&N.

In conclusion, awareness of the topics related to the responsible development of N&N, as well as the level of dissemination of the CoC, are still quite limited. As a first step it is therefore necessary to disseminate information on the EC CoC, mainly using the existing bottom-up coordination initiatives and all other available communication channel. The Czech Nanotechnology Initiative under consideration may play an important role to this end.

2.2.3. France

France is in Europe second only to Germany in terms of government funding to N&N R&D. Investments in nanotechnology are made through the existing R&D programs as well as by special targeted measures, such as NanoInnov[10] and the national investment programme "Grand Emprunt"[11].

The Nano-INNOV plan was launched in mid 2009 by the French Research Ministry (Ministère de l'Enseignement Supérieur et de la Recherche) aiming to develop a strategy for the innovation in the field of N&N. The strategy includes indications and actions to :

- Improve coordination of research activities at the national level
- Foster technology transfer, with a particular attention to Intellectual Property Right Issues
- Improve governance of nanotechnologies, promoting knowledge and dissemination of information through public debate
- Develop education and professional formation to support industrial growth of nanotechnology
- Support strengthening of nanotechnology coordination at the European level

France holds an articulated landscape in terms of research governing bodies, with government departments, agencies and regional governments, public research institutions providing R&D funding and defining R&D policies. A relevant role in supporting N&N R&D is played by the ANR (Agencie Nationale de la Recherche) and by different regional governments

Most of the programmes in R&D in N&N supported by these research governing bodies include a relevant part devoted to research on EHS and ELSA. These funds now include a mandatory component relative to the ethical and societal implications of nanotechnology.

In terms of public research, most of the efforts in this field are concentrated within the CNRS (Centre National de la Recherche Scientifique) and the CEA (Atomic Energy and Alternative Energies Commission),

[9] See for example www.csnmt.cz/en/nanosection/ and www.euronanoforum2009.eu

[10] http://www.enseignementsup-recherche.gouv.fr/cid25281/nano-innov-un-plan-en-faveur-des-nanotechnologies.html

[11] http://www.grandemprunt.net/

having a coordinated approach in the domain of nanoscience [12]. In particular, the CNRS developed a network of "competence centres" C'Nano [13]and of infrastructure needed for nanotech research. The CEA created in Grenoble the two world class research centers Minatec (focusing on electronics and energy) and Clinatec (focusing on medical applications).

All C'Nano centers organize specific programmes on ELSA and CEA created LARSIM, a research centre whose mission is to organize and maintain an ongoing considerations on these matters[14]. CEA coordinates the broad project Nanosafe[15] (safe production and use of nanomaterials) devoted to the development of good practises for the handling of nanomaterials.

In terms of sharing good practices and making easily accessible the scientific knowledge CEA developed an interesting web platform called Nanosmile[16] operating at different levels (discover and explore N&N for consumer, citizens and students, professional training on risks of nanomaterials for scientists and industry).

In terms of regulation, France is the first European country to introduce mandatory declaration of all manufactured or imported products containing nanomaterials to an administrative authority. This provision was approved by French Parliament in June 2010 in the framework of environmental legislation (loi Grenelle II) and currently awaits application.[17]

Several public agencies and institutions have specific activities on EHS issues and ELSA and published opinions and guidelines on the matter. As examples of the many activities and documents published (and detailed in the France Country Report), can be cited:

- The report on nanomaterials from AFSSET (Agence Française de Sécurité Sanitaire de l'Environnement et du Travail), that emphasizes the lack of knowledge on potential risks and the need to implement a precautionary framework for nanomaterials [AFSETT, 2010];
- The permanent "Groupe de Veille sur les Impacts Sanitaires des Nanotechnologies" established by The Ministry of Health, that published several reports on sanitary risks of nanomaterials;
- The Opinion of the Conseil économique, social et environnemental (2008), that emphasizes the need to implement the Precautionary Principle , the need to guarantee fundamental ethical principles and asked for a public debate for the integration of the societal dimension. This opinion played a quite important role in the public debate[18];
- The Opinion on nanoscience (2007) by the National Consultative Ethics Committee (CCNE) that criticized some uses of the notion of convergence and proposed 8 recommendations. These included broader information, research in metrology and normalization, the importance of ethical reflection of the scientists, workplace and consumer safety, etc[19].

[12] http://www.debatpublic-nano.org/_script/ntsp-document-file_download.php?document_id=64&document_file_id=101

[13] http://www.cnrs.fr/inp/spip.php?article15

[14] http://www.cnrs.fr/inp/spip.php?article15

[15] http://www.nanosafe.org

[16] http://www.nanosmile.org/

[17] http://www.senat.fr/rap/l08-488/l08-4881.pdf

[18] http://www.conseil-economique-et-social.fr/ces_dat2/2-3based/base.htm

[19] http://www.ccne-ethique.fr/docs/fr/avis096.pdf

Several other stakeholders, such as industry and professional organizations, trade unions, civil society organizations contributed to the debate, with the publication of research studies and position papers devoted both to EHS issues and ELSA (more than 40 different documents have been identified by the French Country Report).

The attention of most stakeholders towards ethical and societal aspects of N&N seems quite high, likely more than in the other countries surveyed, and there is a clear attitude towards a precautionary approach.

Following the NanoInnov Plan and inputs from many of the initiatives mentioned above, the French government requested that a national debate on risks and opportunities of N&N be organized by the National Public Debate Commission (CNDP), an independent body established under the French law, aiming to establish an inclusive approach on N&N governance.

Only a part of the 17 planned debates took place, while others were cancelled or highly perturbed by anti-nano demonstrations. However the debate continued by electronic means and through written contributions. The final recommendations resulting from the debate published by CNDP have strong similarities with some of the actions of the EC CoC[20]:

- the need to develop research;
- the need to assess benefits and risks and to adapt REACH;
- the need to develop tools and dedicate human resources to metrology and normalization;
- the need for workplace safety and the use of precaution;
- the need to guarantee public and collective freedoms;
- the need to create an ethical framework for responsible development of nanotechnology;
- the need for new governance of nanotechnology;
- and the need for French and European legislative measures and the creation of an Observatory of nanotechnology.

In conclusion, in France there is a a relatively high level of public awareness of nanotechnology and the involvement of many actors, in particular numerous trade unions and civil society organizations, in the dialogue with government bodies and public research organizations. It remains to be seen what measures for the governance of nanotechnology at the national level the Government will undertake as a result of the work of CNDP.

2.2.4 Germany

Germany has always had a relevant role in the European scientific and technological development and this is confirmed in the case of nanotechnologies. In terms of public funding for R&D, Germany is, in fact, one of the countries that has invested more in this field over the last 20 years, and it is estimated that currently approximately half of the European business related to this field is based inside its borders [NanoKommission 2008].

The landscape about research funding organizations is broad and differentiated (mainly federal and federal state departments, institutional funders and private foundations). All have a high degree of independence in choosing the directions of R&D planning and funding. Most of them are supporting N&N research,

[20] http://www.debatpublic-nano.org/_script/ntsp-document-file_download.php?document_id=503&document_file_id=761

including risk related issues such as environmental safety, occupational health, consumer safety and risk communication, nanoregulation and ethical and societal aspects. Interestingly, a relevant part of funding is explicitly devoted to projects following a "precautionary" approach or "accompanying measures".

Among these initiatives can be cited the projects NanoCare, INOS, TRACER, NanoNature [NanoCare 2009] and CarboSafe[21] (within the INNO.CNT project). As an interesting example of a project devoted to make easily accessible and understandable the scientific knowledge on EHS can be mentioned the recently launched project DaNa (acquisition, evaluation and public orientated presentation of societal relevant data and findings for nanomaterials), collecting and combining the results of previous projects to inform the public about effects of nanomaterials on humans and environment[22].

Germany has also a solid tradition of socio-political debates, stakeholder dialogues and participative initiatives. Plenty of such initiatives have been organised since 2004, prompted by institutions, industry and academia, and with the participation of all kind of stakeholders (to cite a few of them: The nanoTruck and NanoDialogue, ForumNano from the Associations of Chemical Industry, VCI, the Dialogforum Nano from BASF, Hessen in Dialogue [23]). An important role in science communication in the field of nanotechnologies is also played by science museums, organising nanotechnology exhibitions and different dialogue formats.

Most of the industrial organizations as well as some multinational corporations based in Germany (see chapter 3) are very active in N&N. They have special programmes or working groups on nanotechnologies, are issuing position papers, research studies on risk related topics and guidelines, participate on a regular basis in stakeholders dialogues[24].

The responsible development of nanotechnologies is amongst the priorities of the "Nano-Initiative–Action Plan 2010" launched by the German Government in 2006 [BMBF 2007] [25] to provide a single strategic framework for the development of nanotechnology at the national level.

The focus of these activities is on [NanoKommission 2008]:

- Funding of cross-departmental, interdisciplinary research and development in the priority areas of electronics, automotive engineering, chemistry, medicine, light engineering and energy;
- Exploration of risk potential for humans and the environment;
- Investment in early training, technology and knowledge transfer;
- Cooperation at the international level on the framework development of norms and standards, the scheduling of potential mechanism for regulation, the recognition of risk potentials.

[21] http://www.nanopartikel.info/cms/lang/en/Projekte/Inno.CNT/CarboSafe

[22] http://www.nanopartikel.info/cms/lang/en/page3.html

[23] The initiative "Hessen in Dialogue: Nano – here comes the future" is one of the largest examples of public dialogues (on the federal state level). The format started in 2006 with some 1,800 participants and 50 experts. Panel discussions were accompanied by small workshops with lay people and experts from all stakeholder groups answering their questions. 50 companies and research centres from the region offered interactive experiments and invited to direct talks with the scientists on small market place booths.

[24] In particular the associations of the chemical Industry (VCI), of the cosmetic Industry (IKW), of the German Coating Industry (VDL), of the German engineers (VDI), the Society for Chemical Engineering and Biotechnology (DECHEMA).

[25] The new German Action Plan is under development and will be published in September 2010.

Since 2006, several coordination actions were enforced to implement the aims of the Action Plan, among them:

- The research strategy "Nanotechnology: Health and Environmental Risks of Nanomaterials" published by the Federal Institute for Risk Assessment (BfR) and The Federal Environment Agency (UBA) [Orthen, B. et al 2007];
- The establishment of a cross-departmental coordination group between ministries and federal agencies that act on a regular basis;
- The establishment of the German Advisory Council on the Environment (SRU), acting as an advisory board of the Government and planning (2011) a "Special Report on Precautionary Regulatory Strategies - Challenge Nanotechnology";
- The development of the German NanoKommission (2006 – ongoing) as a central, national key platform for stakeholders on potential risks and opportunities of N&N.

The German NanoKommission [NanoKommission 2008], involving more than 100 leading experts from all stakeholders groups, in its first period of activity (2006-2008) was organized in 3 working groups:

- The quantification of potential environmental and health benefits (WG 1);
- The development of criteria for a preliminary risk assessment (in the case of an insufficient data base) (WG 2);
- The development of five core criteria for the responsible use of nanomaterials (WG 3).

The five "Principles for Responsible Use of Nanomaterials" are the results of a large consultation of stakeholders and provide a very interesting example of a large effort to promote a voluntary code of practice at national level (more details are provided in chapter 3).

In the second working phase (2009-2011), it has been added a fourth working group (devoted to the monitoring of the five principles, balancing benefits and risks, regulatory issues, risk assessment) and an additional, smaller, group focused on "Green Nanotechnologies" (an updated review report is expected for spring 2011).

2.2.5 Italy

The activity in nanotechnologies is in Italy rather intense, and it refers to both public research institutions and private enterprises. A specific national initiative dedicated to N&N doesn't exist yet, nevertheless various activities and projects are supported by the Italian Government to promote the development of the sector. According to a recent survey carried out by the Italian Association for Industrial Research (AIRI), the National industrial sector considers N&N a key tool of development for most of the high-tech sectors of the Country [AIRI 2009].

The Ministry for Education University and Research (MIUR)[26] coordinates the preparation of the triennial National Research Programme (PNR), the main governmental instrument for R&D planning, allocating funding to universities and research centres, which periodically sets agenda and priorities of the R&D activity. Funds devoted to R&D in nanotechnologies are included in the PNR (2010-1012), not through a specific measure, but with funding initiatives in different sectors of application. A certain (small) amount of the funding is devoted also to research projects investigating EHS issues associated with N&N.

[26] www.miur.it

Funding of R&D, including N&N, is also provided at regional level. These funds are generally related to the activity of the high tech clusters, recently created with the support of MIUR in some Italian regions, having N&N in their mission. Among them it can be cited Veneto Nanotech, started in 2005 with nanotechnologies as sole mission and focused on nanomaterials.

Besides University, also the main public research organisations are actively involved in N&N. In particular, the National Research Council (CNR), the National University Consortium for Materials Science and Technology (INSTM), the Italian Institute of Technology (IIT), the Italian National Agency for new technologies, Energy and sustainable economic development (ENEA) and the National Institute for Nuclear Physics (INFN).

During the past few years the number of Italian enterprises dealing with nanotechnology has steadily increased. Quantitatively the effort is concentrated within the big companies, but there is also an increasing of SMEs active in the field that have an important role to spread the application of this emerging technology within the industrial fabric [AIRI, 2006].

The attention toward the responsible development of nanotechnologies has also steadily increased and several initiatives, involving different stakeholders, have been activated during the last years (mainly on EHS and regulation issues) whose objectives can be referred to the EC CoC.

At institutional level both INAIL (Italian Workers' Compensation Authority) and ISPESL (National Institute of Occupational Prevention and Safety) have established working groups devoted to nanomaterials [27]. The latter will publish in 2010 “The White Book On Occupational Exposure To Engineered Nanomaterials”, an in-depth analysis based on a multistakeholders process and aiming to underline policy needs and perspectives about N&N development and the related risks at workplaces. The document will represent a basis for future policy actions in this field.

At industrial level the National Federation for Chemical Industry (Federchimica) established a Nano Product Stewardship working group (in close collaboration with INAIL) and issued a position paper focused on N&N. The document explicitly refer to the principles listed in the “Responsible Care Global Charter of the ICCA (see chapter 3 for details). The document, though recognizing the need to increase the scientific knowledge on nanoscale materials and related EHS issues, considers the existing regulatory situation generally adequate to cope with the potential risks of nanomaterials. It also outlines specific actions devoted to favour a dialogue with stakeholders and to develop guidelines on safety issues. Federchimica is closely following (and contributing to) the evolution and implementation of REACH.

Some universities and public research centres have specific projects dealing with EHS issues and (few of them) also with ELSA. Most of these projects are focused on basic research aspects but some are also targeted to the application and use of nanomaterials (a relevant example is the recent IIT@NEST initiative for the definition of quality control methods for nanotechnology products).

Legambiente (the largest environmental organization in Italy) and Coop Italia (one of the main retailers’ organisations) both published opinions on N&N underlining the need for a (strict) precautionary approach in the use of nanomaterials.

[27] Note that very recently ISPESL functions have been transferred to INAIL according to D.Lgs.78/2010

Many of the initiatives mentioned above endorse a precautionary approach and mirror the principles characterizing the EC CoC, though, it must be said, there are no examples of formal adoption of it.

Also looking at public perception, even though awareness of both opportunities and risks of N&N is still quite low, when considering S&T in general the most common attitude is toward a precautionary approach in the research [Observa, 2010, Cortese, 2008].

This general attitude, shown by most of the stakeholders, seems to provide a positive background for the dissemination and the implementation of the Code.

2.2.6 The Netherlands

In response to Recommendation 3 of the EC CoC [28], the Netherlands is the first European Member States that has introduced mandatory contractual obligation to comply with the EC CoC in its national funding schemes for N&N R&D. The Dutch Government has adopted a highly integrated governance and coordination framework for nanotechnologies since 2006 with strong positive tone, including seeing research on safety and societal issues as opportunities for economic competitiveness. Precautionary measures for working with persistent synthetic nanoparticles were recommended by the Health Council of The Netherlands and supported by the Minister of Housing, Spatial Planning and the Environment (VROM) and the Ministry of Social Affairs and Employment (SZW).

In April 2006, the Dutch Government presented the *Cabinet Vision on Nanotechnologies* [Kabinetsvisie Nanotechnologieën, 2006] to the Dutch Parliament which outlined an integrated governance and coordination framework for N&N addressing both opportunities and risk of N&N and the importance of public dialogue. Based on the Vision Paper, an interdepartmental committee on nanotechnology[29] was formed to faciliate discussion and coordination between the relevant Ministries. The Risks of Nanotechnology Knowledge and Information Centre (KIR-nano)[30], an observatory and an advisory body to the central Government on risks related to nanotechnologies, were set up in the National Institute for Public Health and the Environment (RIVM) on 1 January 2008.

In July 2008, upon the request from the Dutch Parliament, the Cabinet Vision Paper was further developed and formalised into the Nanotechnology Action Plan [Actieplan Nanotechnologie, 2008]. In the Action Plan, the Dutch Government further envisaged three institutions to support the Government's governance of nanotechnologies:

- The Netherlands Nano Initiative (Nederlands Nano Initiatief, NNI): an umbrella structure which coordinates nanotechnology research in the Netherlands.
- The Sounding Board on Risks of Nanotechnology: an advisory board that consists of experts from Government, industry and civil society on N&N risks.
- The Committee on Social Dialogue of Nanotechnology: an independent committee for the purpose of facilitating social dialogue. The Committee has initiated the NanoPodium platform for funding

[28] Recommendation 3 reads "*That Member States consider such general principles and guidelines on research to be an integral part of institutional quality assurance mechanisms by regarding them as a means for establishing funding criteria for national/regional funding schemes, as well as adopting them for the auditing, monitoring and evaluation processes of public bodies.*"

[29] Interdepartementaal Overleg Nanotechnologieën (ION)

[30] http://www.rivm.nl/rvs/075_nanotechnologie/KIR_nano/

communication projects. Nanopodium, together with NanoDialogue, an initiative from The Rathenau Institute form the backbone of the Dutch social dialogue activities.

The Action Plan contains four main lines of actions:

1. Opportunities and Research Agenda
2. Dealing with risks
3. Ethical aspect, social dialogue
4. Legal aspects

One of the main funding mechanisms for N&N R&D (within the first action line) will be the High Tech Systems and Materials theme of the Economic Structure Enhancing Fund (FES). A relevant part (about 15%) of this funding will be devoted to risk research including development of risk assessment methodologies and examining the cross-linkage and use of methodologies and data.. The government has introduced the mandatory contractual obligation to comply with the EC CoC in the current FES HTS&M call.

Among the activities in the second action line, the Dutch government has also introduced a three-step plan to support the implementation of REACH at European level which include: Step 1 - creating a model for screening of nanoparticles and recommendations for adjusting REACH requirements; Step 2 - supporting cooperation with industry to test and further develop the model; Step 3 - sharing experience with other EU Member States and the European Commission.
Concerning occupational safety, the Social Economic Council (SER) supports and coordinates several activities and programmes related to risk management of nanomaterials in occupational setting. In March 2009 the Council published the "Advisory Report Nanoparticles in the Workplace: Health and Safety Precautions", holding the opinion that precautionary measures should be adopted when working with nanoparticles. In oder to implement the precautionary principle, the Council also addressed in the report the importance of knowledge dissemination with regard to existing laws and risks of nanoparticles and the need for a special reference scheme and good practices guidelines for nanomaterials to assist the implementation of existing safety law.

Special efforts have been made in the Netherlands to address the need of support in risk management of the SMEs. In 2007, a survey report titled *"Dealing with Nanoparticles in the Workplace"*[31] was drawn up at the request of the Ministries of SZW and VROM by the Centre of Expertise in Life Sciences (CEL) at Zuyd University, in collaboration with the Arbo Unie (Labour Union) Expertise Centre for Toxic Substances and the DSM company's Occupational Health and Safety Service to provide an initial understanding of the exchange of health and safety information and dealing with waste of NP especially at SMEs. A free online risk management system, the Stroffenmanager Nano[32], has been developed in 2010 to assist SMEs on risk management and regulatory compliance (see chapter 3 for details). Philips Research has also successfully developed the world first portable NP monitor, AERASENSE®[33], to serve this need. Labor Unions, with support from SER, are conducting research projects to help the government investigate the feasibility for SMEs on sectorial basis regarding proposed regulatory nanomaterial reference values.

[31] *Omgaan met nanodeeltjes op de werkvloer*

[32] For more details please visit the website www.stoffenmanager.nl.

[33] http://www.aerasense.com/

"The Dutch Polder Model"[34], the tri-partite cooperation between employers' organisations, labour unions, and the Government, has offered a unique opportunity for The Netherlands in terms of safe handling of nanoparticles in the work place. The labour unions have served as an important communicator and bridge between the Government and the industry, proposing policy frameworks and supporting the development and implementation of precautionary measures.

On the third action line, the Rathenau Institute has assisted the Government in mapping ethical and societal aspects of nanotechnology[35]. The results have been presented to the Committee on Social Dialogue of Nanotechnology and collected in a public agenda entitled *"Towards a Social Agenda on Nanotechnology"*. Drawing from the lessons of the GM debate, the current Netherlands Government €3 million Nanopodium public engagement initiative is carrying out a large number of small, varied activities throughout the country on the basis of calls for proposals from individual people and organizations instead of a large scale nationwide public consultation or consensus conference[36].

Regarding regulation, the Government is taking the position that legislative activities targeted at nanotechnologies should better be initiated at European level if necessary. Supplementing (temporarily) the national legislation and regulation is not the preferred approach but - depending on the extent of the risks identified – is not entirely excluded. In the Action Plan, the Government analysed the current legal framework for nanotechnology enabled products consisting of 80 international and 20 national regulations and concluded that for the time being that no new regulations were necessary for governing nanotechnology.

In the Netherlands, large international CSOs' involvement in governance of nanotechnologies is in general very modest. There are a few small local consumer, environmental and gender groups that show considerable interest. The government funding programme Nanopodium has attracted over 100 public engagement proposals for N&N from CSOs. However, without a supporting framework to encourage them in working together, their public impact seems to be minimal. Labour unions who propose the principle "No Data, No Exposure" instead of the slogan "No Data, No Market" have been actively involved in the development of exposure limits and reference value for nanomaterials to support government efforts in implementating the Precautionary Principle. Apart from the existing funding strategy to address the responsibilities to comply with the EC CoC to the research community, the government is also considering the possibility to incoorporate the requirement of compliance to the EC CoC to its social dialogue funding programmes. However, the Dutch CSOs and labour unions have expressed their doubt on the effectiveness of the EC CoC in ensuring responsible development of N&N and its overall policy role at European level.

[34] The Dutch "polder model" of consensual decision-making was developed in the 1980s and 1990s which is characterised by the tri-partite cooperation between employers' organisations such as the Confederation of Netherlands Industry and Employers (VNO-NCW), labour unions such as the Federation Dutch Labour Movement, and the Government. These discussions are embodied in the Social Economic Council (Sociaal-Economische Raad, SER) which serves as the central forum to discuss labour issues and has a long tradition of consensus, often defusing labour conflicts and avoiding strikes. This polder model, combined with a neo-liberal economic policy of privatisations and budget cuts has been held to be responsible for the Dutch economic development of the late 1990s to 2008 before the current economic situation.

[35] For more information please visit www.rathenau.nl/en/themes/project/nanotechnology.html.

[36] For more details please visit the website www.nanopodium.nl.

2.2.7 South Africa

The Republic of South Africa is relatively new in its approach to N&N research. The National Nanotechnology Strategy (DST), to support and promote the activity in this field, was launched in 2006 after its approval by the Country's Cabinet [DST, 2005] Its implementation paved the way to the participation of a wide range of research institutions to start research in nanotechnology. Capacity building programmes which include, among others, equipment acquisition, human capital development, have helped to create an enabling environment for nanotechnology research.

While public research activities on N&N are now relevant compared to the national R&D efforts (more than 12 of the Country's 21 universities and at least three of the Country's major science councils are involved in nanotechnology R&D). Industry involvement in the field is still limited.

Research in South Africa is focused on areas identified by the DST. Particular attention is given to projects related to social development (water, energy and health), with health dominating the landscape. Regarding the governance of N&N, the DST has put in place a Nanotechnology Ethics Committee. Its establishment is part of the creation of a platform for analysis and introduction of legislative instruments to ensure that nanotechnology is applied according to international best practice in industrial and environmental safety standards, as required by the National Nanotechnology Strategy. Its responsibilities include:

- Investigate global approaches to ethical, risk and health issues in the research and application of Nanoscience and Nanotechnology (N&N);
- Prescribing frameworks for handling of such issues locally;
- Developing policy framework governing research, manufacture and application of Nanomaterials and monitoring implementation.

As its output, the Committee has developed a draft Code of Conduct to govern nanotechnology research and development. The draft Code is based on the EC CoC and it is still being discussed internally within the DST before being taken out for stakeholder consultation. The two main issues currently raised within the DST include:

- whether the Code of Conduct should be made mandatory or voluntary;
- the capacity, within the DST (and also within the country), to enforce the Code of Conduct;
- ensure that good research is not hampered for fear of violating the CoC.

Regarding the public awareness, the DST has developed a Nanotechnology Public Engagement Plan (NPEP), which maps out the programme for engaging the public on matters referring to nanotechnology.

2.2.8 Spain

Several efforts have been put in place in the last years by the State General Administration (SGA) of the Central Government, and also other national institutions, to promote N&N and this supported a growth in the number of organisations involved in N&N (mainly referring to the public research domain).

The majority of public funding of R&D (including R&D in nanotech) is managed by the Ministry of Science and Innovation (MICINN) and the Ministry of Industry, Tourism and Trade (MITYC), through the two large programmes *Spanish National Plan for Scientific Research, Technological Development and Innovation (PNIDI)* and *Ingenio 2010*.

Regional governments (Autonomous Communities) have also the capacity for the definition, funding and implementation of regional R&D programs.

Within the set of planned Strategic Actions, the new R&D National Plan 2008-2011 [37] includes a S*trategic Action for Nanoscience and Nanotechnology, New Materials and New Industrial Processes* (SANSNT) [MICINN, 2008]. The SANSNT is a cross-programme action, designed for the overall enhancement of Spanish industry competitiveness through the implementation of changes in several industrial sectors, where nanotechnology plays a central role. The SANSNT includes seven thematic lines:

- N&N applied to materials and new materials in the health sector
- N&N for ICT
- N&N for industry and the environment
- Knowledge-based intelligent materials with individually-tailored properties and high performance materials and coatings
- Advances in technology and processing of materials
- Development and validation of new industrial models and strategies. New technologies for design and manufacturing processes. Network-based production
- Exploitation of convergent technologies

Although SANSNT has tried to concentrate and rationalize the strategies of SGA concerning the promotion of N&N, the actual implementation specifically designed to attain the objectives set have been split and distributed across many different programmes and management offices. Furthermore, over the period 2008-2010 no specific calls for projects were launched within SANSNT, even if a few related initiatives were funded in parallel programs (Infrastructures, emerging centres, etc.).

The Ingenio 2010 programme constitutes the main instrument designed to ensure convergence of Spanish R&D with the European Union, by increasing the levels of resources provided and putting strategic actions into practice. Regarding N&N, the most relevant programmes within this initiative are “CONSOLIDER” and “CENIT”, both devoted to improve cooperation and networking among the different R&D players (companies, universities, institutions and public centres, science and technology parks and technology centres) [38].

Despite of these central strategic programs, responsabilities for management of funding activities is spread across several general directorates, subdirectorates, agencies and foundations depending on MICINN and MICyT. Moreover, the current level of coordination and communication between the State General Administration (SGA) and the governments of the autonomous communities in Spain is low.

These factors challenge the definition of a global view of N&N activities in Spain as well as precise figures about the amount of funding devoted to this area, and also cause a lack of information and coordination among the different R&D players.

Most research activity on N&N in Spain are related to public centres, universities and institutes, based on national or regional funding . In the last decade a few “nano”companies have emerged.

[37] http://www.plannacionalidi.es/

[38] http://www.ingenio2010.es/ or http://ingenio2010.fecyt.es/

Among the most active public research organisations can be cited: the International Iberian Nanotechnology Laboratory, the Research Centre on Nanomaterials and Nanotechnology (CINN), the research centre CIC nanoGUNE, the Institute of Nanoscience of Aragon (INA), the Research Centre on Nanoscience and Nanotechnology (CIN2), the Institut Català de Nanotecnologia (ICN), the Institute of Photonic Sciences (ICFO), the Centre of Nanophotonics Technology of Valencia (NTC) , the Andalusian Centre of Nanomedicine and Nanotechnology (BIONAND) and the IMDEA-Nanoscience centre.

Other research groups are present in some Universities, and most of them refer to the Spanish Nanotechnology Network (NanoSpain)[39], a structure created to promote Spanish N&N R&D and commercialisation through a multi-national networking action [MICINN 2008, PH 2008].

In terms of nanoregulation, though Spain is closely monitoring the ongoing activities at European Level, no specific legislative actions have been implemented so far. Few public organisations, including the National Institute of Work, Environment and Health (INSHT), are particularly active in the development of risk assessment procedures and good laboratory practices on N&N.

As resulted by the analysis made for the preparation of the Spanish Country Report, the EC CoC has not being implemented either at national or regional level.

However, some N&N centres and platforms have developed or are developing their own codes of conduct or practical guides, based on good practices in nanosafety. Most of these documents are confidential, still as drafts, or have not yet been implemented [40].

Interestingly, standard procedures for R&D funding of public research organisations requires that projects involving research on humans, the use of their personal data or human biological samples, experiments on animals or the use of biological agents or genetically modified organisms not only have to comply with the requirements established for each case by law, but must also be specifically authorized by the Ethics Committee of the Centre where the research is carried out[41]. No specific aspects of N&N are taken into account, unless the research involves any of the above mentioned cases.

A considerable effort has been made in the last years in Spain to increase the level of knowledge, development and involvement in N&N, but still remains a lack of information and coordination between all interested parties working in this field.

[39] www.nanospain.org, http://www.nanospain.org/members.php

[40] Among the institutions developing such measures can be cited the CIBER-BBN (http://www.ciber-bbn.es) , the Nanotechnology Platform at Parc Científic Barcelona (http://www.pcb.ub.es/homepcb/live/en/p905.asp/), the Institute for Bioengineering of Catalonia (IBEC) for nanomedicine applications (http://www.ibecbarcelona.eu), the Institute of Nanoscience of Aragon(http://ina.unizar.es/index.php), the Institut Català de Nanotecnologia (http://www.icn.cat), Tecnologia Navarra de NanoproductsS.L. (TECNAN) (http://www.tecnan-nanomat.es), Grupo Antolín (http://www.grupoantolin.com), Fundación Leia (http://www.leia.es), INASMET-Tecnalia (http://www.inasmet.es)

[41] See for reference the website of the Network of Ethics Committees in Universities and Research Centres in Spain (Red de Comités de Ética de las Universidades Españolas, available at http://www.ub.es/rceue/index2.htm

2.2.9 Switzerland

Switzerland is a small country with comparably high funding rates into nanotechnologies on a *per capita* basis (SER, 2010). In absolute terms, however, the funding is lower compared to the big European countries, even if the commitment to nanotechnologies is strong.

The "Swiss Action Plan on Synthetic Nanomaterials" [FOEN, 2006]. was launched in 2006 by the Federal Office for the Environment (FOEN) and the Federal Office of Public Health (FOPH), and involves Federal authorities, researchers, NGOs, associations and industry representatives. The Action Plan is based on a precautionary approach and focuses on risks and regulatory aspects related to manufactured nanoparticles.

In the context of the Action Plan, a set of actions for nanotechnology governance were approved by the Swiss Federal Council in 2008 with the aim to [Federal Council, 2008]:

- Provide a summary of the uses of nanoparticles in Switzerland;
- Develop exposure scenarios;
- Conduct a dialogue with relevant stakeholders;
- Devise scientific principles for danger and risk assessment;
- Draw up harmonized definitions, measurement methods and validated test guidelines (in cooperation with the OECD, EU, ISO);
- Motivate the research and business communities to develop and apply self-regulation measures;
- Adapt existing legislations if necessary to guarantee safety;
- Introduce immediate measures to protect employees in industry and research.

Since the Action Plan has been in force, several measures have been introduced in the following areas:

- **The "Precautionary Matrix"** is a structured and informative tool which provides the industry and trade with information on risk potentials of manufactured nanomaterials. The adhesion to the protocol is voluntary (Höck et al., 2010).
- **Guidelines for safe and sustainable disposal of nano wastes**
- **Guidelines for the provision of safety information along the value chain** will supplement the currently used Materials Safety Data Sheets (MDMS) with requirements proposed for manufactured nanomaterials.
- **Review of the Hazardous Incident Ordinance (StFV) concerning nanomaterials** to clarify the need for adaptations of the StFV due to the novel properties of manufactured nanomaterials.
- **A dialogue event on labeling of nanomaterials in consumer products.**

Over the short and medium term, the measures considered under the Action Plan will strengthen the industry's own responsibility, and support the industry in identifying and managing nanospecific risks through the development of practically applicable tools and guidelines.

A public review of the level of implementation of these measures and a re-assessment of the need for regulatory measures for N&N will be provided in 2011 by the Federal Council [Stadler, 2009].

With the National Research Programme NRP 64, a dedicated 5-years research initiative on the benefits and risk aspects of manufactured nanomaterials has been activated in 2009 by the Swiss National Science Foundation [SNF, 2010]. Moreover, the country is active in various intergovernmental initiatives on EHS issues and nanotechnology governance in general.

As for regulation, the Swiss Federal Council has taken the position that the existing regulatory framework is considered adequate in principle, but specific guidance and standards should be developed to support the implementation of existing provisions. However, an adaptation of the regulatory framework was not excluded in case further evidence indicates a need for modification.

Particular attention is paid to the developments on the international level and in particular in the European Union in order to avoid regulatory divergence. The European Union is the main trading partner for Switzerland.

In the area of communication and the promotion of public dialogue, the Swiss approach proposed a "participatory and inclusive process". The Action Plan identifies three areas of action: communication of scientific findings, risks and regulatory aspects; supporting existing dialogue platforms with different stakeholders groups and implementing new ones if necessary; and, technology assessment in a participatory process.

In terms of stakeholder communication, an interesting example is given by the Authorities Dialogue (Behördendialog), an inter-governmental dialogue platform involving representatives from public authorities and stakeholder groups of German speaking countries (Germany, Austria, Switzerland, Principality of Liechtenstein). The initiative aims to foster the exchange of ideas and experiences about nanotechnology governance, to support the identification of critical trends (early warning) and to promote cooperation on a supranational, but informal level.

In conclusion, many aspects mentioned in the EC CoC have been addressed also within Swiss Action Plan, and some concrete tools (such as the Precautionary Matrix) have been developed to support a practical application of the precautionary principle. The review of the Action Plan provided to take place in 2011 will provide further input on the level of implementation of these measures and on the need for further (regulatory) action.

Besides the initiatives under the lead of the Federal Government, one voluntary private initiative can be specifically mentioned. In 2008, the Swiss Retailers Association (IG DHS) published their own Code of Conduct on Nanotechnologies to address the potential risks and concerns associated with the nano-products already available on the market. This initiative (described in detail in chapter 3) may serve as an example of proactive action to address consumer concerns in relation to nano-products.

2.2.10 United Kingdom

The UK has an acknowledged primary role in the N&N sector in terms of economic commitment in the field, number of nanotechnologies companies and activities in the public research domain [MIGT, 2010].

Among the main institutions planning and funding R&D are the Technology Strategy Board (TSB), the leading government agency devoted to promote technology innovation and the UK Research Councils, publicly-funded agencies responsible for coordinating and funding particular areas of research.

Twenty-four Micro and Nanotechnology (MNT) facilities were set up by the UK Government between 2003 and 2007 and form a major part of the UK's micro and nano technologies infrastructure. The centres are open access facilities and are supported by combined TSB, Regional Development Agencies (RDAs), Devolved Administration and industrial funding. A significant research portfolio in nano science is also hold by Research Councils, that mainly support investments to help address the commercialization of N&N, with

actions in areas such as nano manufacturing and technology scale up[42].

The Government announced its intention to develop a UK Strategy for nanotechnologies in its 2009 response to the Royal Commission on Environmental Pollution's report *Novel materials in the Environment: The case of Nanotechnology* . The Strategy, published by the UK Government in March 2010 under the title *UK Nanotechnologies Strategy: Small Technologies*, *Great Opportunities*, was informed by the views of those involved in nanotechnologies from a wide range of interested parties across academia, industry and non-Governmental organizations.

Within this strategy are identified several actions to pursue in order to ensure a successful and safe development of these technologies. These actions are divided into four categories [HM, 2010]:

- **Business, Industry and Innovation:** provide a transparent, integrated, responsible and skilled nanotechnologies industry with good links to, and support from, Government.
- **Environmental, Health and Safety (EHS) Research:** contribute to EHS research crucial issues by government funded initiatives and collaboration with international work programmes.
- **Regulation:** ensure better informed policies and regulations relating to nanomaterials and nanotechnologies.
- **The Wider World:** well-informed public and stakeholders and a leading position on nanotechnologies for the UK on the world stage**.**

Aim of the first action is to improve the coordination in the sector through the establishment of a Nanotechnologies Leadership Group (NLG) chaired by the Department for Business Innovation and Skills (BIS) which will provide a strategic industry leadership. It will promote the participation of companies and academics to Grand Challenge calls (a programme of investment for the applications of N&N in the energy, healthcare and the environment sectors) from the Technology Strategy Board (TSB) and Research Councils[43].

The second action aims to improve coordination of EHS research, develop a portfolio of research project into crucial EHS issues and promote cooperation at the international level (OECD).

In terms of regulation (third action) the UK supports EU initiatives and will continue to keep the regulatory situation under review as research results and other evidence become available.

It will also continue to foster the development of guidance and other advice tools to respond to any potential risks posed by nanotechnologies. With this respect, it is worth noting that the UK chairs the ISO Technical Committee 229 Nanotechnologies, and the corresponding Committee of the UK national standard body (The British Standard Institute) has published in the last years several standard documents both on nomenclature and risk management issues.

Special care will be given to the effectiveness of existing regulation in a number of key areas where nanomaterials are most likely to come into contact with humans (food, cosmetics, healthcare devices and medicines, workplace health and safety and chemicals). In particular a 'case-by-case' approach will be promoted regarding the risk assessment and the suitable use of individual nanomaterials in food and food

[42] www.rcuknano.org.uk/

[43] www.ukinvest.gov.uk/Nanotechnology/en-GB-list.htm and http://www.rcuknano.org.uk/index.php?option=com_content&view=article&id=16&Itemid=22

contact materials. Activities on REACH and nanomaterials will also be carefully monitored in order to ensure that nanomaterials are robustly covered.

As it regards the Defra voluntary reporting scheme (see chapter 3 for details), the scope and aims of the initiative will be expanded to include products as well as nanomaterial [Milieu, 2009].

With reference to public engagement (4th action) the Nanotechnologies Collaboration Group will be established to facilitate ongoing communication and collaboration between Government, academia, industry and other interested parties, including consumer groups. Information about Government's ongoing actions on nanotechnologies will be made accessible to the public on a portal website.

Regarding the EC CoC, whilst the document has been discussed in the UK in different stakeholders meetings, very limited efforts have been devoted to further disseminate it. Both the existence of the Responsible NanoCode initiative (see chapter 3) and the focus on the development of the UK strategy could be responsible for the tepid attention to the EC CoC. The complex scenario in terms of governance structures and relationships between government and the different research partners may be another factor making the dissemination of the EC CoC difficult.

3 (Voluntary) Initiatives relevant for the application/implementation of the EC CoC

In spite of the activity just described above specific legislation and regulations for nanotechnologies are, as said, still rare. Existing provision are generally used, but various governments are recommending a precaution-based strategy of risk control when working with manufactured nanoparticles. Both the research community and the private sector have responded to this advice adopting a series of voluntary measures to this end.

This chapter provides the analysis of a set of such measures pointed out (mainly) in the individual Country Reports. Some of them have been selected to be compared with the EC CoC. The aim is to highlight the topics addressed, the level of adoption, incentives and disincentives envisaged for their implementation and, in general, strengths and weaknesses characterizing these measures. This should provide indications useful for the eventual further articulation of the EC CoC and therefore support its use. The findings are illustrated below and condensed in the table in the Annex.

For the sake of clarity the initiatives have been grouped referring to three main categories: codes of conduct/practice, risk management systems and reporting schemes.

3.1 Codes of conduct/practice

As examples of codes of conduct for a safe responsible development of nanotechnologies, a series of initiatives promoted by different types of stakeholders have been chosen. These initiatives define a set of principles and practices which aim to guide the activity in this field and increase the level of trust and confidence amongst the stakeholders.

3.1.1 German NanoKommission

The work of the German NanoKommission [NanoKommission 2008], anticipated above and here described in more detail (see chapter 2, Working Group 3), has lead to the development of the "principles for the responsible use of nanomaterials" that have the character of a voluntary framework (code of conduct) intended to be complementary to existing regulation. This first set of principles was published in 2008. They are synthesised below:

1. Definition and disclosure of responsibility and management (good governance);
2. Transparency with regard to nanotechnology related information, data and processes;
3. Commitment to dialogues with stakeholders;
4. Establishment of risk management structures *based on the precautionary principle;*
5. Responsibility within the value chain.

Besides these principles, the NanoKommission has made other recommendations addressed to a variety of stakeholders (policy-makers, administration, industry and associations). The main points are:

- Cross-departmental research on safety and risk assessment;
- Implementation of preliminary assessment criteria and of principles for a responsible use of nanomaterials;
- Market transparency for consumers;

- Continuation of the NanoKommission's work[44] .

There are several analogies between the Responsible NanoCode and the EC CoC. In first place its principles-based structure and its voluntary character and the sharing of the attention for similar principles, such as **Sustainability**, **Transparency**, **Inclusiveness** and **Stakeholder's dialogue** and **Precaution**. **Responsibility** is used instead of **Accountability**.

The full document provides a set of accompanying actions. Some of them are particularly interesting, providing more detailed information compared to the actions specified in the EC CoC and making explicit reference to REACH and the work of the OECD and ISO. In particular:

- Definition of responsible corporate management system for N&N that should include precise programmes, objectives and responsibilities and procedures for monitoring the implementation of the system itself *(principle 1)*
- Data transparency must at least comply with REACH requirements and include public access to information on human and environmental safety as regulated by REACH. In particular the following information should be disclosed: Nanomaterials used and their products; Relevant information for a safety assessment over the entire life cycle; Implemented and recommended measures for safe use *(principle 2)*.
- Link to OECD/ISO activities: *"until uniform global standards for testing nanomaterials are available (OECD guidelines/tests) reasons should be given as to why the spectrum of methods applied is considered adequate." (principle 4)*.
- All partners along the value chain share responsibility for the flow of information along the entire chain and in keeping with REACH requirements. Safety data sheet should include information on nanomaterials and also ensure transparency of the use of other methods of communication *(principle 5)*.

It is worth noting that the level of implementation of this code, both by German departments (in their strategies or call for projects) and other stakeholders (industry, academia, etc) seems quite limited.

Until the end of the second phase of the NanoKommission 2009-2011, Working Group 1 will discuss awareness and the application of the principles in the chemical industry, in public authorities and NGOs. WG 1 and WG 3 (which is dealing with regulatory issues and questions of soft law) will publish their recommendations in the NanoKommission's Report 2011 (spring 2011 in English).

3.1.2 IG DHS Code of Conduct

The Swiss Retailers Association (IG DHS), founded in 2005 by six of Switzerland's largest retailers, has published in 2008 a Code of Conduct to be adopted by its members to answer the rising consumer concerns about the use of manufactured nanomaterials in publicly available products [IG DHS, 2009a, b]. By adhering to this Code of Conduct, the retailers commit themselves to openly inform the consumers about the use of manufactured nanomaterials in products on their shelves, and they require from their suppliers to pass the

[44] Including the following points: discussion of regulatory issues; consideration of additional applications; intensified use of life-cycle analyses; broadening of the dialogue on social and ethical issues; further development of precaution-oriented procedures for risk assessment and evaluation; intensified public communication of ongoing efforts and current findings; Intensified participation in the relevant international discussion; Stronger involvement on the part of industries applying nanotechnologies.

necessary safety data along the distribution chain. Upon examination of a potential new product, this information is exchanged with a basic questionnaire and, if nanotechnology is involved, further details are collected with the filling of the "Precautionary Matrix" (already quoted as measure introduced by the Swiss Action Plan). Based on this information, the retailer can decide whether to include a certain nano-related product in its product line or not and support this by initiating appropriate communication.

The Swiss IG DHS Code of Conduct encompasses a number of general principles that are either directed to the retailing organisations, or to their suppliers. Principles 1 to 3 are self-imposed by the signing retailers, while the company-specific and product-specific requirements are mainly directed to the suppliers:

1. **Personal responsibility** *(only products considered to be harmless to humans, animals and the environment may be included in the product range).*
2. **Procurement of information** *(the members of IG DHS are responsible for requesting information about nanotechnologies from their manufacturers and suppliers and must actively inform themselves about current developments concerning legal rulings and the latest scientific findings concerning nanotechnologies).*
3. **Information for consumers** *(the retail trade is responsible for informing consumers openly about products that incorporate nanotechnology)*
4. **Company-specific requirements** *(nanospecific aspects must be taken into account in the suppliers' risk management)*
5. **Product-specific requirement** *(manufacturers and suppliers are required to disclose and forward decision-relevant product data throughout the production and distribution chain)*

Although different in scope and aim from the EC CoC, the IG DHS Code of Conduct also refer to the basic principles of **Precaution, Inclusiveness** and **Accountability t**hat are part of the EC CoC. However, the main purpose of the IG DHS Code of Conduct is to determine duties and responsibilities concerning the exchange of information about nanomaterials between suppliers, retailers and (to a limited extent) consumers, describing procedures and tools regarding how such information should be exchanged.

The IG DHS Code has been signed by the largest Swiss retailers (including Coop, Manor and Migros). They make up a large share of the overall retail market in Switzerland and as a consequence, the effective implementation of the IG DHS CoC among their suppliers is strongly backed by the high market power of the undersigning retailers. Complying with the Code principles from the supplier's perspective is therefore not fully voluntary as non-compliance could (ultimately) result in the loss of an important channel of distribution. Under oligopoly-like market structures, the strong disincentives for non-compliance with the Code seem to compensate for the lack of formal (binding) enforcement.

Although considered in principle favourably, the IG DHS Code of Conduct has also been subject to criticism, as further detailed in the "Swiss Country Report", in terms of:

- the lack of indications on how compliance with the Code is evaluated and verified (e.g. either by an independent third party or by the signatories themselves);
- the absence of sanctions in case of non-compliance however established;
- the lack of review and updating procedures.

The example of the IG DHS CoC suggests that the relevant economic implications linked to the use of the Code, represent for the suppliers of the Swiss retail companies a strong incentive to increase the level of implementation of this (technically) voluntary measure. The introduction of a set of incentives and

disincentives, not contemplated at the moment, could be considered also for promoting the adoption of the EC CoC.

3.1.3 Responsible NanoCode

The *Responsible NanoCode*[45] *is* an initiative of four UK stakeholders. Insight Investment (a part of the Halifax Bank of Scotland Group), the Nanotechnology Industries Association (NIA), the Nanotechnology Knowledge Transfer Network (NanoKTN) and the Royal Society. This principles-based, voluntary code is designed to provide, in particular to governing bodies of organisations involved in the research, development, manufacturing, retailing, disposal and recycling of nano-related products, a "... strategic guidance on the governance of nanotechnology ..." and "... offer potential indicators of good practice to guide their responsible behaviour [...] during the transitional period while the appropriate national and international regulatory frameworks are being evaluated and, if necessary, developed, and to complement any existing regulation."

Seven principles, complemented by a set of guidelines and examples, form the basis of the Responsible NanoCode. These principles are:

1) ***Board Accountability (****accountability to reside with the board or is delegated to an appropriate senior executive committee).*
2) ***Stakeholder Involvement***
3) ***Worker Health and Safety (****ensure high standards of occupational health and safety for its workers handling nano-materials and nano-enabled products and during other stages of the product lifecycle)*
4) ***Public Health, Safety and Environmental Risks (****minimize any potential public EHS risks relating to its products using nanotechnologies throughout the product lifecycle)*
5) ***Wider Social, Ethical, Environmental & Health Impacts***
6) ***Engaging with Business Partners (****engagement with business partners to encourage and stimulate their adoption of the Code)*
7) ***Transparency and Disclosure (****report regularly and clearly on how the Responsible Nano Code is implemented).*

There are several analogies between the Responsible NanoCode and the EC CoC. In first place its principles-based structure and its voluntary character and then the attention towards shared principles, such as **Transparency**, **Inclusiveness** and **Workers/Public EHS issues**.

However, there are also important differences. As the UK Country Report pointed out, a fundamental difference is a more business-oriented destination of the NanoCode (*Adopt a policy or adapt an existing policy to specify its approach to sales, advertising, public relations and promotion of products using nanotechnologies."*) which shows also a lack of reference to the precautionary principle, of restrictions or limitations to the N&N research practices, a less defined sustainability principle.

The Code was launched in October 2008 and so far it seems to have experienced little implementation. However, the principles at the base of the Code are considered as important also for other codes, including the EC CoC and it is worth noting that these principles result from an in-depth consultation process

[45] Detailed information available at www.responsiblenanocode.org

involving different kinds of stakeholders (industry, research bodies and civil society organizations), which indicates the general value of these priorities.

3.1.4 Industry codes of conduct/practices

The concept of Corporate Social Responsibility (CRS) is now widely accepted among industrial companies and as a consequence many of them have adopted internal codes of conduct/practices to comply with it. Information about this behavior has become an important feature of the communication strategy. Giving indications about principles and key guidelines that the company commits itself to respect and follow while carrying out its business to assure responsibility and transparency, not only contributes to provide better relationships among its employees but it is also vital to build a greater sense of trust and safety among its customers and the public in general. To this end is working also the International Standard Organization (ISO) [46].

The above mentioned lack of specific provisions regulating nanotechnologies has made these voluntary schemes even more important. The **ICCA** (International Council of Chemical Associations) **"Responsible Care Global Charter",** the **BASF "Code of Conduct on Nanotechnology" ,** the **Bayer "Code of Good Practice on the Production and on-site-use of Nanomaterials",** and the **DuPont** "**Nano Risk Framework,** are telling examples of this type of initiatives. Though developed independently and in different times, the first three have many points in common as described below.

The "Responsible Care Global Charter", is probably one of the most widely adopted, global industrial codes [Responsible Care, 2010]. Developed and modified since the mid-1980s, was born as an initiative of the International Council of Chemical Associations (ICCA) to improve the environmental, health and safety performance of the chemical industry, and adopted as reference for CRS by 53 national chemical associations worldwide. Since 2007 this code has been accompanied by the Product Stewardship Guidelines, to form a comprehensive management system that includes existing codes and best practice guidelines for occupational health, environmental protection and product safety.

The code has six fundamental rules:

1) *Continuously improve the environmental, health and safety knowledge and performance of our technologies, processes and products over their life cycles to avoid harm to people and the environment;.*
2) *Use resources efficiently and minimize waste;*
3) *Report openly on performance, achievements and Shortcomings;*
4) *Listen, engage and work with people to understand and address their concerns and expectations;*

[46] ISO is working since 2005 on the development of an International Standard providing guidelines for social responsibility, the *"ISO 26000 Guidance on Social Responsibility (SR)"*, to be published at the end of 2010. ISO 26000 should be usable for organizations of all sizes and type (not only industry) and in countries at every stage of development, providing practical guidance to address SR. ISO 26000 is based on 7 principles: *accountability, transparency, ethical behaviour, respect for stakeholder interest, respect for rule law, respect for international norms behaviour, respect for human rights*. Further information available at:

http://isotc.iso.org/livelink/livelink/fetch/2000/2122/830949/3934883/3935096/home.html?nodeid=4451259&vernum=0

5) *Cooperate with governments and organizations in the development and implementation of effective regulations and standards, and to meet or go beyond them;*
6) *Provide help and advice to foster the responsible management of chemicals by all those who manage and use them along the product chain.*

The key features of Responsible Care, can be referred to those indicated by the EC CoC of **Sustainability**, **Excellence** in research and use of resources, **Openness** and **Transparency** with respect to the public and business.

A whole section is dedicated to the duties for the companies implementing the code, including obligations regarding the development and actualization of systematic procedures for verifying the implementation levels of all measurable indicators every two years. Companies are also requested to initiate, in accordance with the precautionary approach, risk-based and cost effective management measures to prevent negative human health and environmental impacts. Furthermore, they make a commitment to share best practice through mutual assistance with upstream suppliers and downstream users.

Materials at nano scale are not mentioned in specific terms, but according to those promoting the Responsible Care Charter, its principles can cover them adequately.

These principles are shared also by the **BASF "Code of Conduct on Nanotechnology"** and the **Bayer "Code of Good Practice on the Production and on-site-use of nanomaterials"** specifically developed for nanotechnologies, although both are slightly different from the Responsible Care in several aspects.

The **BASF Code** [BASF, 2010] faithfully traces out the principles and values of the Responsible Care Charter but includes also a much more strict statement of the precautionary principle with particular reference to the market. According to it, the products are marketed only if *"... their safety and environmental impact can be guaranteed on the basis of all available scientific information and technology".*

The **Bayer Code** [Bayer AG, 2010], even if stating that *"... the potential hazardous properties of nanomaterials are a matter of ongoing research activities ...."*, gives numerous practical operational indications to minimise worker exposure. It advices, for instance, to use, when possible, nanomaterials in an embedded form such as *"... suspensions, pastes, granular materials or composites.",* and with respect to the production processes, when it is impractical conducting the activities *"... in closed systems ..."* it recommends *"... the use of effective exhaust ventilation and filtration systems ...".*

In comparison to the EC CoC, the three codes described above appear less complete and binding. It must be considered, however, that they have been developed seeking to build confidence and trust referring to internal operational activity and it is therefore plausible that they do not consider specifically the more far reaching social and ethical implications which are nevertheless underlining the actions envisaged.

The **Accountability** principle, for example, probably one of the most binding of the EC CoC, appears to be substituted by a less constraining "**Responsibility**" principle in all the three codes In the other hand, they include a precise description of methods for identification and elimination of risks for workers that is not present, and maybe should be, in the EC CoC.

The **DuPont Nano Risk Framework,** finally, is the result of a two-year stakeholder dialogue project on nanotechnologies between **DuPont** and the **Environmental Defense Fund (EDF)**, a US-based NGO [Dupont, EDF, 2007]. The Framework (launched in June 2007) proposes a process to describe materials and

applications, for exploring properties, hazards and exposure, and for evaluating risks to help ensure proper handling of nanomaterials.

It is designed for those manufacturing or using nanomaterials and states clearly that it is not meant to be a substitute for government regulation or public discussion, but it hopes that its use will inform further dialog. It is based on the assumption that the basic risk equation must include not only suspected hazard, but also exposure. Also the "reasonable worst-case" should be considered. The Framework describes a systematic process for identifying, quantifying, managing, and reducing potential risks in six steps providing more concrete advice than the other codes mentioned in this document. The actions proposed are:

1. **Describe material and application** (Develop a general description of nano material and its intended use);
2. **Profile lifecycle(s)** (Develop three sets of profiles of the material's properties, inherent hazards, and associated exposures throughout the material's lifecycle);
3. **Evaluate risks** (Identify and characterize the nature, magnitude, and probability of risks; prioritize information gaps in the lifecycle profiles, and determine how to address them);
4. **Assess risk management** (Evaluate the available options for managing the risks identified in Step 3, and recommend a course of action);
5. **Decide, document, and act** (Decide whether to continue development, document the decision and its rationale, share appropriate information with internal and external stakeholders, and determine and initiate any necessary further action); and
6. **Review and adapt** (Through regularly scheduled and triggered reviews, update and re-execute the risk evaluation, ensure risk management systems are working as expected, and adapt those systems as necessary).

The document tailors standard risk management approaches to accommodate the current lack of knowledge about nanomaterials by requesting more information as a material progresses from R&D to commercial production.

The Nano Risk Framework is probably the most detailed and, at the same time, practical code available. It concludes with a 14-page worksheet (an editable version is available online) that helps reviewers track all relevant information, assumptions, and decisions discussed in the rest of the book and it has received both praises and critics.

The points of strength are represented by the inclusive process for development of the document, as well as its professionalism, thoroughness, and rationality. Criticism centers generally around the fact that the document is skewed in favor of larger companies. Smaller nanotechnology developers face obvious gaps in knowledge. However, the Environmental Defense Fund described the base set of information as *"… a bare minimum for the conduct of a thorough risk assessment …"* if fully completed and also stressed that the framework incorporates flexibility and makes allowances for precautionary risk management and transparency measures in the face of incomplete testing, especially at early stages of product development. This may help its adoption by smaller companies.

Finally, some companies have adopted less stringent and comprehensive code of conduct, but nevertheless in dealing with nano-related products they follow a precautionary approach purposely looking for processes minimizing potential risks associated with them.

As an example for this approach can be cited **Colorobbia** Italia, one of the most experienced Italian

company in the ceramic sector, actively involved in the production of nanomaterials. With its Research Centre (Ce.Ri.Col), Colorobbia has devoted particular attention to address health and safety issues associated with the synthesis and the use of nano related products. To this end, Ce.Ri.Col has developed a particular liquid phase, bottom-up approach for the preparation of materials at the nano scale. In this way the presence of nano powder is avoided in every step of the process eliminating the risks connected. Additional benefits, such as, for example simpler industrial scale-up have also been gained.

3.1.5 Other industry (voluntary) initiatives

Besides scientific studies and research projects, the **German Chemical Industry Association (VCI)** has invested considerable resources in EHS activities linked to nanotechnologies. In 2009 the document for "Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials" was developed and the document "Guidance for Handling and Use of Nanomaterials at the Workplace" was build up in cooperation with the German Federal Institute for Occupational Safety and Health. Thirdly, the document "Guidance for the Passing of Information along the Supply Chain in the Handling of Nanomaterials via Safety Data Sheets" was delivered in 2009 and published together with the other two documents (VCI 2009). These guidelines were well received at the international level [VCI, 2009 and 2010].

The Confederation of Netherlands Industry and Employers (VNO-NCW) has developed "pointers for Working with Nanomaterials" that sketch the outlines for approaching risk policy when working with nanomaterials [VNO-NCW, 2009]. The basic principle is that there needs to be a difference in approach in order to reduce exposure; activities that utilize dry nanomaterials that can easily be released require a different approach and measures to activities involving nanomaterials in solid and fluid matrices. The standard order for managing risks also applies when working with nanomaterials. The measures involved deal with technical, organisational and personnel matters: collect as much relevant information as possible and process free nanoparticles as far as possible in an enclosed area, otherwise make sure that the area used has good ventilation or some other type of breathing protection and wear protective clothing. The main approach is then worked out in detail according to the steps in the proposal for a set of best-practices guidelines. Amongst other things, these comprise:

- carrying out a hazard assessment;
- identification of all tasks and actions involving potential exposure, the measures to be taken, and their effectiveness;
- providing information and training for employees and health monitoring

3.2 Reporting schemes

Several countries, actively involved in nanotechnologies, have started in the past years campaigns aimed to gather data on nanomaterials useful to promote collaboration between government and industry and ensure that nanomaterials and nano-related products are introduced without risks into the market. The information gathered is intended, in fact, to help to design regulatory and policy decisions bound to promote the responsible development of nanotechnologies.

The most structured examples of these reporting schemes are those promoted in Canada, USA, UK and Australia. All of them, except of that planned in Canada, are voluntary. Recently also France[47] has introduced a provision within the environmental legislation framework, including mandatory declaration of

[47] http://www.senat.fr/rap/l08-488/l08-4881.pdf

all manufactured or imported products containing nanomaterials to an administrative authority. However, both the Canada and France actions are still waiting for implementation.

Environment Canada and Health Canada are going to promote a mandatory survey under the authority of Section 71 of the *Canadian Environmental Protection Act, 1999* statute [OECD, 2010]. The information gathering will focus on obtaining information on nanomaterials from industry to build a firm scientific base to inform risk assessment and management approaches. Respondents will be required to provide information on:

- Nanomaterials imported or manufactured in excess to 1 kg (including R&D materials);
- Basic use patterns, including volumes, sectors of utilization, types of products;
- Physical-chemical property or toxicological data;
- Available stewardship best practices.

As Canada, other industrialized nations, most notably the United States and UK, are making efforts in the implementation of reporting schemes

In 2008 the U.S. Environmental Protection Agency (EPA) promoted the **Nanoscale Materials Stewardship Program (NMSP)**, a voluntary programme to collect information on engineered nano scale materials (sized from 1 to 100 nanometers) manufactured or imported for commercial purposes, to support its programme for these materials under the Toxic Substances Control Act (TSCA)[48]. The information requested is similar to that of the Canadian reporting scheme.

As pointed out by EPA in the first interim report issued in January 2009 [EPA NSMP, 2009] and confirmed also later on, the Program has seen a limited industry participation and the Agency is considering how best use the Federal Toxic Substances Control Act to overcome this problem and gather more risk data. Due to this shortcoming the NMSP has therefore (so far) produced mixed results that EPA summarizes as it follows:

- *"In the aggregate, the NMSP has sufficiently advanced EPA's knowledge and understanding to enable the Agency to take further steps towards evaluating and, where appropriate, mitigating potential risks to health and the environment."*
- *"It appears that nearly two-thirds of the chemical substances from which commercially available nanoscale materials are based were not reported under the Basic Program."*
- *"It appears that approximately 90% of the different nanoscale materials that are likely to be commercially available were not reported under the Basic Program."*
- *"The low rate of engagement in the In-Depth Programme suggests that most companies are not inclined to voluntarily test their nanoscale materials."*

UK's Defra ran between September 2006 and September 2008 a two-year trial **Voluntary Reporting Scheme (VRS)** for engineered nanoscale materials, with which it invited to provide information on engineered nanomaterials with two or more dimensions up to 200nm that are "free" at any point in the product's life-cycle.

This VRS was open to all manufacturers or users of nanomaterials, or involved in nano science research or managing wastes incorporating engineered nano scale materials. Detailed information was requested

[48] http://www.epa.gov/nanoscience/

about the reporting organization and the nano material(s) being used (including properties, exposure, toxicity and eco toxicity).

Like the EPA's NSMP, also the Defra reporting scheme has attracted limited industry participation**.** Only thirteen responses were received and therefore the indications gathered about research priorities and how to manage the potential risks associated with nanotechnologies were considered not really representative.

The Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the regulatory authority responsible for industrial chemicals, started in 2008 (closed on 23rd of January 2009) a voluntary call to Australian industry for information to gauge the extent of the use of nano material in the country and ascertain which physicochemical and toxicological data are available.

The aim was to gather indication useful for introducing a regulatory reform of industrial nanomaterials and in the report "Proposal for Regulatory Reform of Industrial Nanomaterials Public Discussion Paper", are proposed a series of short to long term actions tackling gaps identified in terms of application of the existing regulation to nanomaterials [NICNAS 2009].

The report laments the limits of the voluntary character of the reporting scheme which lowers the participation, in particular of the industry, but it points also out that a mandatory reporting scheme would require relevant legislative changes and thus could only be considered as a possible medium for long term options. Commencing on a voluntary basis and progressing to mandatory option is considered as an acceptable compromise.

3.3 Risk management systems

Risk management systems are another way adopted at the industrial level to increase safety in relation to the manufacturing, production and use of nanotechnologies. Their main aim is to provide specific guidelines and best practices with reference to risk management and EHS issues and then certify their application. They do not have a regulatory role, and, as in the case of certification/accreditation, can work similarly to product quality certification systems. Independent organisations are usually responsible for the definition of principles and actions and the monitoring of their implementation.

3.3.1 AssuredNano®

AssuredNano™ was established in 2008 in UK by a collaboration between the Centre for Process Innovation (CPI) and the Institute of Occupational Medicine (IOM). It is a Health, Safety and Environment (EHS) accreditation scheme for organizations producing nanomaterials, nano-enabled products and users of nanotechnology in general [49].

Companies and organizations which gain accreditation to the AssuredNano® standard can offer demonstrable proof of a commitment to good EHS practice to employees, customers and other stakeholders. The centerpiece of the AssuredNano Accreditation Scheme is a standard which considers all EHS aspects associated with a nanomaterial or a nano-enabled product throughout its lifetime including:

- Management of manufacturing risk and exposure;
- Packaging and transportation;
- Life cycle analysis;

[49] Further information on the AssuredNano system can be found at http://www.assurednano.com/

- Disposal or recycle.

The standard is constructed on the basis of a business pre-existing quality system, such as ISO 9000:2000. Its modular approach, together with the power to de-register companies which cease to demonstrate adequate compliance with the annual audit protocol, ensures relevance to organizations of all sizes and continuing conformance.

3.3.2 CENARIOS®

In collaboration with TÜV SÜD Industry Service (Munich) and the Innovation Society, St.Gallen, the first certifiable nanospecific risk management and monitoring system (CENARIOS®) has been developed in 2007. As a fully voluntary measure in risk management, the CENARIOS® system complements existing parts of a risk management system and introduces specific requirements to responsibly and safely handle manufactured nanomaterials in production, processing and along the value chain.

CENARIOS® has been designed to enable companies to perform risk assessment under the best available knowledge under conditions of change and uncertainties. It comprises a set of tools and procedures to complement existing risk management approaches in nanotechnology businesses[50]:

- nanospecific risk estimation and risk evaluation to assess nanotechnology products based on the state of the art of science and technology;
- risk monitoring to provide continuous updates on the state of the art in science and technology, on societal and regulatory trends, risk perception, and market risks;
- tools for issues management and communication to react in the case of crisis;
- certification to review compliance with the CENARIOS® standard and to allow for increased external visibility. The certification is assigned by the independent certification unit of TÜV SÜD Industry Service.

CENARIOS® is implemented according to a catalogue of criteria documented in the CENARIOS® Certification Standard which is freely available. The criteria to be achieved include requirements referring to personnel, organisational structure, risk assessment and risk management. It should however be noted that the CENARIOS® certificate is assigned to the risk management system and not to individual nano-products.

3.3.3 Stoffenmanager Nano

The Stoffenmanager [51] is an internationally accepted Exposure Assessment and Control Banding tool. It is a free-of-charge internet based instrument developed by Arbo Unie, Netherlands Organisation for Applied Scientific Research(TNO)[52] and BECO[53] with funding from the Ministry of Social Affairs and Employment of The Netherlands. The Stoffenmanager is a generic tool initially developed for SME's to support them in assessing, prioritizing and controlling risks from chemicals at the workplace. It supports companies in performing a risk assessment and controlling exposure by taking proper risk management measures.

The Stoffenmanager is also a European Commission recommended tool that was designed to support downstream users (SMEs, sectors) to comply with the requirements set in REACH. Key elements of this

[50] Further information on the CENARIOS® system can be found at www.cenarios.eu.

[51] Further information on the Stoffenmanager system can be found at www.stoffenmanager.nl

[52] www.tno.nl

[53] www.beco.nl

system for use under REACH are:

- User friendly, understandable and transparent output for down stream users;
- Exposure estimates in quantitative numbers;
- General guidance on risk management measures according to the STOP principle is provided;
- Effectiveness of measures can be evaluated;
- Focus on tasks with highest risk;
- Export of data for communication on exposure scenarios can be built in easily;
- Information requirements in line with Annex I of REACH;

With the growing concern on managing the risks of nanoparticles, a special module of Stoggenmanager for nanomaterials (Stoffenmanager Nano) have been developed earlier this year. Stoffenmanager normally provide both qualitative (risk prioritising) and quantitative assessments. However, due to the lack of exposure limits for nanomaterials and limited available data at present time, the current version of Stoffenmanager Nano only provide the opportunity to estimate a qualitative risk when working with nanomaterials and advice for users on appropriate control measures to reduce a potential health risk. As the knowledge and governmental efforts in setting exposure limits advances, the subsequent version of Stoffenmanager Nano is expected to achieve the ultimate goal of providing quantitative assessment for nanomaterials in the near future.

Conclusions

The information gathered in the Consortium Countries (Country Reports) and in a number of countries outside it (desk survey), and summarized in this document, has confirmed that the responsible development of nanotechnologies represents a key topic in the agenda of all of them. The interest and the activity in this field, however, vary from country to country and this variability is somehow mirrored by a similar difference of the efforts with respect to governance and regulation

The overall situation can be roughly referred to two settings:

A. **Countries with a relevant activity in N&N.**
   The majority of countries most active in nanotechnology, both in terms of industrial involvement and research, have specific national initiatives to support and promote their effort. Within this framework, the responsible development of nanotechnologies has gained an increasing attention and several initiatives to this end have been activated or are in the offing. Though often different from country to country in scopes and extent, the principles and the issues guiding these initiatives are generally common.

B. **Countries with a (quantitatively) lower level of activity in N&N**
   In these countries national initiatives supporting N&N do not exist (or have been started only recently) and the activity in nanotechnologies is less structured and this applies also to the initiatives to address it's responsible development. The importance of the issue is, however, well acknowledged and there are initiatives in this field particularly with respect to EHS issues. Normally for regulation, in the European countries the tendency is to look at the regulatory regimes coming from the European Commission. The activations of national initiative supporting N&N could modify the situation giving a boost both to R&D and regulation.

As for the European Commission Code of Conduct on nanotechnology research (CoC), it has been found that the EC CoC, whilst often known and sometimes discussed in stakeholders meetings, has not been yet formally adopted or implemented in the countries investigated, although it must be pointed out that its compliance is being made a mandatory condition for government funding in The Netherlands.

The voluntary nature of the EC CoC could be a reason for this situation, but there are also several relevant **structural and organizational challenges** that could influence the dissemination and application of the EC CoC at national level. In particular:

- **Research (and its directives) is generally considered a core competence of Member States**. Generally, in particular in the case of type A countries, in which the scenario favour relationships amongst governing bodies and the different stakeholders, there is the preference to develop national schemes and recommendation and this may hinder the implementation of a code proposed from outside, such as the EC CoC.
- **The research landscape at the national level is generally broad and highly differentiated** (in particular again, but not only, in countries of type A). Even in the presence of a national strategy on N&N, responsibility for research planning and funding is spread across different national/regional levels and among different research departments and involve also different non governmental research governing bodies. This challenges both the dissemination and formal adoption/recommendation of the EC Code.

- In all type of countries, and in particular in those less involved in N&N and across the different research players (public and private research governing bodies, industry, research centres, NGOs, etc) **activities on N&N may be just a niche theme**. In this case, the Code may be seen too specific and the institution could prefer more simple/general codes to address responsible research and good practices in this field.

In this setting, the voluntary initiatives on N&N that have been prompted by different stakeholder can be seen as a means to initiate a constructive dialogue among stakeholders and to combine evidence-based risk assessment with a precautionary approach for cases in which high uncertainty and ambiguity prevail, so providing an interesting benchmark on the implementation of the EC CoC.

Among these initiatives, voluntary reporting schemes, that government agencies in some countries have started since 2006 in order to gather information on the production and use of nanomaterials as a base for possible regulatory actions in this field, have received, as said several times, a (at best) tepid response. A combination of reasons have been given for this behaviour, such as the often confidential and strategic character of the information requested, the desire to avoid any (potential) additional regulatory burdens, the potential high costs for complying with the request (in particular for SMEs). Circumventing/overcoming these issues, may be, together with implementation of incentives and disincentives, fundamental for the success of these measures.

When considering the codes of conduct developed by the industry (practice and risk management systems both specific to N&N or more general initiatives that could be tailored to the case of N&N), it turns out that many of the key actions and principles guiding them are the same as, or similar to, the ones endorsed by the EC CoC.

The principles of precaution, accountability, inclusiveness, meaning and sustainability are shared in all of them, though wording could be different (for example often the term responsibility instead than accountability is used).

Some points are instead missing in the EC CoC. In particular, some industry related initiatives propose interesting business-oriented guidelines for the marketing and promotion of nano-enabled products in a responsible way (e.g. Responsible NanoCode) and provide specific supporting documents, such as guidelines for characterisation, risk assessment, risk management, risk evaluation, documentation and communication (e.g. IG DHS, Responsible Care Global Charter, The Nano Risk Framework). The latter, providing precise and practical indications for the application of the principles stated are an important factor to help the implementation of the initiatives analyzed.

In conclusion, principles and (many) actions endorsed of the EC Code of Conduct are deeply debated among stakeholders (likely more than what happened with previous disruptive technologies, such as biotechnologies), but, as pointed out several times, this Code has been so far tepidly received.

From the finding reported in this document a set of (preliminary) issues to be further explored, which may help to improve its dissemination, content, and implementation, can be, however, highlighted:

Dissemination

- **The level of dissemination of the EC CoC (awareness of the document), in particular among research bodies and researchers, seems quite limited** and specific actions should be foreseen to this end.
- The research landscape is generally highly differentiated. **Dissemination should be carefully targeted in order to reach the several players responsible for research funding and planning across Europe.**
- **At least in some countries, it could be necessary to overcome eventual language barriers.**

Contents

- Though principles of the EC CoC are generally acknowledged by most stakeholders, it seems that there is **the need to further discuss the document with all potential recipients, in order to make it a more effective and concrete tool**. The whole document may need to be simplified, avoiding duplications and overlapping, and better focused in terms of actions and guidelines. Adequate incentives/disincentives as well as evaluation mechanisms may need to be introduced.
- The diverse social groups expected to be the recipients of the EC CoC have different and sometimes contradictory interests and values, and thus it appears hard to define a document that could stimulate and respond to the needs of all of them. **A "one size fits all" solution, as is perceived the current version of the CoC, could prove difficult to be adopted by all stakeholders. An issue is whether to focus the EC CoC only on "hot" topics (facilitating implementation) or, on the contrary, continue to have a broader and foresight view (making more challenging implementation).**
- The situation in terms of governance of N&N is rather differentiated across the different Countries and thus **there could be the need to adapt the EC CoC (or part of it) to the national situation** (but maintaining unchanged the basic principles and actions across countries). This is particularly true for countries outside Europe.
- One of the most urgent needs of stakeholders is to have guidelines and practices on EHS issues (in particular with respect to occupational health and safety aspects). Some international organizations (ISO and OECD in first place) and several stakeholders worldwide, have published guidance documents on these matters. **Whether and how EHS/OSH practical guidance should be part of the EC CoC is an open question.**

Implementation

- **Only measures autonomously being self-imposed (such as e.g. industry codes) or associated with precise sanctions or incentives for their adoption likely guarantee a good level of implementation.**
- At the industry level, a key factor for the application of a voluntary measure is how its adoption/non-adoption might influence company strategies, competitiveness and market parameters. **Advantages in adopting the EC CoC (at least for private research) should be clearly pointed out.**

- **In terms of advantage/incentive** the possibility to include the adoption of the Code as a condition in European funding mechanisms, such as the FP7 could be explored.
- **Monitoring/verification of compliance with the principles and actions of the EC CoC is a key** both to support implementation and to avoid a discretionary use of the code. Tools should be developed to allow self or independent verification of compliance.
- At the moment the EC CoC is intended for research. According to some preliminary comments the Code should be extended also beyond that stage.

As it can be seen, the points raised are numerous and multifaceted and require a particular effort to find the right answers to help the adoption of the EC CoC. Useful indications to this end are expected from the consultation of the relevant stakeholders which is carried out within a specific Work Package of this project (which could complement the activity on this matter of the EC). The results will be condensed in a forthcoming Report.

ANNEX I: Synthesis tables

In the following tables the codes of conduct (practices analysed in chapter 3 are summarised and compared with the EC CoC, in terms of developers/promoters, recipients (stakeholders targets of the initiative), scope, level of implementation, similarities and differences with key actions and principles of the EC CoC and some other parameters (relation with existing regulation, cooperation with governments on regulation and standardisation).

Table 1a: Comparison between the EC CoC and the other Codes of conduct analyzed: Scope and extent of the initiatives

	EU Code of Conduct for Research	German NanoKommission	The IG DHS Code of Conduct	The Responsible NanoCode	Multinational Code of Practices (The Responsible Care Global Charter, BASF, Bayer,…)	The NanoRisk Framework
Developers and Promoters	The Commission of the European Communities	German government, based on stakeholder dialogue	The Swiss Retailers Association	Insight Investment, NIA, NanoKTN, Royal Society	Chemical Industries	DuPont and the Environmental Defense Fund (EDF)
Recipients	Member States, employers, research founders, researchers and all individuals and civil society organisations involved or interested in N&N research.	Mainly at businesses, but also address other stakeholders.	Retailers, suppliers and manufacturers of nano-enabled products	Boards of governing bodies of organizations involved in the research, development, manufacturing, retailing, disposal and recycling of nano-enabled product	Chemical Industries	Industries manufacturing or using nanomaterials
Extent of Implementation	Low	Low	High at National level	Low	High at global level	High
Aim	Ensure that N&N research is undertaken in the Community in a safe, ethical and effective framework, supporting sustainable economic, social and environmental development	Provide a stakeholder orientated framework for the responsible use of nanomaterials. Cover R&D, manufacturing, processing including private use and recycling or disposal of products.	Regulate the communication between suppliers and retailers of product containing manufactured nanomaterials	Establish consensus of good practice in the research, production, retail and disposal of products using nanotechnologies and to provide guidance on what organisations can do to demonstrate responsible governance	Promoting human health and environmental safety while realizing nanotechnology's benefits	Establish a systematic and disciplined process for ensuring the responsible development of nanoscale materials, identify and reduce potential risks
Relation with existing regulation	Complementary	Complementary	Complementary	Complementary	Complementary	Complementary
Cooperation with Governments on Regulation and Standardisation	Directly mentioned	Directly mentioned	Directly mentioned	Directly mentioned	Directly mentioned	Directly mentioned

Table 1b: Comparison between the EC CoC and the other Codes of conduct analyzed: principles

		EU Code of Conduct for Research	German NanoKommission	The IG DHS Code of Conduct	The Responsible NanoCode	Multinational Code of Practices (The Responsible Care Global Charter, BASF, Bayer,…)	The NanoRisk Framework
Principles	**Meaning**	Directly mentioned	Not mentioned	Not mentioned	Directly mentioned	Directly mentioned	Directly mentioned
	Sustainability	Directly mentioned	Directly mentioned	Indirectly mentioned	Indirectly mentioned	Directly mentioned	Directly mentioned
	Precaution	Directly mentioned	Directly mentioned	Directly mentioned	Not mentioned	Directly mentioned	Directly mentioned
	Inclusiveness	Directly mentioned	Directly mentioned	Directly mentioned (for marketed products)	Directly mentioned	Directly mentioned	Directly mentioned
	Excellence	Directly mentioned	Not mentioned	Not mentioned	Not mentioned	Directly mentioned	Directly mentioned
	Innovation	Directly mentioned	Indirectly mentioned	Not mentioned	Not mentioned	Directly mentioned	Directly mentioned
	Accountability	Directly mentioned	Substituted with “Responsibility”	Directly mentioned	Not mentioned	Substituted with “Responsibility”	Directly mentioned

Table 1c: Comparison between the EC CoC and the other codes of conduct analyzed: actions to be taken

		EU Code of Conduct for Research	German NanoKommission	The IG DHS Code of Conduct	The Responsible NanoCode	Multinational Code of Practices (The Responsible Care Global Charter, BASF, Bayer,…)	The NanoRisk Framework
Key priorities	**Adopt N&N standard terminology**	Directly mentioned	Directly mentioned	Not mentioned (out of the scope)	Directly mentioned (referred to the market)	Directly mentioned	Directly mentioned
	Funding risk assessments	Directly mentioned	Directly mentioned	Not mentioned	Directly mentioned	Directly mentioned	Directly mentioned
	Priority to N&N research with "positive" impact	Directly mentioned	Not mentioned	Not mentioned (out of the scope)	Not mentioned	Not mentioned	Not mentioned
	Adopt specific health, safety and environmental measures	Directly mentioned	Directly mentioned	Directly mentioned	Directly mentioned	Directly mentioned	Directly mentioned
Prohibition, restrictions or limitations	**Prohibition to fund research involving the violation of fundamental rights or ethical principles**	Directly mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned
	Prohibition to undertake research aiming for human enhancement	Directly mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned
	Prohibition of deliberate intrusion of nano-objects in the human body	Directly mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned
Responsible Sales/Marketing		Not mentioned	Directly mentioned	Directly mentioned	Directly mentioned	Indirectly mentioned	Not mentioned
Guidelines for Characterisation, Risk Assessment, Risk Management, Risk Evaluation, Documentation and Communication		Not mentioned	Directly mentioned	Not mentioned	Not mentioned	Directly mentioned (in the Product Stewardship Guidelines)	Directly mentioned

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