

**Report on the European Commission's
Public Online Consultation**

**TOWARDS A STRATEGIC
NANOTECHNOLOGY ACTION PLAN
(SNAP) 2010-2015**

Open: 18.12.2009 to 19.02.2010

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- Creation and maintenance of the online version of the questionnaire, online data management, data mining, graphic analysis and writing of this report was done by Dr George Kirmizidis.
- Special thanks go to the members of the Inter-Service Group on Nanotechnologies.

STRUCTURE OF THE REPORT

This report outlines the purpose of the questionnaire and the methodologies that were followed in its design, execution and analysis. It provides an overview and summary of the main conclusions and highlights the overall opinions of respondents. References to specific responses can be found in the Results section.

- Annexes I & II present the actual questionnaire as published for the consultation, as well as itemised graphs for each group of respondents.
- Annex III presents the responding organisations, non-governmental organisations (NGOs) and public authorities in alphabetical order.
- Annex IV presents all responder comments for questions 2, 9 and 11 in alphabetical order.
- Annex V presents responder comments that were sent, in addition to the completed questionnaire.

PURPOSE AND METHODOLOGY

This open consultation was launched to support the preparation of a new action plan for nanotechnologies in Europe for 2010 to 2015. It was designed to collect the views of both experts active in the field and the public at large regarding the benefits, risks, concerns and awareness of nanotechnologies. The action plan also sought their opinions on future directions for governance and all relevant policies for the integrated, safe and responsible development and commercialisation of nanotechnologies and nanotechnology-enabled processes and products.

The instrument used for the public consultation was a questionnaire (see [ANNEX I](#)) jointly designed and worded by the Inter-Service Group (ISG) on nanotechnologies. The online version of the questionnaire was prepared using the internet-based software package IPM (Interactive Policy Making), expressly designed to create, launch and analyse replies to online questionnaires. The questionnaire was accompanied by the Specific Privacy Statement and a statement for the protection of personal data.

The public consultation was open for contributions between 18 December 2009 and 19 February 2010. The launch of this consultation was announced through the Directorates General involved in the Interservice Group (i.e. DGs RTD, SANCO, ENTR, ENV, JRC, INFSO, EMPL). All contributions collected during this period were analysed and used to generate the graphs found in this report. Comments submitted outside these dates or by means other than the online version of the questionnaire are also annexed to this report.

The analysis and review presented is based on the overall and detailed profiling of six groups of respondents: individual researchers, individual non-researchers, research organisations, industrial organisations, public authorities and NGOs.

There were 716 respondents who sent in their contributions electronically, while a large number of organisations also provided written responses. The majority of the responses were provided by individuals (61%). Two thirds (62.5%) of all individual responses were given by researchers.

The second biggest contributor group (22.8%) was made up of individual non-researchers including interested citizens, workers in companies dealing with nanotechnologies or nano-enabled products, and those working for authorities, trade unions or NGOs (22.8%). The industrial sectors (17.7%), including for example manufacturing and trading companies involved in nanotechnologies, also made a respectable contribution. NGOs (5.3%) and public authorities (4.5%), although smaller in absolute numbers, represented collective societal and governmental interests featured in one of ten responses.

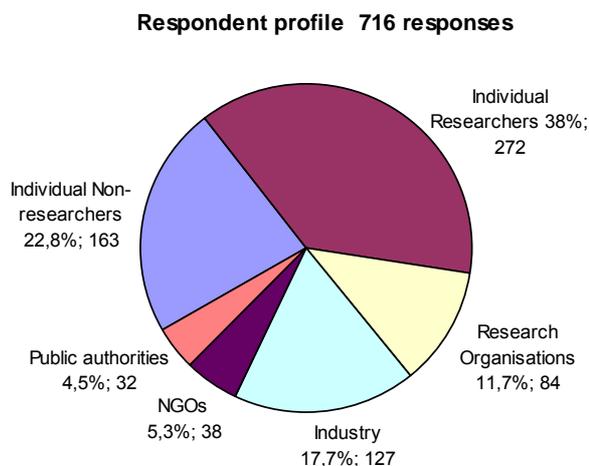


Figure 1: Groups of respondents used in the analysis and review of questionnaire responses

In terms of gender, individual respondents were 70% male and 30% female.

In terms of geographical contribution, the top three countries were Germany, France and Belgium in this order. It terms of responses submitted from outside the EU, input was received from Australia (1), Brazil (1), China (1), Egypt (1) India (2), Israel (3), Mexico (1), Norway (4), Russia (2), Serbia (2), Switzerland (16), Turkey (5), and the US (4).

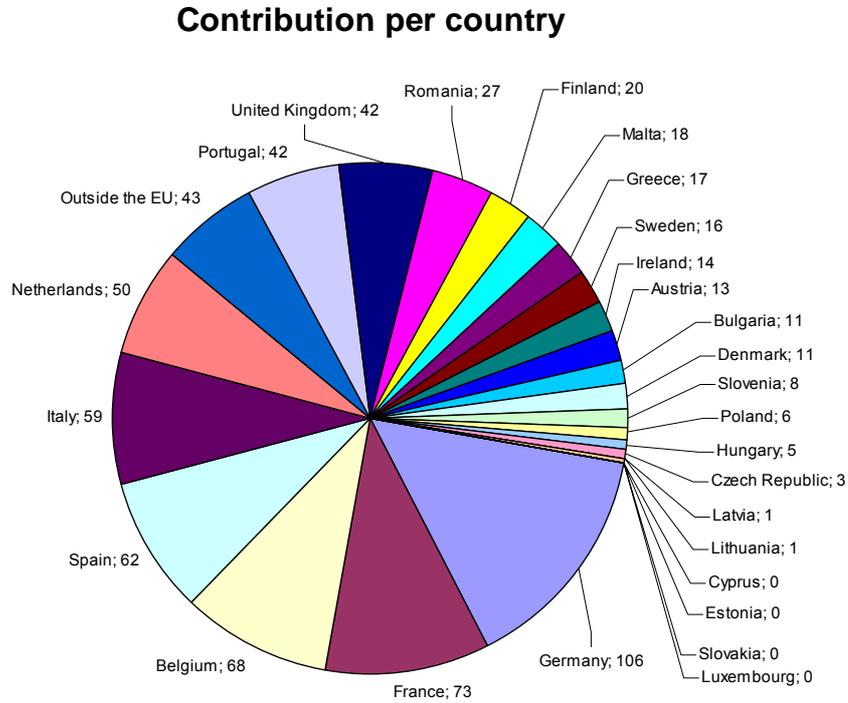


Figure 2: Geographical contribution of questionnaire respondents

MAIN CONCLUSIONS

This public consultation on the needs and policies of nanotechnology over the next few years, as perceived by experts and the general public, was open from 18 December 2009 to 19 February 2010. More than 700 responses were received from the general public, individual researchers, research organisations, industry, public authorities and NGOs. The main conclusions are:

- Both experts and the general public see many benefits in nanotechnologies, as well as potential risks.
- More than 80% of respondents have either high or reasonable expectations of nanotechnologies in general.
- Some areas are seen as more promising than others, with regard to their expected benefits and potential risks. There was a sharp difference of opinions between experts and the general public, as well as among different nanotechnology applications.
- ICT and energy are seen as the areas of application where the benefits far outweigh any potential risks.
- Applications in healthcare are universally seen as very promising, but there is a strong perception of potential risks.
- Applications in aerospace, construction, sustainable chemistry, security and environment are seen as areas that would bring high benefits.
- Applications in agriculture, food and household items are regarded with more scepticism, although potential benefits in these areas were also identified by many respondents.
- The major concerns regarding policy centre on the safety of nanomaterials and their regulation. Generally, more action is expected to ensure safety.
- Another major concern, primarily raised by industry, is the rate of innovation in Europe and the risk that Europe may fall behind in the exploitation of its scientific base in nanotechnology.
- There is overwhelming demand for an inventory of the types and uses of nanomaterials that would include safety aspects. Demand is also high for requirements to ensure that adequate information is provided on consumer products.
- There is a good or very good perception of EU governance related to nanotechnologies in terms of stakeholder consultation and setting research priorities. All other areas did poorly.
- EU documentation and activities related to research and research funding – and to a lesser extent the European Strategy and Action Plan (SAP) on nanosciences and nanotechnologies – seem to be well known and are often used. Conversely, the opinions of the European Group on Ethics (EGE) regarding nanomedicine are largely unknown.
- There is a perceived need to strengthen action in all areas of nanotechnology strategy pursued until now, from research and innovation to safety and outreach.

SUMMARY TABLE OF RESULTS

	Individual Researchers	Individual Non-researchers	Research Organisations	Industry	Public Authorities	NGOs
<p>Benefits</p> <p>Very high/high</p> <p>Modest-none</p>	<ul style="list-style-type: none"> • Healthcare • Energy • ICT <ul style="list-style-type: none"> • Household • Food • Agriculture 	<ul style="list-style-type: none"> • Healthcare • Energy • Construction • Aerospace <ul style="list-style-type: none"> • Household • Food • Agriculture 	<ul style="list-style-type: none"> • Healthcare • Energy • ICT <ul style="list-style-type: none"> • Household • Food • Agriculture 	<ul style="list-style-type: none"> • Healthcare • Energy • ICT • Aerospace <ul style="list-style-type: none"> • Household • Food • Agriculture 	<ul style="list-style-type: none"> • Healthcare • Energy • ICT • Construction <ul style="list-style-type: none"> • Household • Food • Agriculture 	<ul style="list-style-type: none"> • Healthcare • Energy • Environment <ul style="list-style-type: none"> • Household • Food • Agriculture • Nano-bio-cogno • Textiles
<p>Risks</p> <p>None</p> <p>Very high</p>	<ul style="list-style-type: none"> • ICT • Energy • Construction • Aerospace <ul style="list-style-type: none"> • Environment • Food • Agriculture 	<ul style="list-style-type: none"> • ICT • Energy • Construction • Aerospace <ul style="list-style-type: none"> • Environment • Food • Agriculture • Nano-bio-cogno 	<ul style="list-style-type: none"> • ICT • Energy • Construction • Aerospace <ul style="list-style-type: none"> • Environment • Food • Agriculture • Nano-bio-cogno 	<ul style="list-style-type: none"> • ICT • Energy • Construction • Aerospace <ul style="list-style-type: none"> • Food • Agriculture • Environment • Nano-bio-cogno 	<ul style="list-style-type: none"> • ICT • Energy • Construction • Protective equipment <ul style="list-style-type: none"> • Food • Healthcare • Environment • Agriculture 	<ul style="list-style-type: none"> • Food • Household • Agriculture • Environment • Nano-bio-cogno • Textiles

	Individual Researchers	Individual Non-researchers	Research Organisations	Industry	Public Authorities	NGOs
<p>Concerns</p> <p>Major issue</p> <p>Smaller issue</p>	<ul style="list-style-type: none"> Nanomaterial toxicity Nanomaterial and Worker's health Nanomaterial and Environment 	<ul style="list-style-type: none"> Nanomaterial toxicity Nanomaterial and Worker's health Nanomaterial and Environment 	<ul style="list-style-type: none"> Nanomaterial toxicity Nanomaterial and Worker's health Lack benefit/risk info 	<ul style="list-style-type: none"> Innovation obstacles Europe lagging behind in exploitation 	<ul style="list-style-type: none"> Nanomaterial toxicity Nanomaterial and Worker's health Nanomaterial and Environment Lack of regulatory tools 	<ul style="list-style-type: none"> All others except for: Europe lagging in exploitation benefits and removal of innovation barriers
<p>Governance</p> <p>Very good/good</p> <p>Fair/poor</p>	<ul style="list-style-type: none"> Stakeholder consultation All other areas 	<p>Stakeholder consultation</p> <ul style="list-style-type: none"> All other areas 	<ul style="list-style-type: none"> Stakeholder consultation Set of research priorities All other areas 	<ul style="list-style-type: none"> Stakeholder consultation Set of research priorities All other areas 	<ul style="list-style-type: none"> Stakeholder consultation All other areas 	<ul style="list-style-type: none"> All areas
<p>Awareness</p> <p>Use/know/ have read</p> <p>Do not know</p>	<ul style="list-style-type: none"> FP7 docs Nano-Action plan All others 	<ul style="list-style-type: none"> FP7 docs Nano-Action plan All others 	<ul style="list-style-type: none"> FP7 docs Nano-Action plan All others 	<ul style="list-style-type: none"> FP7 docs Nano-Action plan All others 	<ul style="list-style-type: none"> FP7 docs Nano-Action plan 20%-30% for all others 	<ul style="list-style-type: none"> All 30% for nanomedicine ethics

	Individual Researchers	Individual Non-researchers	Research Organisations	Industry	Public Authorities	NGOs
<p>EU policies in new AP</p> <p>Do more</p> <p>Do less</p>	<ul style="list-style-type: none"> • Education and training • International cooperation • Active communication and dissemination 	<ul style="list-style-type: none"> • Education and training • Active communication and dissemination • Address safety concerns • Develop better tools 	<ul style="list-style-type: none"> • Education and training • Develop infrastructure • International cooperation 	<ul style="list-style-type: none"> • Incentives and tools • Remove innovation barriers • Education and training • Develop better tools 	<ul style="list-style-type: none"> • Address safety concerns • Develop better tools • Adapt existing nanomaterial legislation 	<ul style="list-style-type: none"> • ALL OTHERS • Incentives and tools • Remove innovation barriers
<p>Envisaged policies</p> <p>YES, do</p> <p>NO, do not</p>	<ul style="list-style-type: none"> • Nano-inventory • Consumer product info • Develop new targeted nano-regulation 	<ul style="list-style-type: none"> • Nano-inventory • Consumer product info • Develop new targeted nano-regulation 	<ul style="list-style-type: none"> • Nano-inventory • Consumer product info • Develop new targeted nano-regulation 	<ul style="list-style-type: none"> • Nano-inventory • Consumer product info • •(30%) Develop new targeted nano-regulation 	<ul style="list-style-type: none"> • Nano-inventory • Consumer product info • Develop new targeted nano-regulation 	<ul style="list-style-type: none"> • Nano-inventory • Consumer product info • Develop new targeted nano-regulation

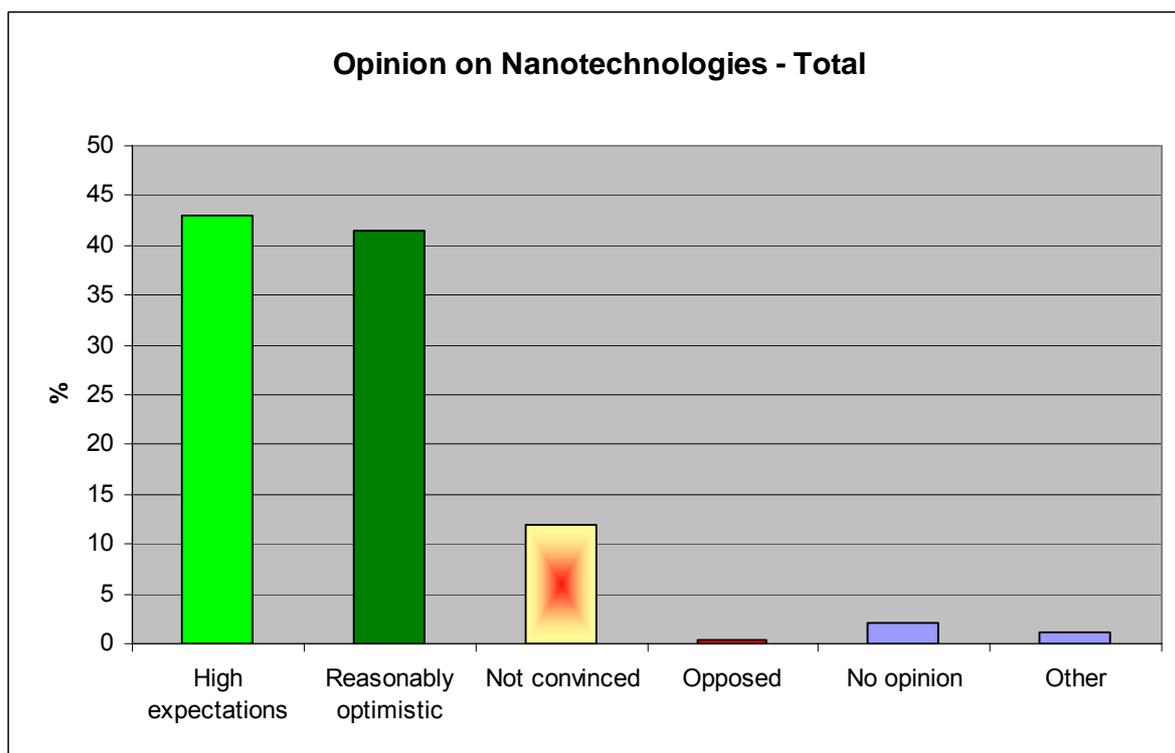
	Individual Researchers	Individual Non-researchers	Research Organisations	Industry	Public Authorities	NGOs
<p>EU Research policies Do more</p>	<ul style="list-style-type: none"> • Enabling research • Applications for EU policy objectives • Research Infrastructure 	<ul style="list-style-type: none"> • Enabling research • Applications for EU policy objectives • Implement regulations 	<ul style="list-style-type: none"> • Applications for EU policy objectives • Support industrial applications for innovation, employment and market • Enabling research 	<ul style="list-style-type: none"> • Support industrial applications for innovation, employment and market • Promote industrial involvement • Applications for EU policy objectives 	<ul style="list-style-type: none"> • Implement regulations • Enabling research • Applications for EU policy objectives 	<ul style="list-style-type: none"> • Implement regulations • Ensure ethical reviews
<p>Do less</p>						<ul style="list-style-type: none"> • <i>Support industrial applications for innovation, employment and market</i> • <i>Support industrial involvement/ exploitation of results</i>

RESULTS

OPINION ON NANOTECHNOLOGIES

This question invited respondents to reflect on their overall opinion about nanotechnologies. They indicated whether they have high expectations from nanotechnologies, are 'reasonably optimistic' about them, or are not really convinced that the benefits justify the effort and potential risks. Respondents opposing nanotechnologies, or without an opinion, also had the option to express these views.

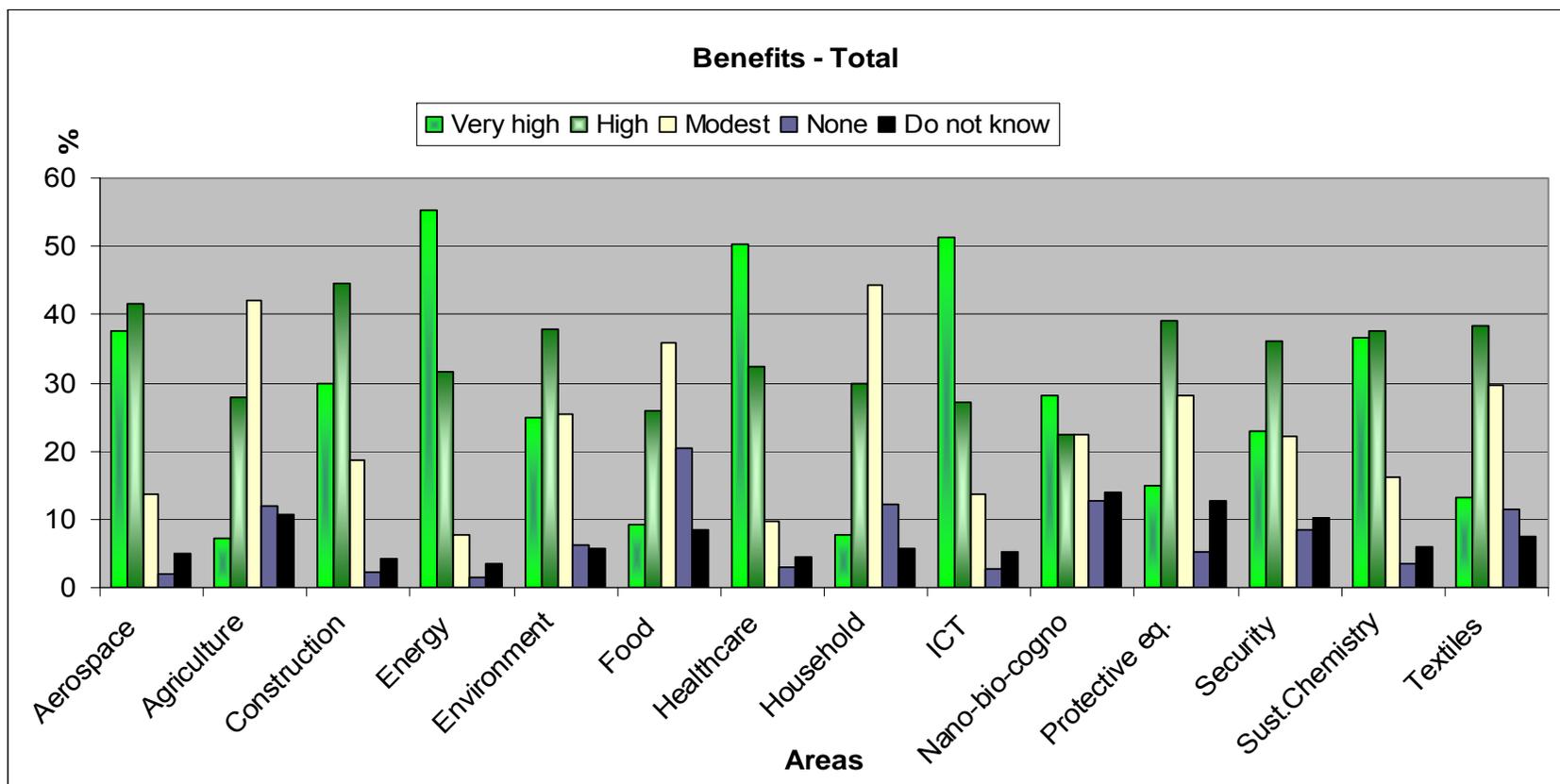
The vast majority of respondents expressed high expectations or were reasonably optimistic about nanotechnologies. Both answers scored more than 80%. There were 11% of participants who were not convinced that the benefits justify the effort and potential risks.



The vast majority of respondents, of all profiles, tend either to have high expectations from nanotechnologies or to be reasonably optimistic about them. Scores were between 40% and 50% for each of these two answers. NGOs represented the only group of respondents in which high expectations and reasonably optimistic views together (40%) were balanced by a 50% response expressing that they were not really convinced about the benefits justifying the effort and potential risks. (For a detailed breakdown for each group of respondents, please see [here](#)).

BENEFITS

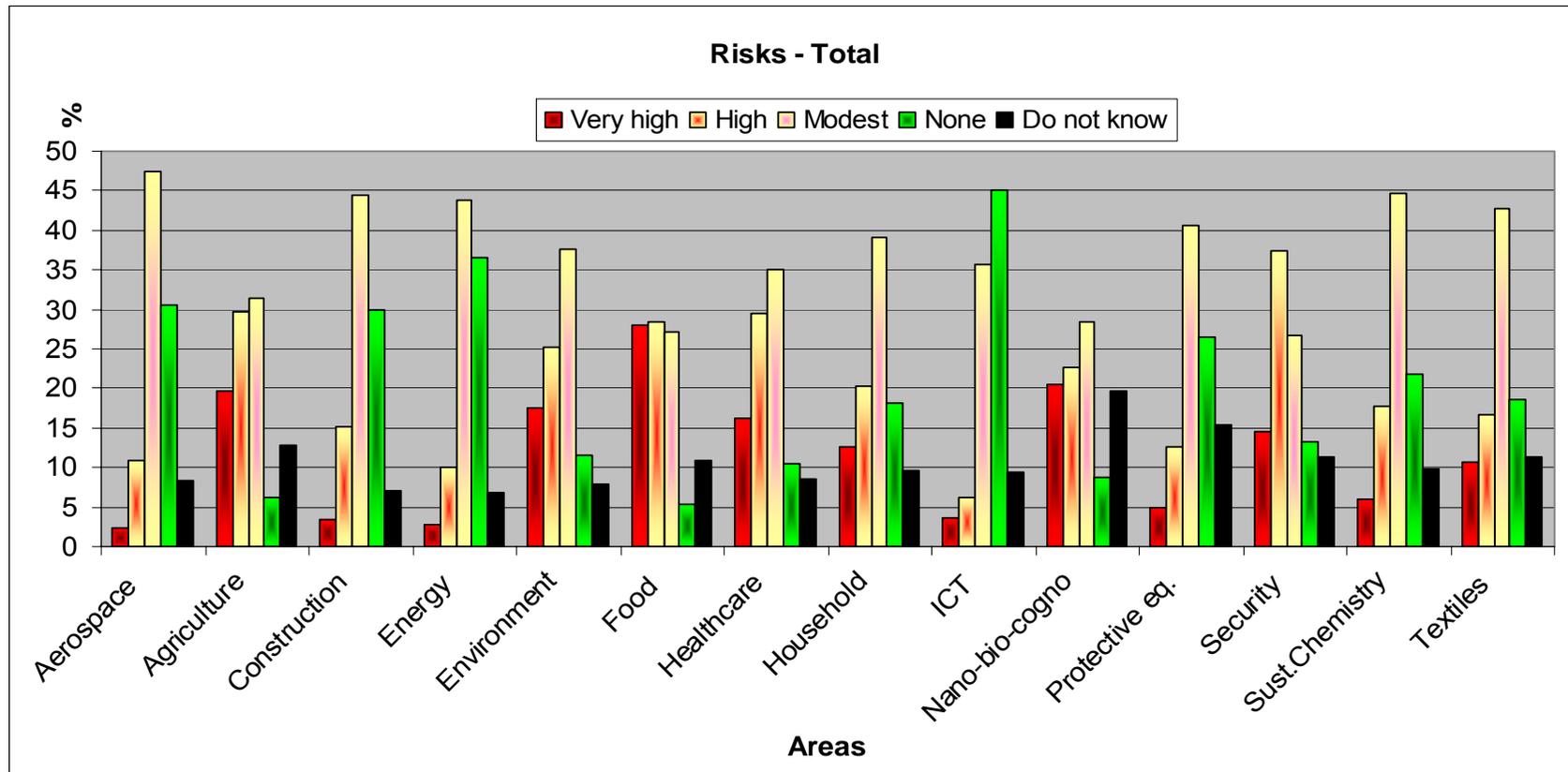
The respondents were asked to express their opinions regarding the most important areas of nanotechnology application and the level of benefits they expect from it. The respondents consider that the areas of energy, healthcare and information and communication technologies (ICT) will benefit the most from advances in nanotechnology. Household and agriculture are the two areas with the least expected benefits.



The expectations of individuals (both researchers and others) as well as research institutes are very high in the fields of ICT (e.g. computing, storage, communication, media), healthcare, energy and aerospace (50% to 60%). The Industry has high expectations also in the fields of energy (over 60%), construction (50%) and sustainable chemistry (40%). Most respondents see modest benefits for household (45%), food (40%) and agriculture (35% to 50%). NGOs expect high benefits in environment (60%), energy (58%) and healthcare (50%), as well as modest benefits in aerospace, security and protective equipment. Conversely, they expect no benefit in food, household, 'nano-bio-cogno' (nanotechnology, biotechnology and cognitive science) or textiles. (For a detailed breakdown for each group of respondents, please see [here](#)).

RISK

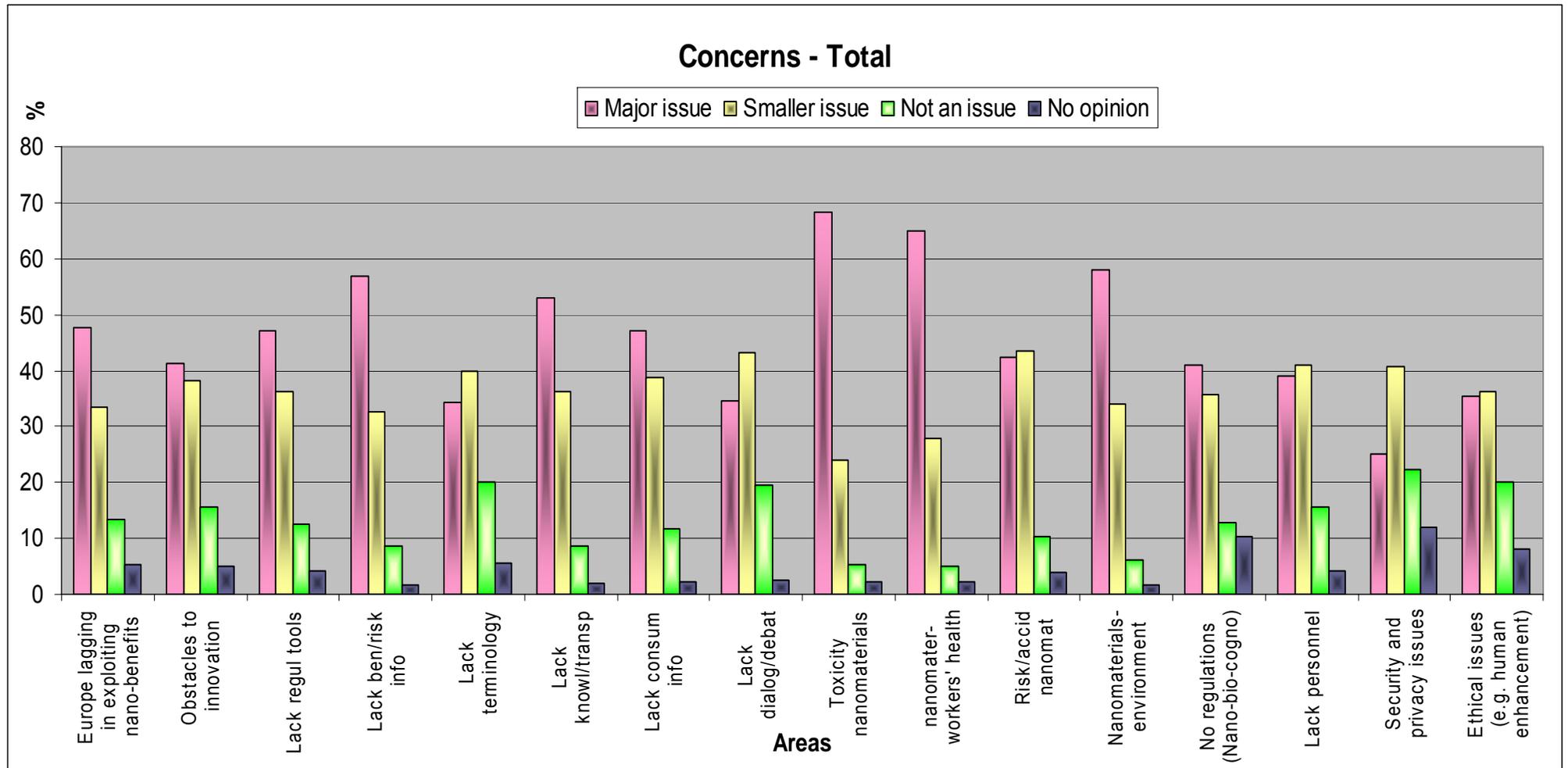
The respondents indicated the level of risk they expect from nanotechnologies in several areas. Risk expectations in areas such as ICT, energy, construction, aerospace and protective equipment are modest or nonexistent. Food, environment, agriculture and nano-bio-cogno are considered to be areas of high or very high risk.



ICT, energy, construction, aerospace and protective equipment were highlighted as areas of 'no-risk', regardless of the profile of the respondent. NGOs see balanced risks in security and ICT, and very high risks (60%) in agriculture, food, nano-bio-cogno and household. Similarly but to a lesser extent (20% to 30%), individual non-researchers see very high risks in the areas of food, healthcare, agriculture, environment and nano-bio-cogno technology applications (e.g. human enhancement). This attitude differentiates them from individual researchers, as well as from industrial respondents and public authorities who, in the same areas, believe that there are modest or no expected risks from nanotechnologies. (For a detailed breakdown for each group of respondents, please see [here](#)).

CONCERNS

Respondents indicated their main concerns about the current state of development of nanotechnologies, covering a whole range of issues from risks to exploitation, governance and social dialogue. Great concerns were expressed about the possible toxicity of poorly understood nanomaterials, as well as their possible effects on workers' health and on the environment, followed by the lack of adequate information imparted to the public on benefits and potential risks.

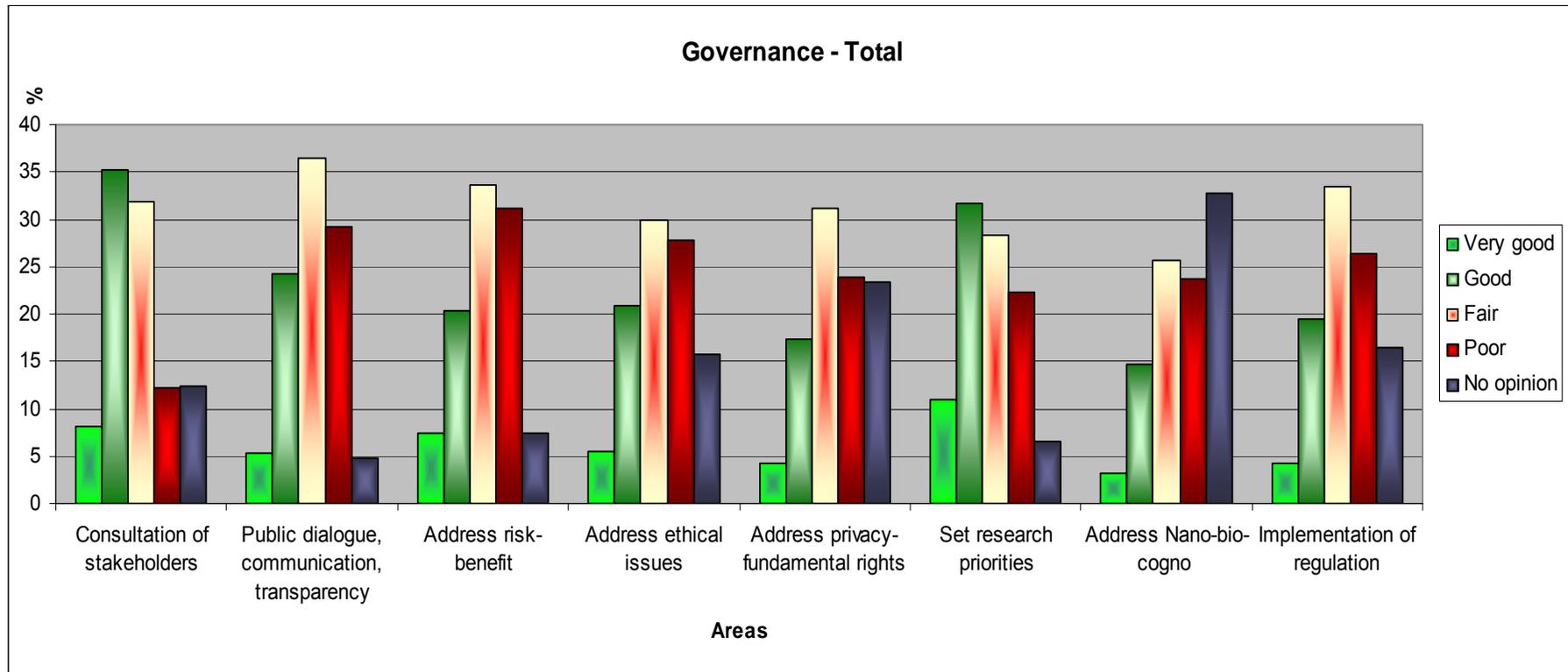


For individual researchers, the major concern is the possible toxicity of poorly understood nanomaterials (70%) followed closely by the possible effects of nanomaterials on workers' health (63%) and on the environment (55%). Individual non-researchers are concerned not only about these areas (in the range of 65% to 70%) but also about the lack of adequate information imparted to the public on benefits and potential risks (64%), the lack of knowledge and transparency regarding products on the market containing nanomaterials (59%), and the lack of proper consumer product information (59%).

Research organisations are mainly concerned about the possible toxicity of poorly understood nanomaterials (79%) followed closely by the possible effects of nanomaterials on workers' health (75%). They are also concerned about Europe lagging behind its competitors in exploiting the benefits of nanotechnologies (61%). A major issue of concern for industrial respondents is the existence of obstacles to innovation (60%) followed again by concerns that Europe is lagging behind its competitors in exploiting the benefits of nanotechnologies (56%). This group is also concerned about the possible toxicity of poorly understood nanomaterials (52%). NGOs have major concerns in all areas except for the exploitation of benefits from the removal of obstacles to innovation and to being competitive. There were 90% of these respondents who expressed concerns regarding the possible toxicity of poorly understood nanomaterials and their possible effects on workers' health. Europe lagging behind and nanomaterial toxicity, together with the lack of tools to implement and enforce existing regulation on environment, health and safety, are the major concerns of public authorities (68% to 80%). (For a detailed breakdown for each group of respondents, please see [here](#)).

GOVERNANCE

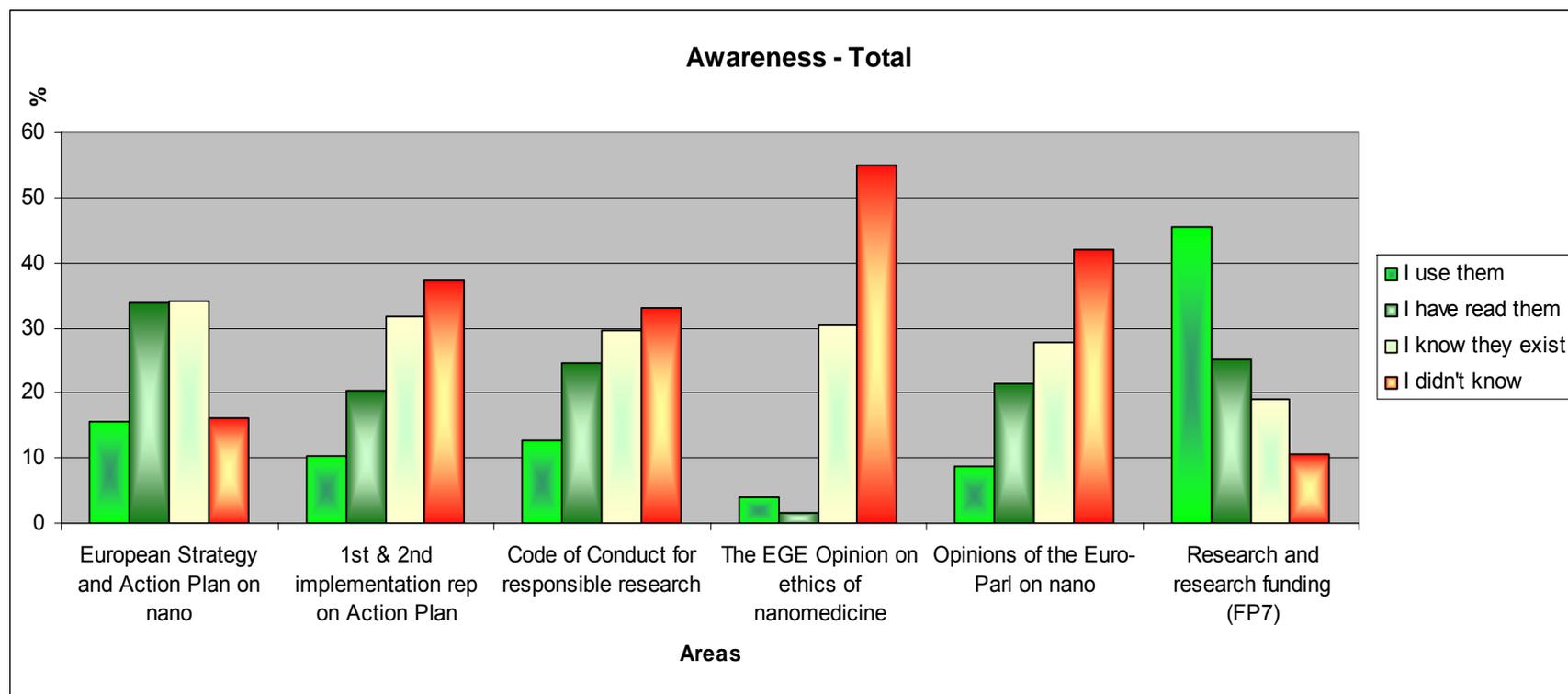
Respondents were asked to present their perceptions of the present level of governance related to nanotechnologies at the EU level. The results show that most respondents have a good or very good perception of the present EU-level governance related to nanotechnologies in terms of consultation of stakeholders. Setting research priorities is also perceived positively. All other areas are perceived as doing poorly.



All profiles except for NGOs have a good or very good perception (35% to 50%) regarding the consultation of stakeholders. NGOs perceive the level of consultation to be fair. Except for NGOs, all other profiles are satisfied with the EU's research priorities. Individual researchers, research institutions and industrial organisations have fair perceptions regarding public dialogue, communication and transparency (35% to 40%). Fair opinions of the same range were also given for the governance to address risk and ethical issues (35% to 40%), privacy and fundamental rights (35% to 45%) and implementation of regulations (40%). Individual non-researchers highlighted the same areas, opting for a poor rather than fair opinion on the same issues (40%). NGOs perceive the present governance at EU level as poor (55% to 70%). Public authorities have a fair opinion or no opinion on governance at EU level, with a mixed opinion on implementation of regulation. (For a detailed breakdown for each group of respondents, please see [here](#)).

AWARENESS

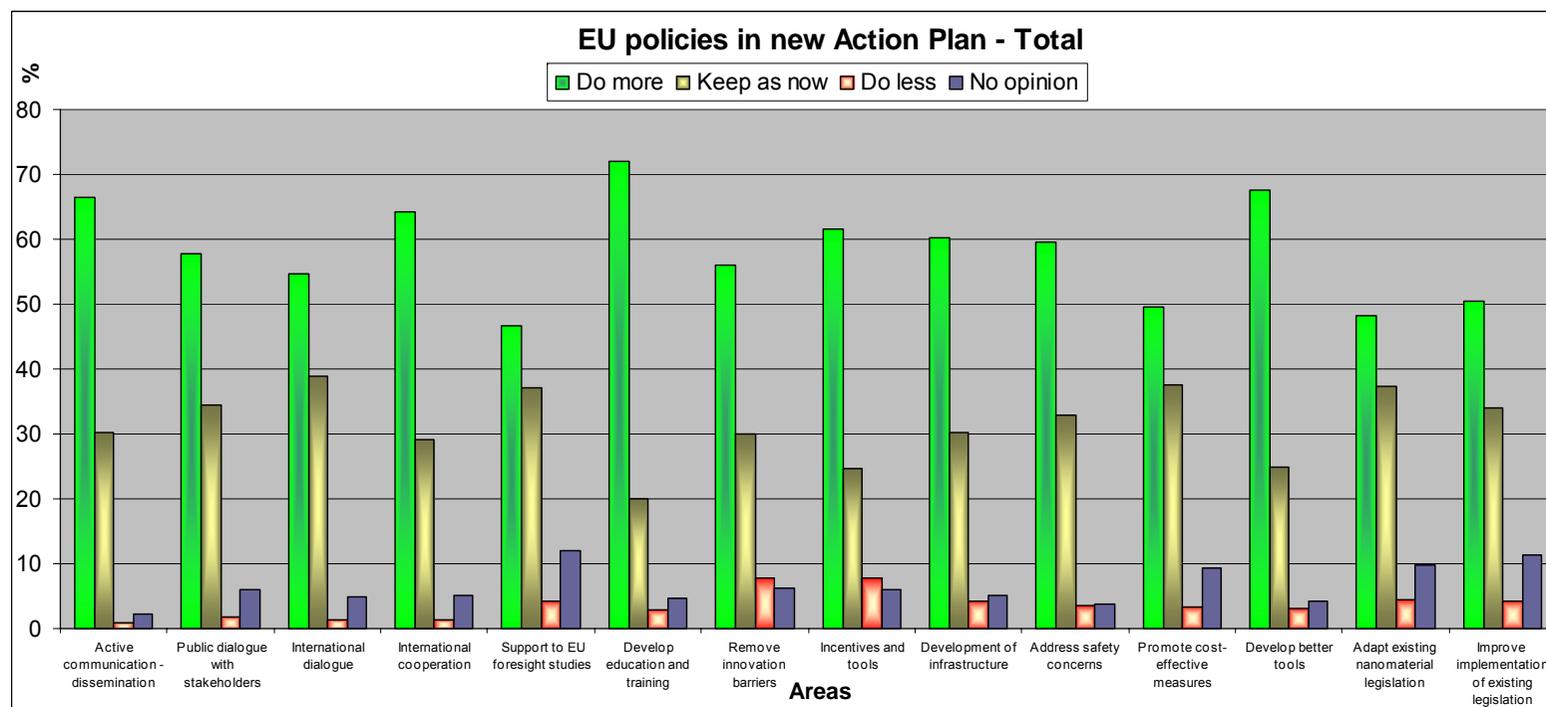
Respondents were asked to indicate their degree of awareness for a number of EU documents and activities: if they use them, have read them, know they exist or do not know of them. Overall, respondents know and use EU documentation and activities related to research and research funding (i.e. the Seventh Research Framework Programme, FP7). In addition, half the respondents have read and use the European Strategy and Action Plan on nanosciences and nanotechnologies. However, the European Group on Ethics (EGE) opinion on the ethics of nanomedicine is largely unknown.



Researchers (both individuals and organisations) as well as industrial respondents appear to know and use EU documentation and activities related to research and research funding extensively. This category was the only one that gathered an overwhelming 50% to 60% of replies, with the European Strategy and Action Plan on nanosciences and nanotechnologies having been read by 45% of the industrial respondents, and with 40% of individual researchers knowing that it exists. The European Group on Ethics (EGE) opinion on ethics of nanomedicine is largely unknown (50% to 70%) among all profiles. However, respondents indicated in an earlier section of the questionnaire that they are concerned about ethics. NGOs and to a lesser extent public authorities were the most aware of EU documents and activities among all respondents; they had read all of the documents mentioned and had used the opinion of the European Parliament on nanotechnologies (50% to 55%). (For a detailed breakdown for each group of respondents, please see [here](#)).

EU POLICY AREAS

The respondents indicated how a number of EU policy actions related to nanotechnologies should be continued in the new Action Plan. The majority of respondents want to see more done in all suggested areas of EU policies in the new Action Plan. Most favoured were the development of education and training in nanosciences and nanotechnologies, the active communication and dissemination of information, international cooperation and the development of better tools for assessment of risk and benefits for nanotechnologies.

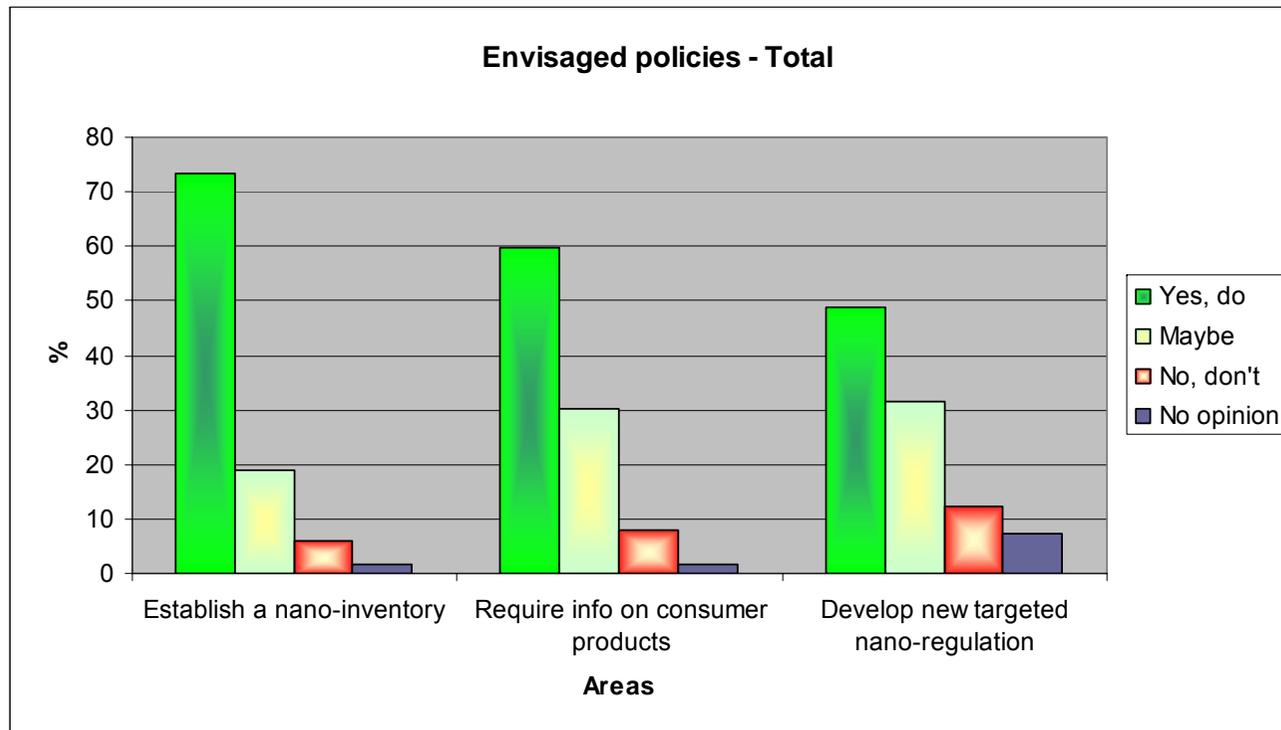


The majority of individual researchers want to see more done for education and training (75%) and international cooperation (72%), as well as for communication and dissemination of information (67%). Most also want the new Action Plan to do more to facilitate innovation in nanotechnologies (67%). Education and training was the top choice for both non-researchers and research institutes, and was among the top three choices of the industrial respondents (65%), ranking slightly lower than issues related to innovation (removing barriers, 67%; providing incentives and facilitating tools, 71%). In terms of ethical issues, research organisations, industry and to a lesser extent public authorities believe that enough is being done. NGOs want less to be done in the fields of removing barriers to innovation in nanotechnologies (40%) and incentives and tools facilitating innovation in nanotechnologies (40%). They expect more to be done with respect to active communication and dissemination of information (92%), public dialogue (87%), developing better tools to assess risk and benefits for nanotechnologies (90%) and addressing safety concerns (84%). The latter two areas are also priorities for the public authorities (75%), who also believe that policies removing barriers to innovation should be kept as they are (53%). (For a detailed breakdown for each group of respondents, please see [here](#)).

NEW EU POLICY AREAS

The respondents were asked to express their opinions on new EU policy actions related to nanotechnologies. Respondents strongly supported all three envisaged policies:

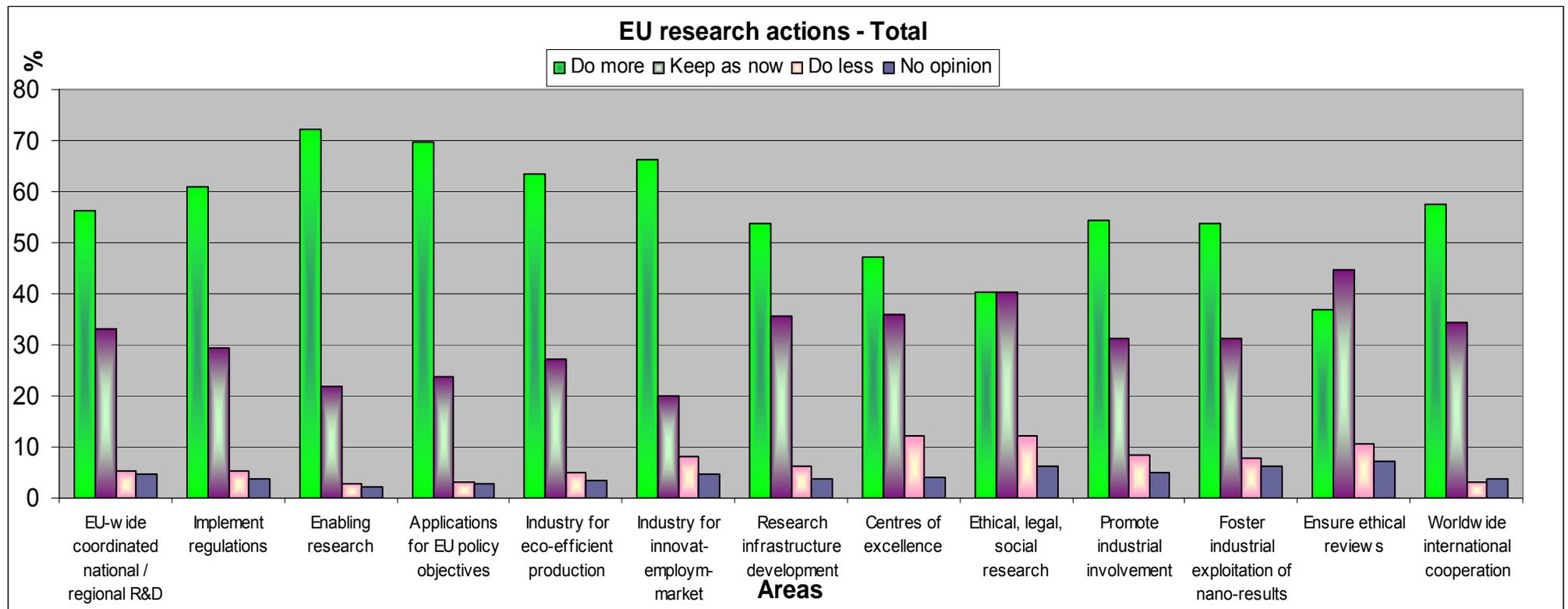
- establishment of an inventory of types and uses of nanomaterials, including safety aspects,
- requirement for adequate information on consumer products (e.g. claims verification, labelling of nano-content of consumer products), and
- development of new, specifically targeted regulation for nanotechnologies, especially related to nano-bio-cogno-applications (e.g. human enhancement).



An overwhelming 60% to 90% of respondents of all profiles are strongly in favour of policies establishing an inventory of the types and uses of nanomaterials (including safety aspects) and requiring adequate information on consumer products (e.g. claims verification, labelling of nano-content of consumer products). The policy action of new, specifically targeted regulation for nanotechnologies, especially related to nano-bio-cogno-applications (e.g. human enhancement) was supported by 50% of respondents, with the industrial partners having mixed views about it and NGOs strongly supporting it (79%). (For a detailed breakdown for each group of respondents, please see [here](#)).

EU RESEARCH ACTIONS

Respondents were asked which EU research actions related to nanotechnologies should be reinforced or reduced. They are in favour of supporting research into understanding, measurement, testing, imaging, and modelling of materials and properties at the nanoscale. They want to see more research into applications that can contribute to EU policy objectives (e.g. health, environment and climate, energy, water, workers' protection). They are also in favour of actions that support research into other industrial applications of nanotechnologies with high potential for innovation, new employment and new markets, as well as for industrial applications leading to more eco-efficient production (e.g. chemicals, biotechnology). Conversely, respondents do not expect more actions in the fields of ethical, legal and social aspects of nanotechnology, or in terms of ensuring ethical reviews of EU nano R&D projects. At the same time, they do not want to see less done.



The priorities for action among individual researchers are on supporting research into understanding, measurement, testing, imaging, and modelling of materials and properties at the nanoscale (78%), followed by encouragement (68%) to conduct more research into applications that can contribute to EU policy objectives (e.g. health, environment and climate, energy, water, workers' protection). Almost equally important is doing more for the development of research infrastructures (67%).

Research institutes expect more (70% to 80%) on research into other industrial applications of nanotechnologies with high potential for innovation, new employment and new markets. They also expect more research into applications that can contribute to EU policy objectives (see above), as well as enabling research into understanding, measurement, testing, imaging, and modelling of materials and properties at the nanoscale. The institutes also call for increased research into industrial applications leading to more eco-efficient production (e.g. chemicals, biotechnology) and worldwide international cooperation.

Individual non-researchers expect more policy actions to support research into applications that can contribute to EU policy objectives and enable research on understanding, measurement, testing, imaging, and modelling of materials and properties at the nanoscale. Both fields scored above 70%.

Industrial respondents insisted (more than 70%) on the development of new EU research policies to support research into other industrial applications of nanotechnologies with high potential for innovation, new employment and new markets. These respondents also insisted that research policies promote industrial involvement in EU R&D projects. They believe (more than 50%) that ethical review of EU nano R&D projects and the policies supporting the development of research infrastructures should be kept as they are.

NGOs believe that less needs to be done to support research into other industrial applications of nanotechnologies with high potential for innovation, new employment and new markets (42%) and in fostering industrial exploitation of nano R&D results (42%). Opinions were divided on support to centres of excellence and promotion of industrial involvement in EU R&D projects, with the 'keep as is' option slightly prevailing (37%). NGOs want to see more support for research needed for implementing regulations (i.e. research into the safety of nanomaterials and methods for monitoring and toxicity testing) by an overwhelming 92%. They also want to see more done to ensure ethical review of EU nano R&D projects (79%), to support research on ethical, legal and social aspects of nanotechnology (76%) and to enable research into understanding, measurement, testing, imaging and modelling of materials and properties at the nanoscale (74%).

Implementing regulation and enabling research are also areas where public authorities want to see more action. This group believes that the centres of excellence and research infrastructure development should be kept as they are (50% and 60% respectively). (For a detailed breakdown for each group of respondents, please see [here](#)).

Annex I: Questionnaire

This public consultation invited views on the needs in nanotechnology over the next five years, as perceived by experts active in the field and by the public at large.

Nanotechnologies hold great potential in areas as diverse as health, energy production and efficiency, transport and manufacturing. This potential may help achieve sustainable development and enhancing Europe's industrial competitiveness. To unlock this potential and gain the greatest benefits while minimising adverse impacts on health and the environment, the European Commission follows an 'integrated, safe and responsible approach'. The Nanotechnology Action Plan 2005-2009 provided a first impetus on the road towards diverse developments, combined with a high level of attention to the protection of workers, consumers and the environment, as well as to public dialogue and ethical issues.

Public funding in nanotechnology research in the five years leading up to 2009 has exceeded EUR 7 billion, nearly a third coming from the Community Research Framework Programmes. Hundreds of projects have enhanced fundamental understanding and produced promising results for applications in areas ranging from nanoelectronics to nanomedicine. The Commission and Member States have supported research infrastructures and also education and training in nanosciences and nanotechnologies.

These developments have been matched by a wide range of activities to ensure the responsible development of nanotechnology applications in a way that takes people's expectations and concerns into account. These activities were complemented by a careful review of the regulatory landscape, reflections on ethical issues and outreach. This work is being carried out in close cooperation with Member States and Europe's international partners.

Details of all this work can be found in the recent Commission Communication on the Implementation of the Nanotechnology Action Plan – COM(2009)607 – and its accompanying Staff Working Document – SEC(2009)1468.

To capitalize on the benefits from all these efforts, Europe must develop further its ability to translate research results into innovative products and processes. This is one of the reasons why the Commission is now considering a new Action Plan for Nanotechnology.

The main objective of this Action Plan will be to address the technological and societal challenges of the next five years and to strengthen the research and innovation efforts, with increased emphasis on sustainable development, competitiveness, health, safety and environmental issues. It is necessary to advance the fundamental understanding of how nanomaterials behave throughout their life cycle to ensure product safety and a high level of protection of human health and the environment, while taking full advantage of the benefits of the new technologies. In parallel, work on effective implementation of regulation will continue. Also essential is interdisciplinary collaboration. All this must be done in a climate of trust built on direct and continuous societal dialogue.

Respondents were then invited to confirm their status (citizen, organisation or public authority) and complete the short questionnaire that follows:

TOWARDS A STRATEGIC NANOTECHNOLOGY ACTION PLAN (SNAP) 2010-2015

1. Respondent profile

For individuals:

- Name, age, gender, country, e-mail.

- From which perspective are you interested in nanotechnologies:

- I am an interested citizen
- I work in a company dealing with nanotechnologies or with nano-enabled products
- I am a researcher
- I work for an authority
- I work for, or I am active in, a trade union
- I belong to a non-governmental organisation
- Other specific reason: _____

For organisations / companies:

- Name of organisation, register ID or not, country, e-mail.

- Type of organisation:

- Manufacturing or trading company involved in nanotechnologies
- Manufacturing or trading company not involved in nanotechnologies
- Association of companies (sector: _____)
- Research institute or Higher education institute
- Trade union
- Non-governmental organisation
- Other: _____

For public authorities:

- Name, country, e-mail.

- Type of public authority:

- Regulatory authority
- Authority involved in research policy
- Authority involved in market surveillance
- Authority involved in market authorization
- Decentralised, regional authority
- Centralized authority

2. Which of the following reflects your opinion about nanotechnologies best?

- I have high expectations from nanotechnologies
- I am reasonably optimistic about nanotechnologies
- I am not really convinced that the benefits justify the effort and the potential risks
- I am opposed to nanotechnologies
- I am without an opinion so far

Comment: _____

3. Please indicate for each area what level of benefits you expect from nanotechnologies

	Very high	High	Modest	None at all	Don't know
Aerospace, automotive, and transport (e.g. weight reduction, self-cleaning coatings)					
Agriculture (e.g. efficient fertilizers, pesticides delivery)					
Construction (e.g. stronger materials, insulation materials, self-cleaning windows)					
Energy (e.g. solar cells, other forms of energy conversion, batteries, other forms of energy storage)					
Environment (e.g. supply of drinking water, wastewater treatment, soil remediation, emission reductions)					
Food and feed (e.g. active packaging, preservatives, enriched food, flavour, smell, taste and colours)					
Health care (e.g. diagnostics, treatment, pharmaceuticals)					
Household products and other consumer products					
ICT (e.g. computing, storage, communication, media)					
Nano-bio-cogno-technology applications (e.g. human enhancement)					
Protective equipment					
Security (e.g. detection of dangerous substances, tracking of objects or of persons)					
Sustainable chemistry (e.g. enhanced process efficiency by catalysis)					
Textiles/Clothing					

4. Please indicate for each area what level of risk you expect from nanotechnologies:

	Very high	High	Modest	None at all	Don't know
Aerospace, automotive, and transport (e.g. weight reduction, self-cleaning coatings)					
Agriculture (e.g. efficient fertilizers, pesticides delivery)					
Construction (e.g. stronger materials, insulation materials, self-cleaning windows)					
Energy (e.g. solar cells, other forms of energy conversion, batteries, other forms of energy storage)					
Environment (e.g. supply of drinking water, wastewater treatment, soil remediation, emission reductions)					
Food and feed (e.g. active packaging, preservatives, enriched food, flavour, smell, taste and colours)					
Health care (e.g. diagnostics, treatment, pharmaceuticals)					
Household products and other consumer products					
ICT (e.g. computing, storage, communication, media)					
Nano-bio-cogno-technology applications (e.g. human enhancement)					
Protective equipment					
Security (e.g. detection of dangerous substances, tracking of objects or of persons)					
Sustainable chemistry (e.g. enhanced process efficiency by catalysis)					
Textiles / Clothing					

5. What are your main concerns about the present situation of nanotechnologies?

	Major issue	Smaller issue	Not an issue	No opinion
Europe lagging behind its competitors in exploiting the benefits of nanotechnologies				
Obstacles to innovation				
Lack of tools to implement and enforce existing regulation on environment, health and safety				
Lack of adequate information to the public on benefits and potential risks				
Lack of uniform terminology				
Lack of knowledge and transparency regarding products on the market containing nanomaterials				
Lack of proper consumer product information				
Lack of public dialogue / debate				
The possible toxicity of poorly understood nanomaterials				
The possible effects of nanomaterials on workers' health				
The possible risks from accidents when manufacturing nanomaterials				
The possible effects of nanomaterials on the environment				
Lack of new specific regulations - especially related to Nano-bio-cogno-applications (e.g. enhancement)				
Lack of adequately skilled personnel				
Security and privacy issues (e.g. the possibility to track persons)				
Ethical issues (e.g. human enhancement)				

6. How do you perceive the present governance at EU level related to nanotechnologies?

	Very good	Good	Fair	Poor	No opinion
Consultation of stakeholders					
Public dialogue, communication, transparency					
Addressing issues of risk (for workers, consumers, and the environment) and benefit					
Addressing ethical issues					
Addressing issues of privacy and fundamental rights					
Setting of research priorities					
Addressing especially Nano-bio-cogno-applications (e.g. enhancement) by additional targeted regulation					
Implementation of regulation					

7. Are you aware of the following EU documents and activities related to nanotechnologies?

	I know and use them	I have read them	I know they exist	I didn't know
The European Strategy and Action Plan on nanosciences and nanotechnologies				
The 1st and 2nd implementation reports on the Action Plan				
The Code of Conduct for responsible research				
The EGE Opinion on ethics of nanomedicine				
Opinions of the European Parliament on nanotechnologies				
Research and research funding (FP7)				

8. How should the following EU policy actions related to nanotechnologies be continued in the new Action Plan?

	Do more	Keep as now	Do less	No opinion
Active communication and dissemination of information				
Public dialogue with stakeholders including targeted feedback				
International dialogue				
International cooperation				
Support to the EU foresight studies				
Develop education and training in Nanosciences and Nanotechnologies				
Remove barriers to innovation in Nanotechnologies				
Incentives and tools facilitating innovation in Nanotechnologies				
Development of infrastructure for nanotechnology application studies including assessment				
Address safety concerns linked to Nanotechnologies				
Promote cost-effective measures to minimise exposures				
Develop better tools for assessment of risk and benefits for Nanotechnologies				
Adapt existing legislation for nanomaterials				
Improve the implementation of existing legislation				

9. Which new EU policy actions related to nanotechnologies should be envisaged?

	Yes, do	Maybe	No, don't	No opinion
Establish an inventory of types and uses of nanomaterials, including safety aspects				
Require adequate information on consumer products (e.g. claims verification; labelling of nano-content of consumer products)				
Develop new specifically targeted regulation for nanotechnologies - especially related to Nano-bio-cogno-applications (e.g. enhancement)				
Other :				

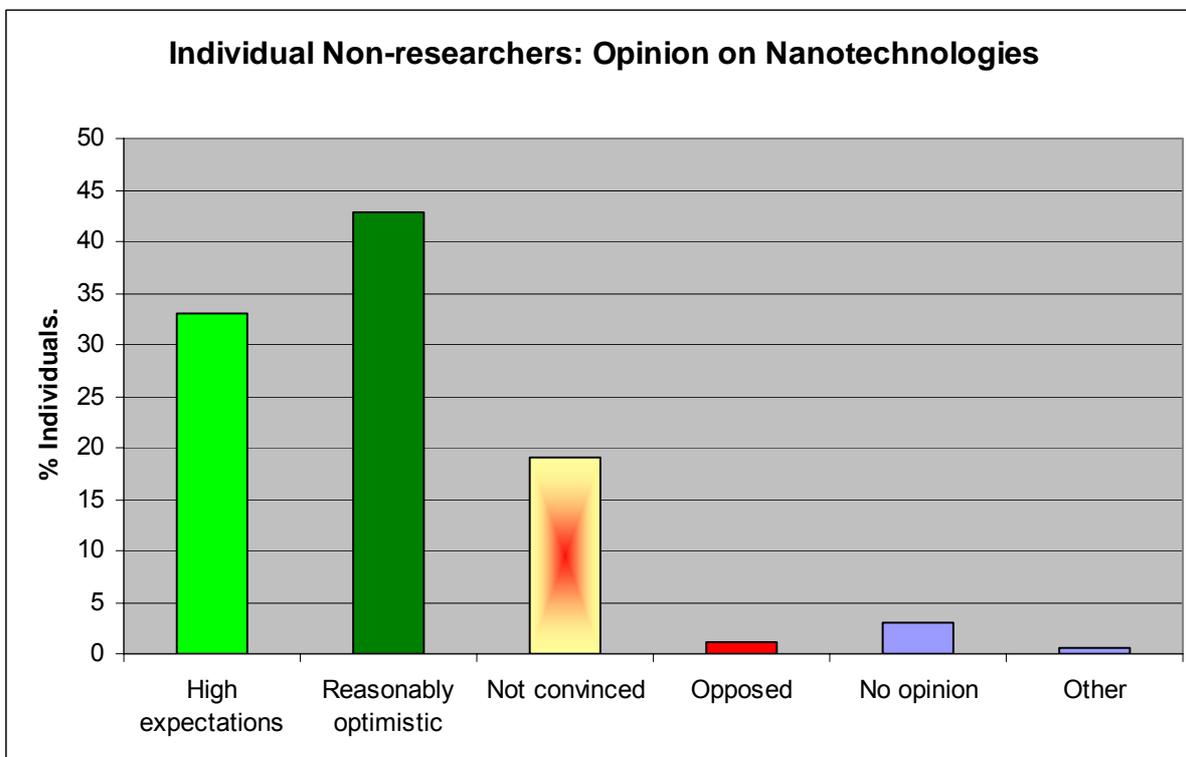
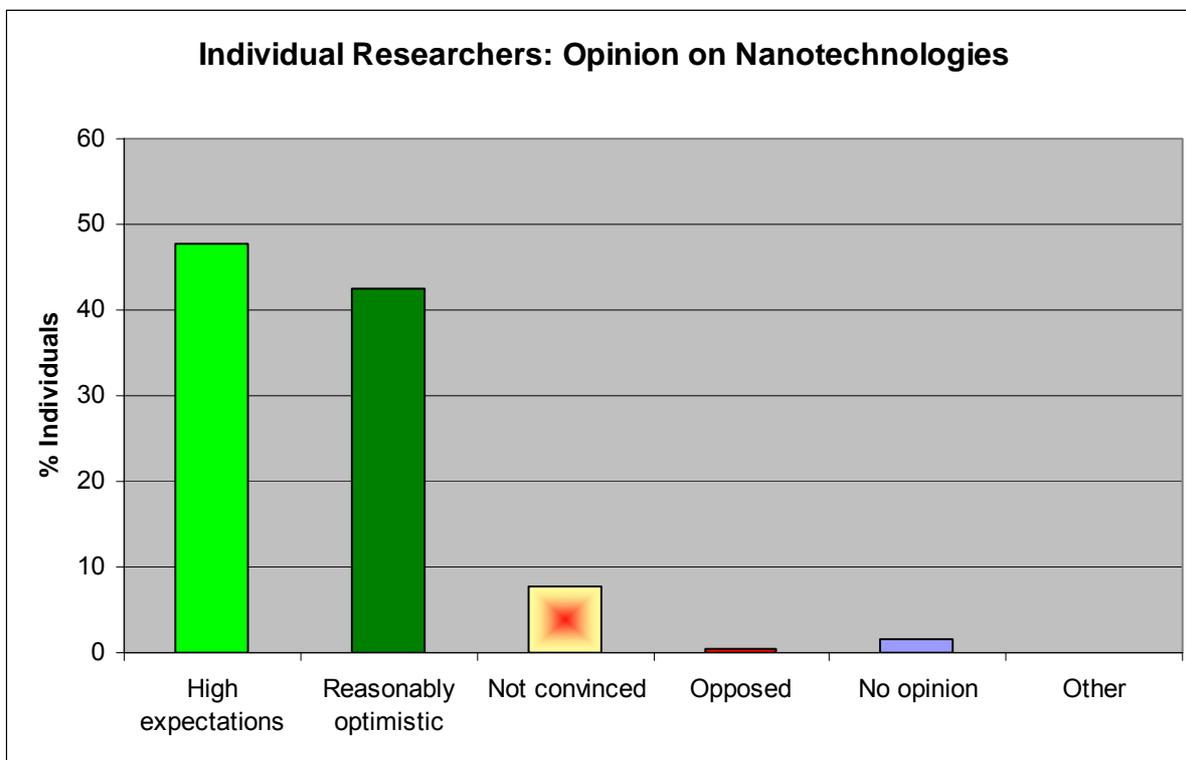
10. Which EU research actions related to nanotechnologies should be reinforced or reduced?

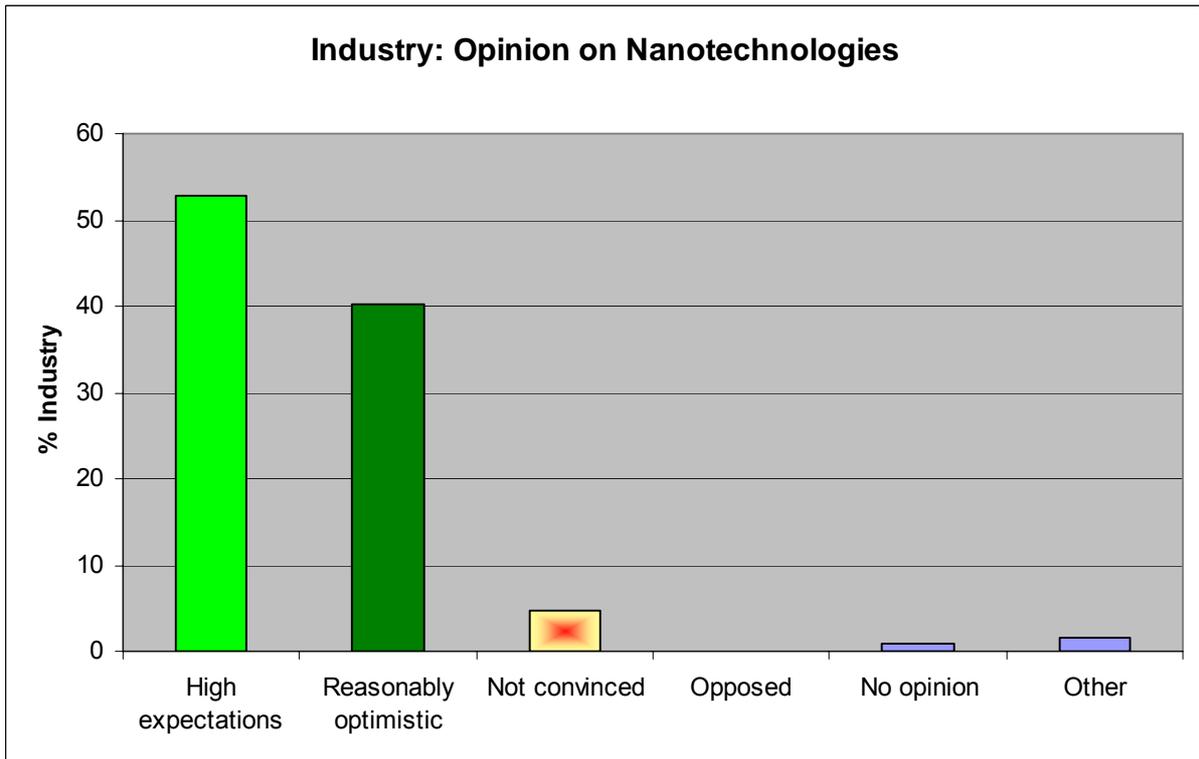
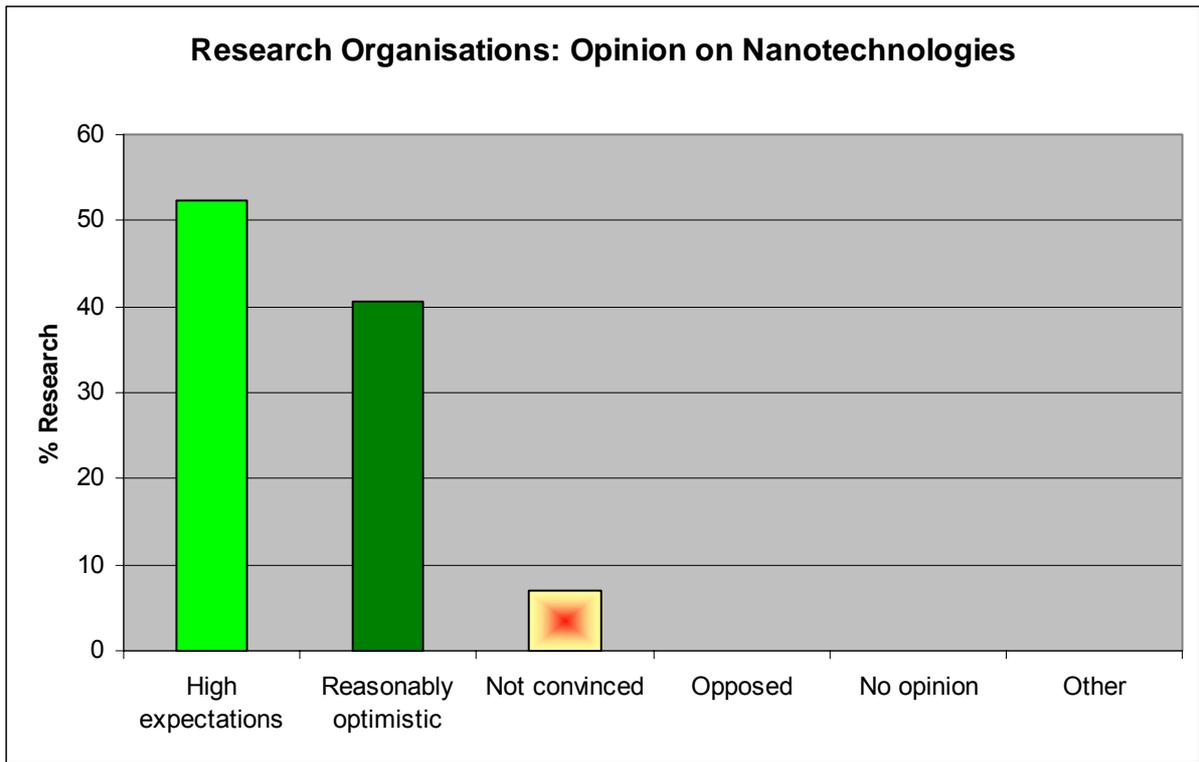
	Do more	Keep as now	Do less	No opinion
EU-wide coordination of national / regional R&D				
Support research needed for implementing regulation (research into the safety of nanomaterials and into methods for toxicity testing and for monitoring)				
Support enabling research (into understanding, measurement, testing, imaging, and modelling of materials and properties at the nanoscale)				
Support research into applications that can contribute to EU policy objectives (such as health, environment and climate, energy, water, workers' protection, ...)				
Support research into industrial applications leading to more eco-efficient production (e.g. chemicals, biotechnology)				
Support research into other industrial applications of nanotechnologies with a high potential for innovation, new employment and new markets				
Support the development of research infrastructures				
Support centres of excellence including their networking				
Support research on ethical, legal and social aspects of nanotechnology				
Promote industrial involvement in EU R&D projects				
Foster the industrial exploitation of nano R&D results				
Ensure ethical review of EU nano R&D projects				
World-wide international cooperation				

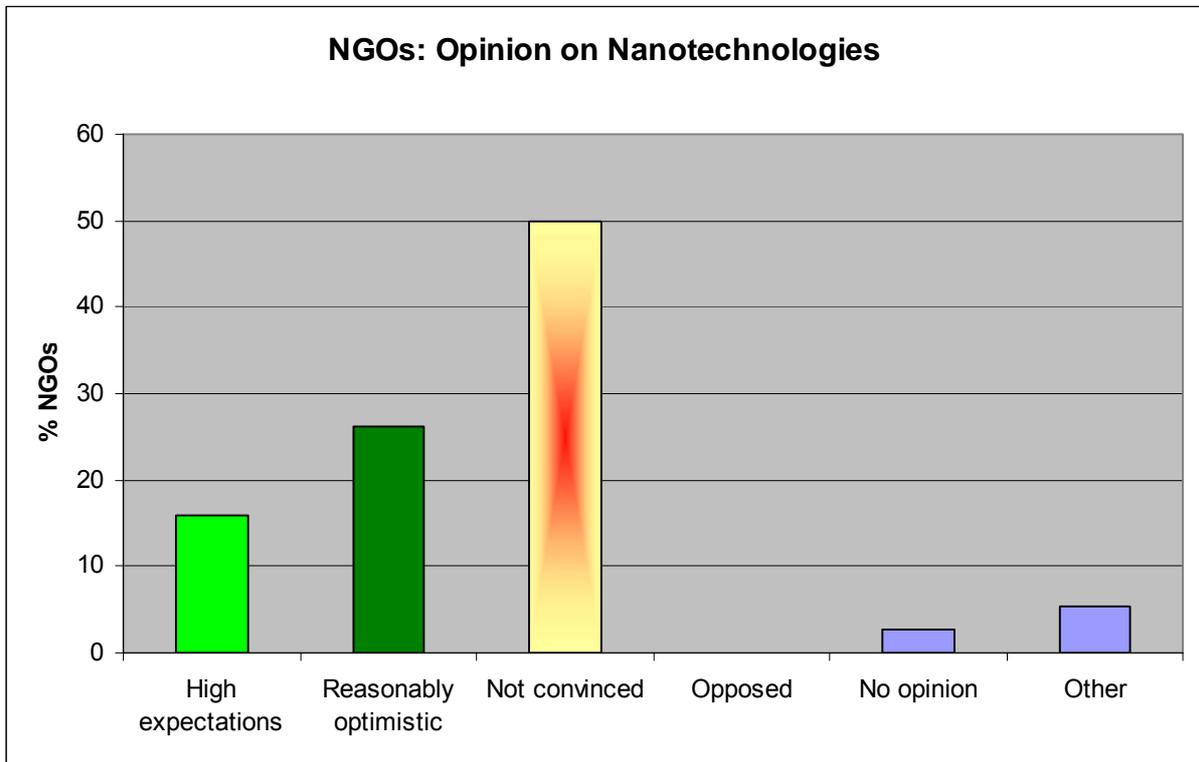
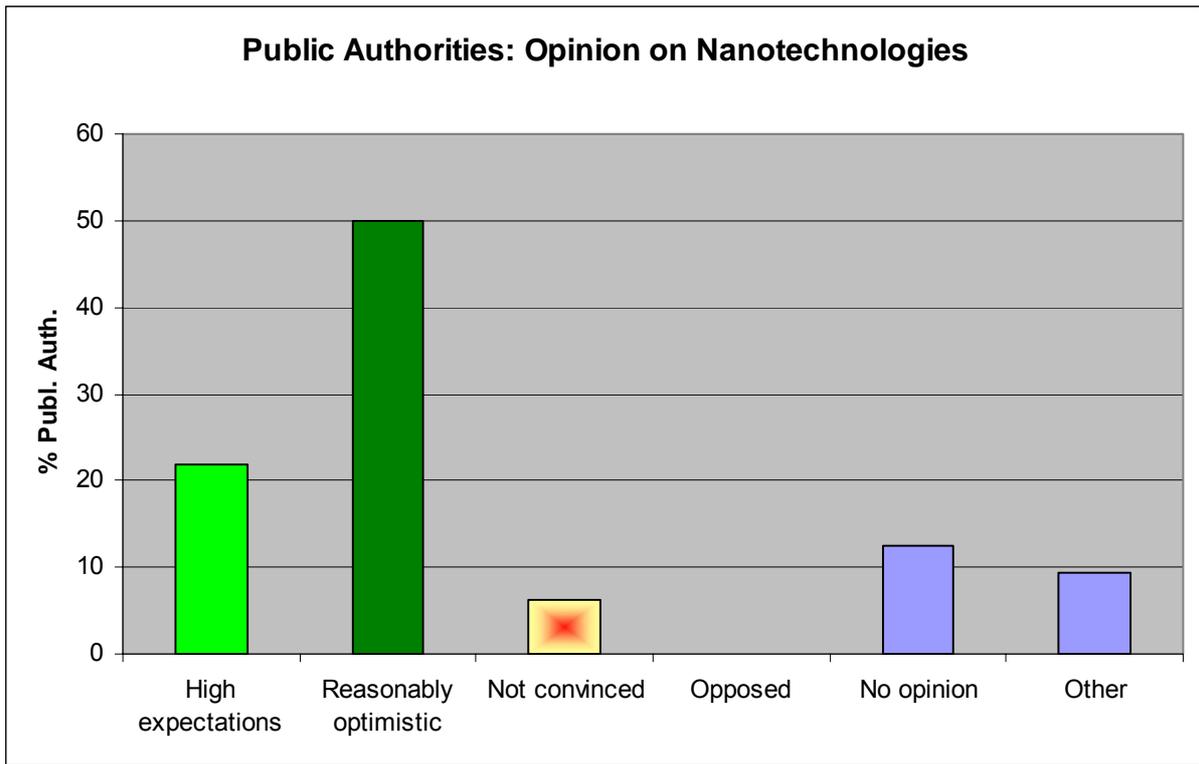
11. Other suggestions - Comments

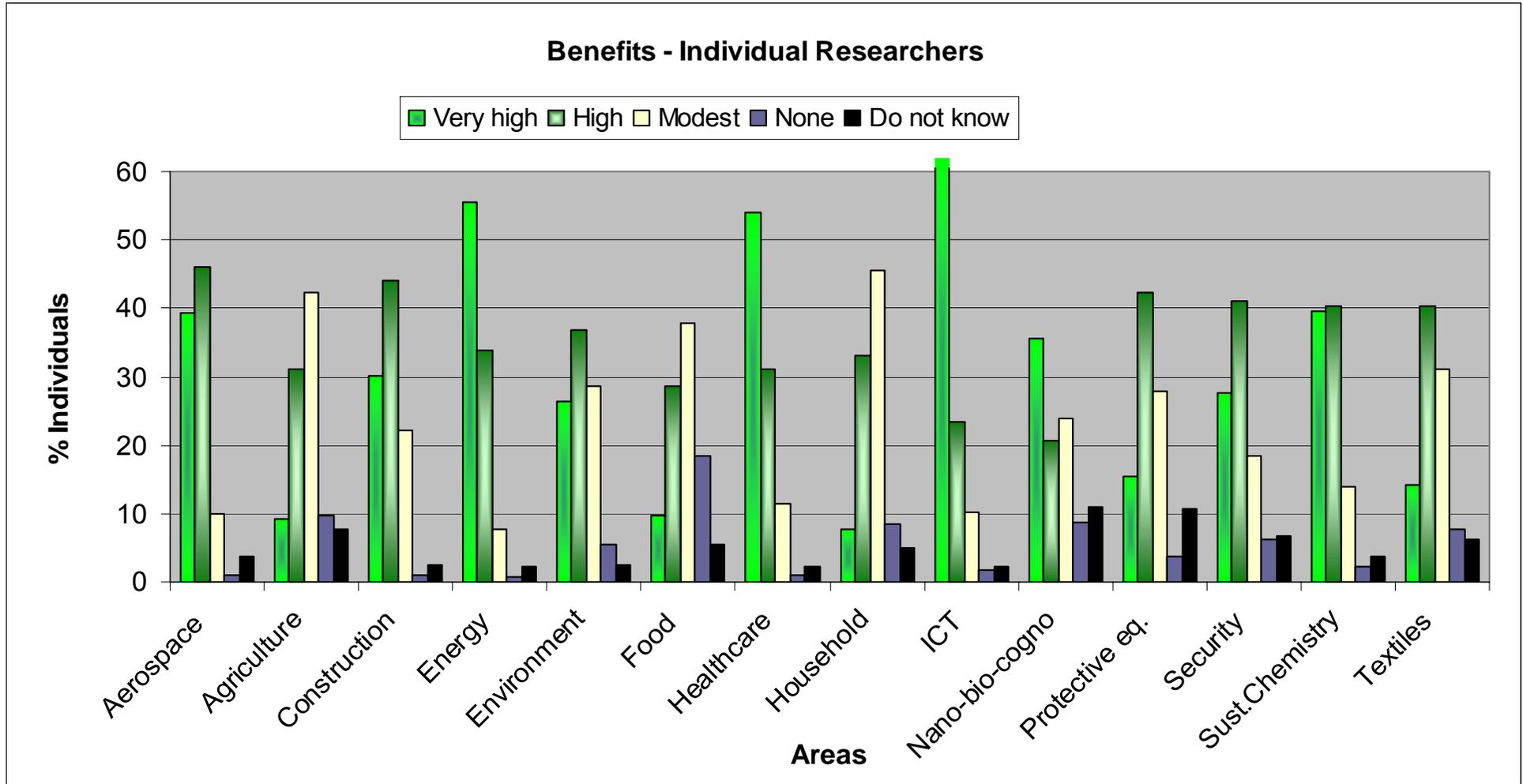
Annex II: Itemised Graphs

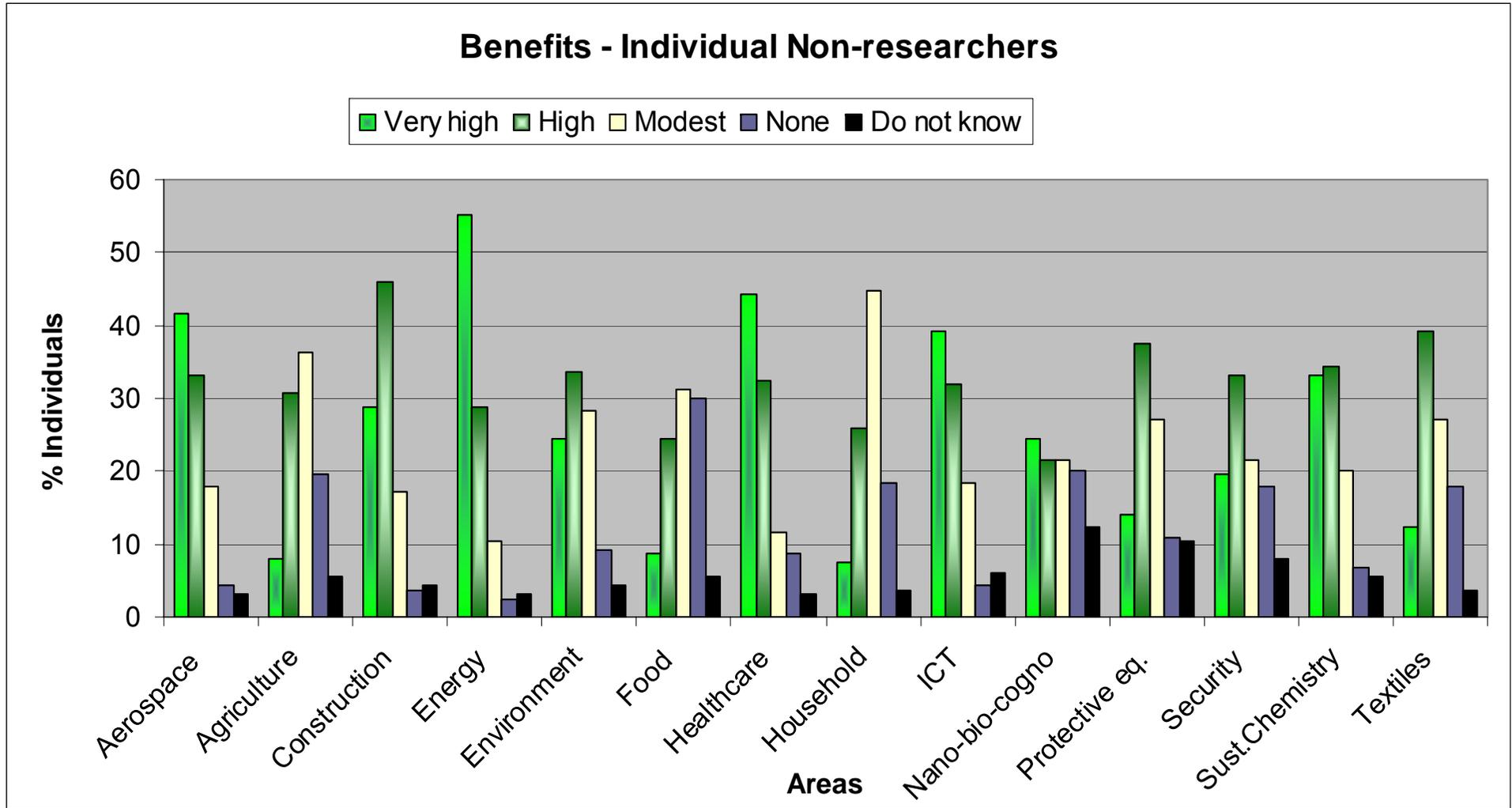
All collected contributions were analysed and used to generate graphs based on the overall and detailed profiling of six groups of respondents: individual researchers, individual non-researchers, research organisations, industrial organisations, public authorities, NGOs).

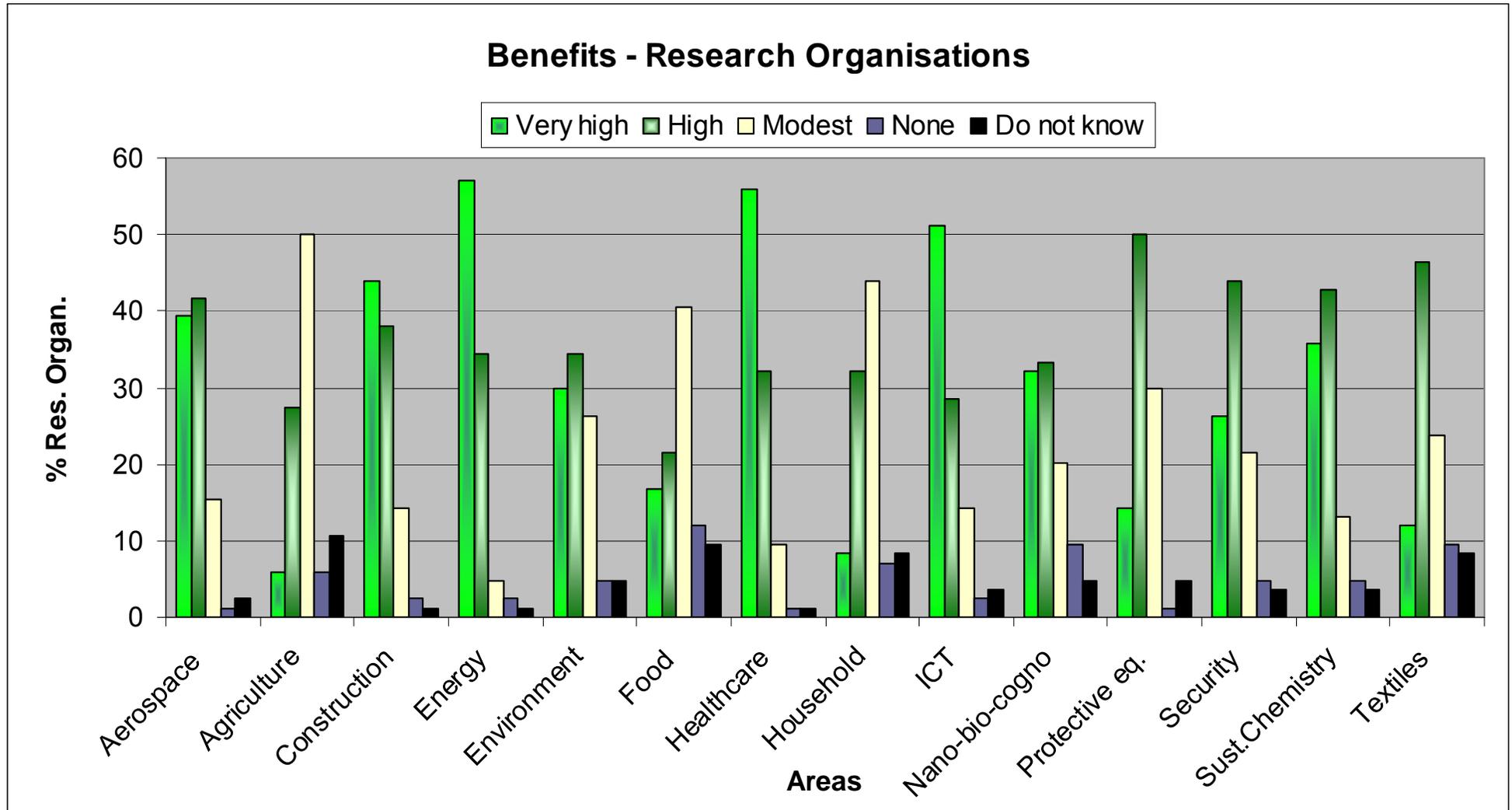


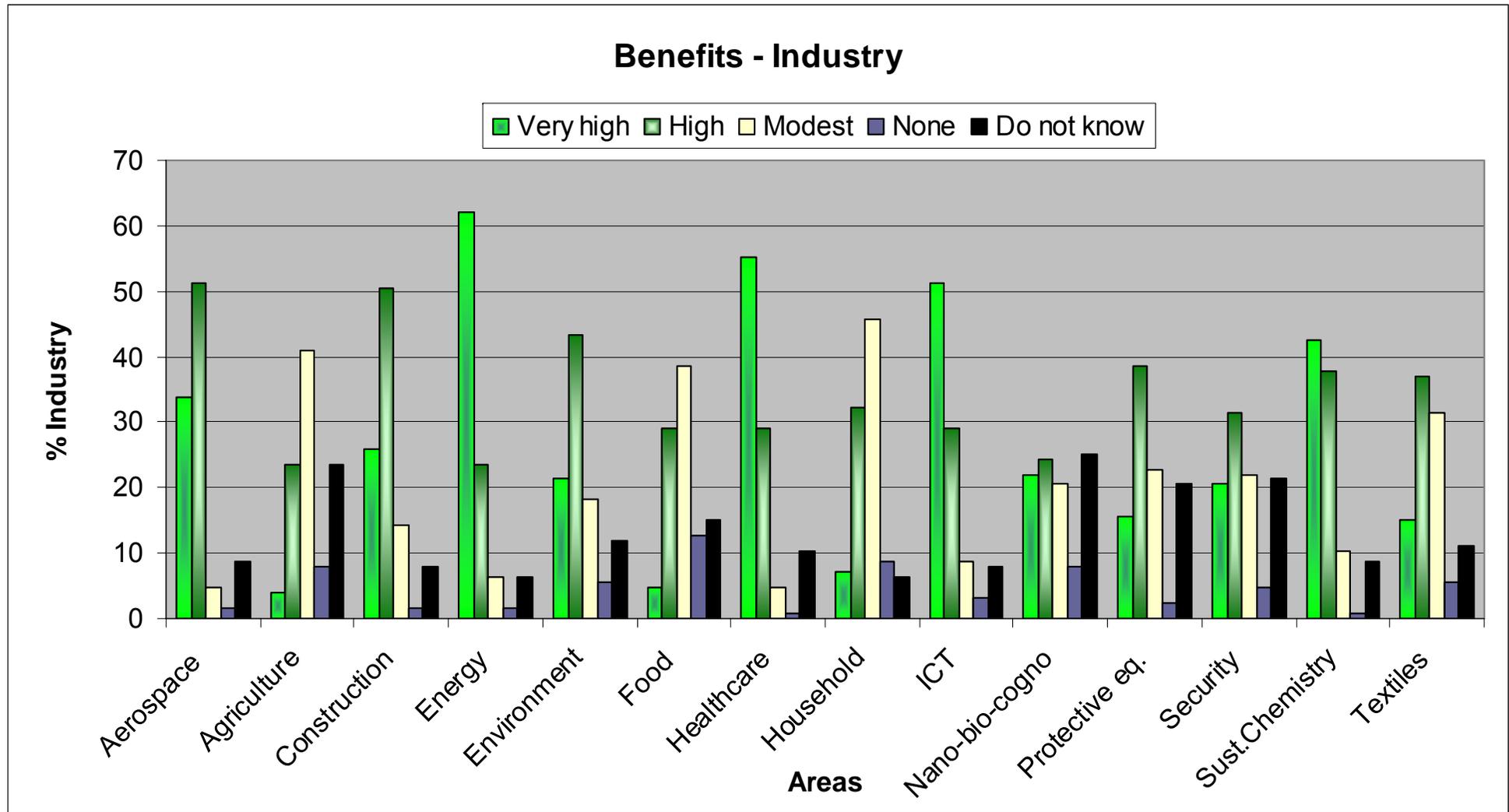


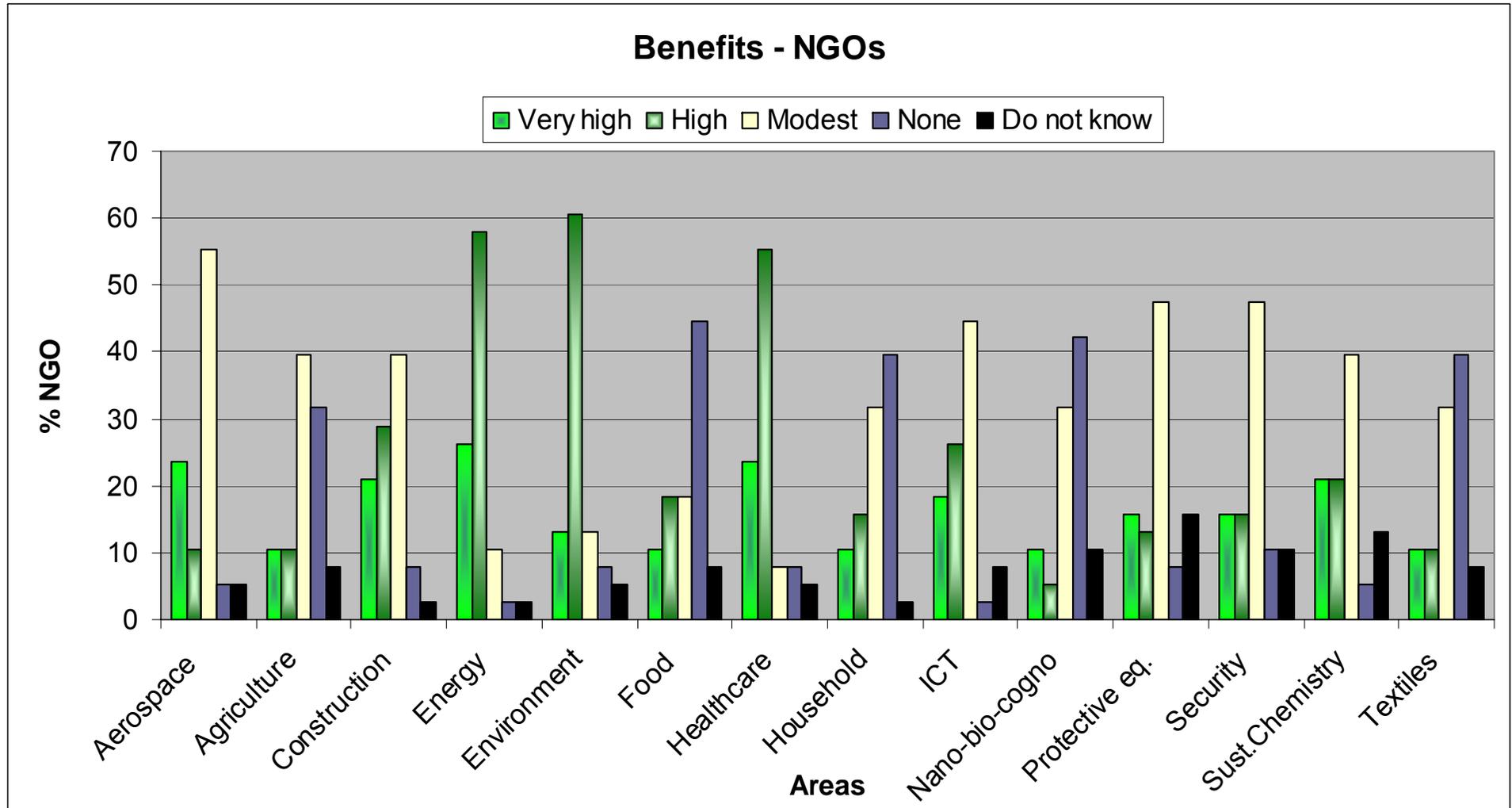




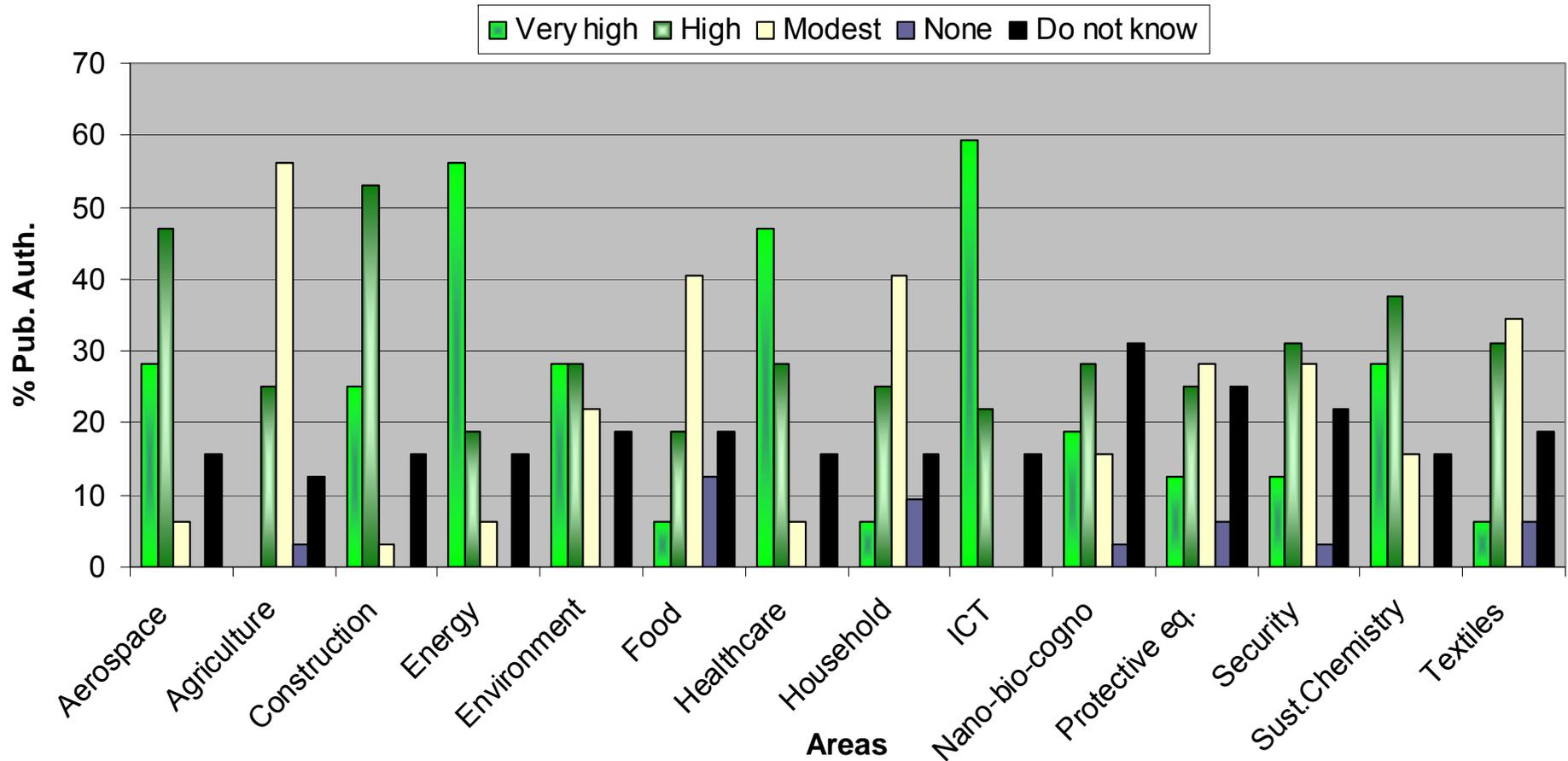


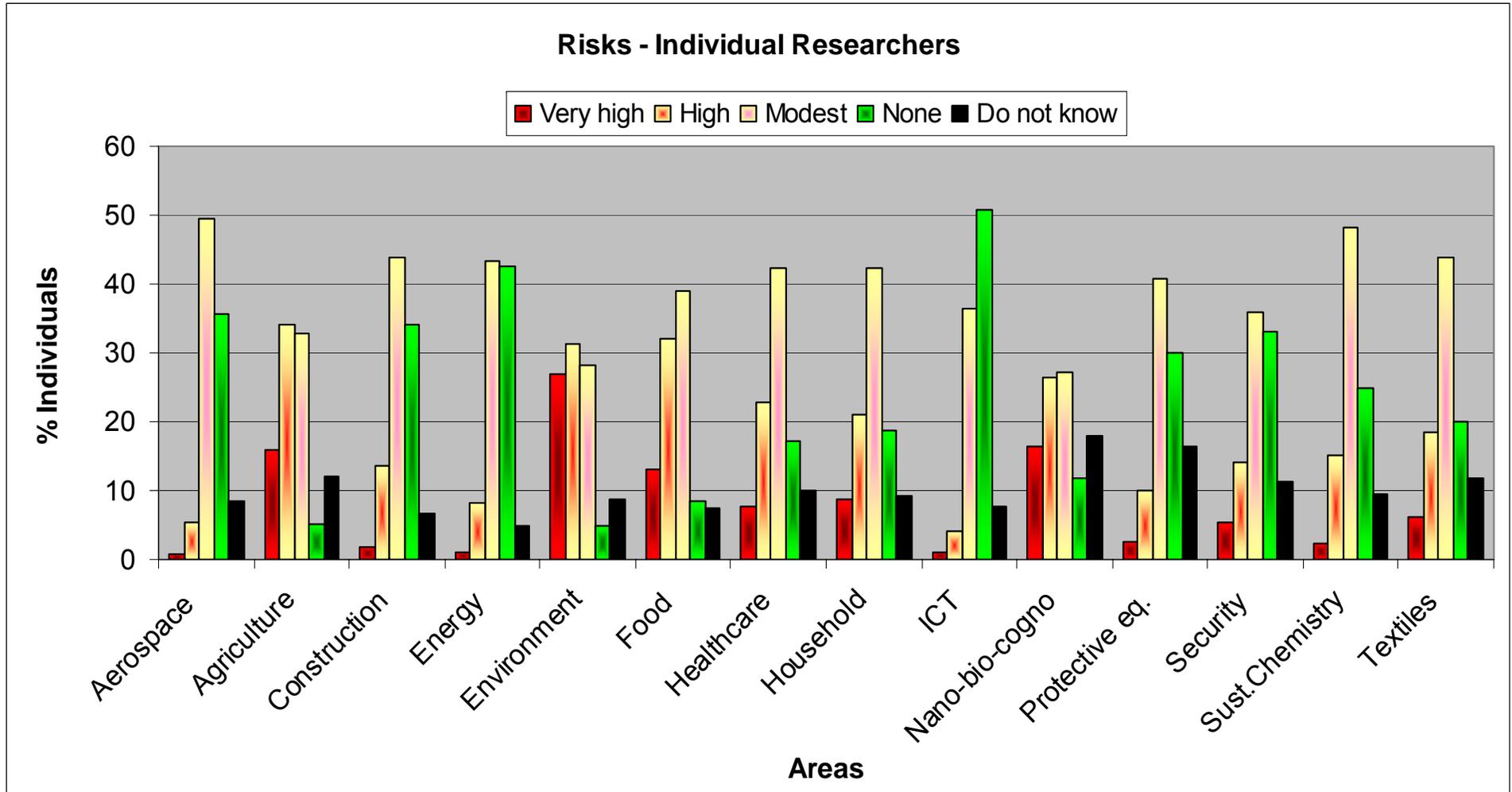


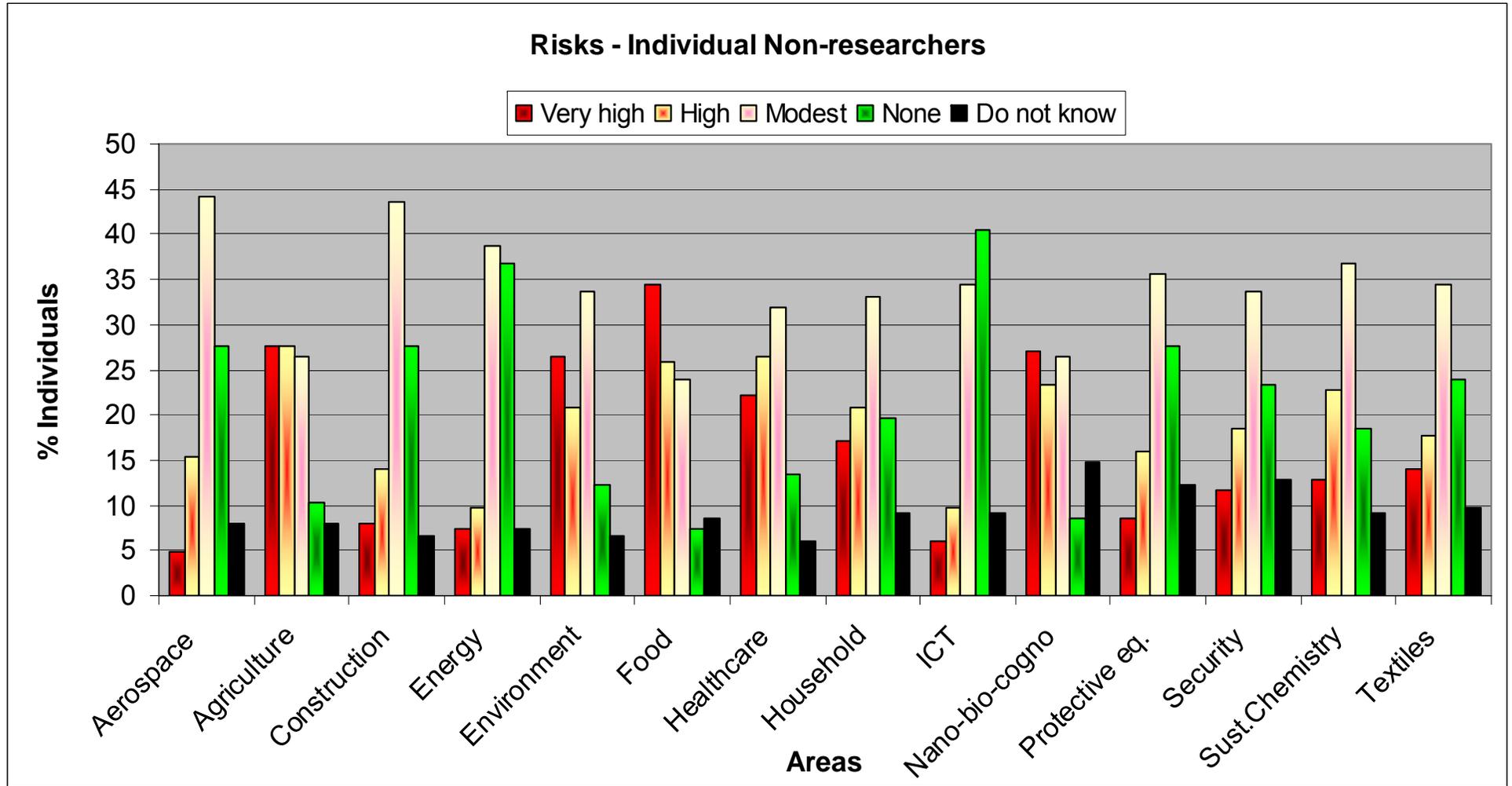


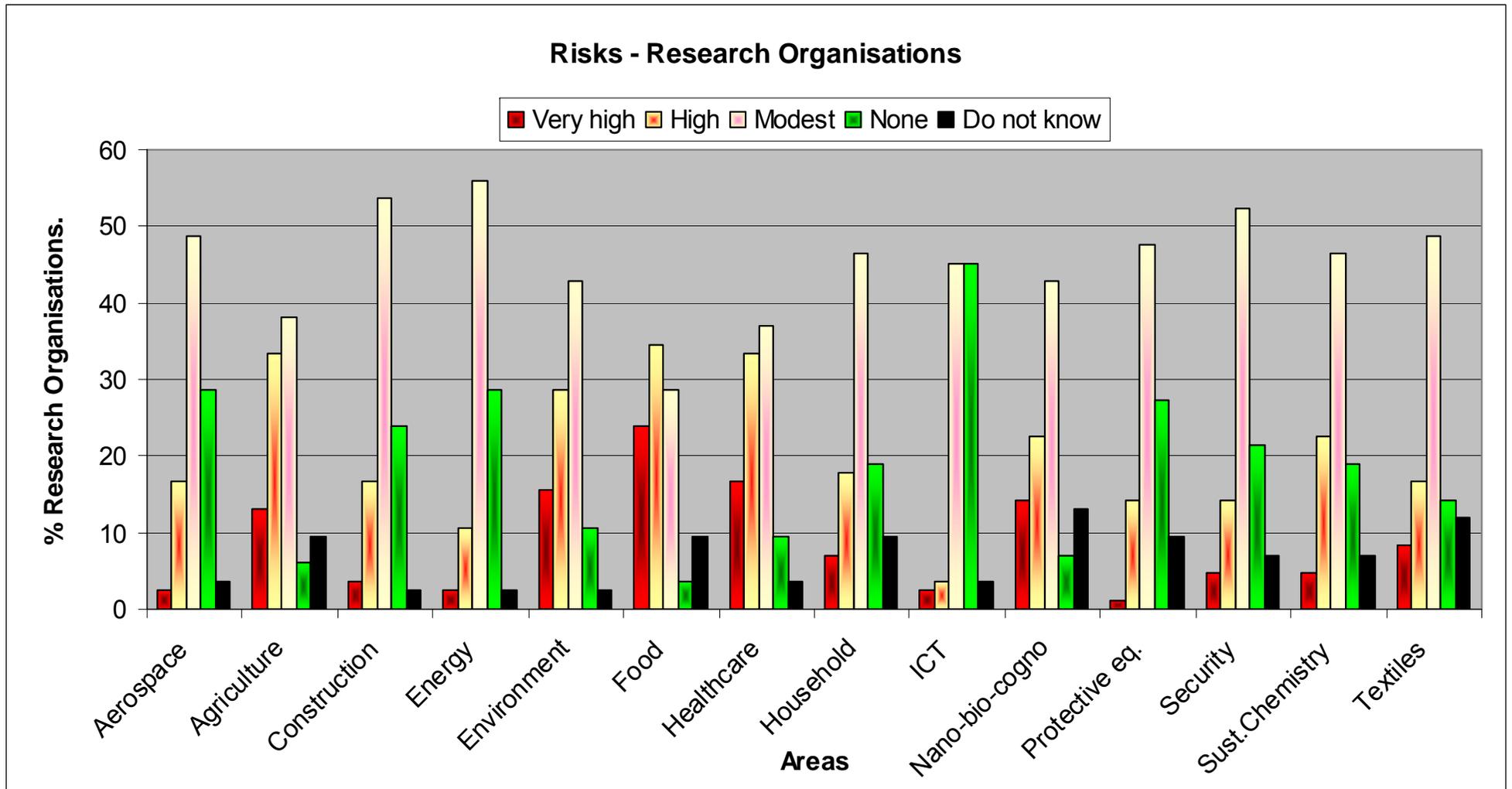


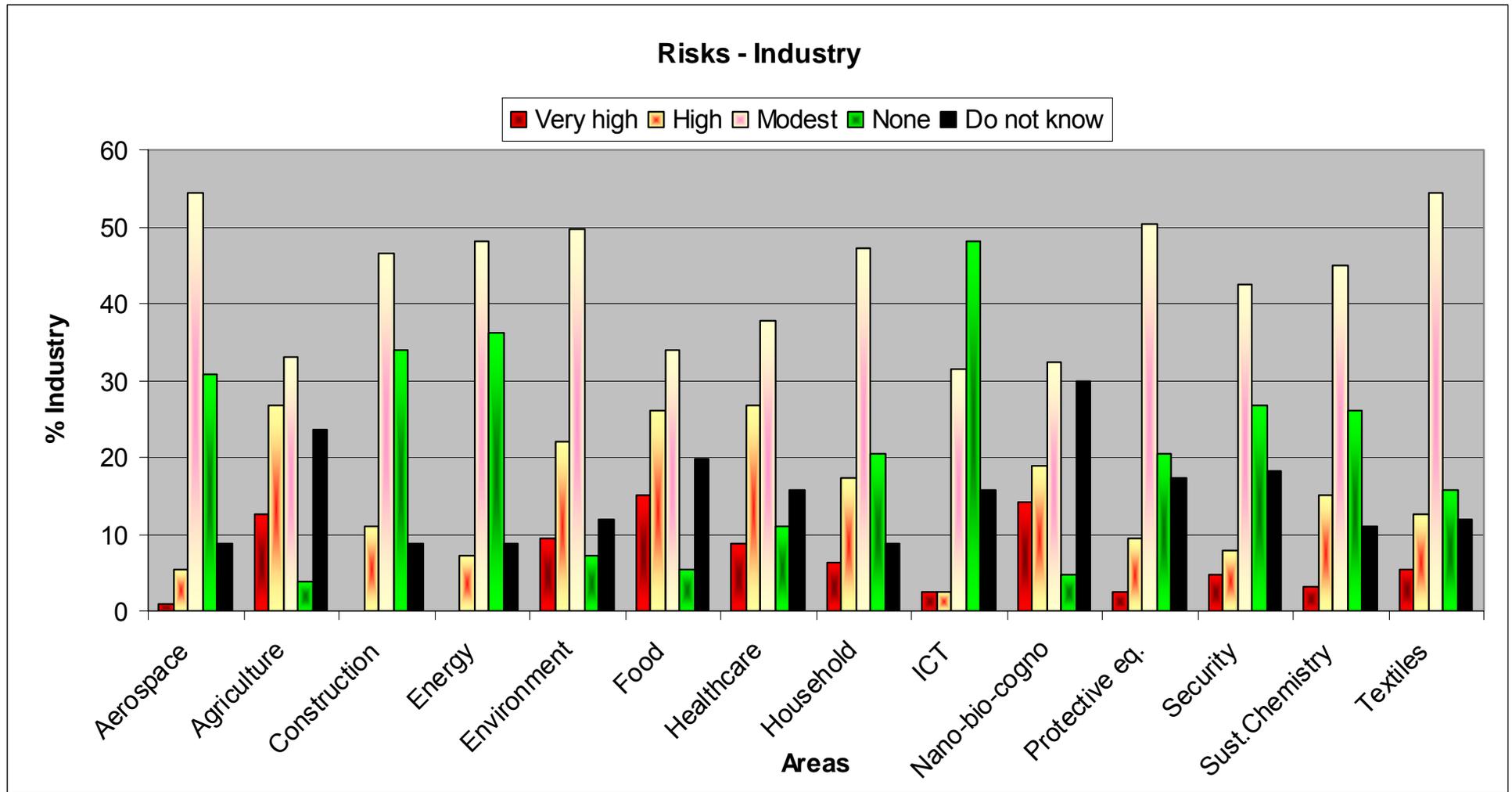
Benefits - Public Authorities

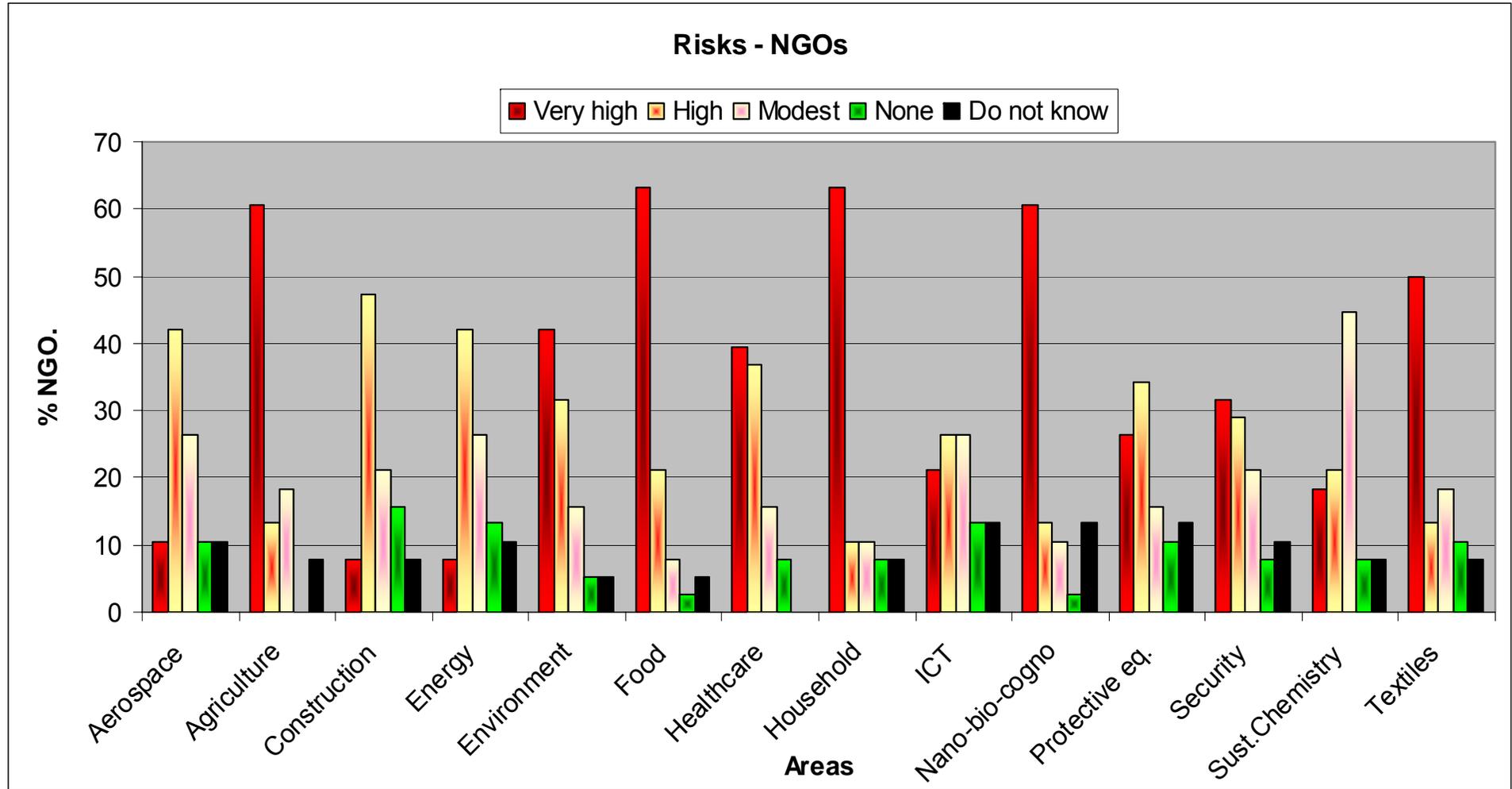


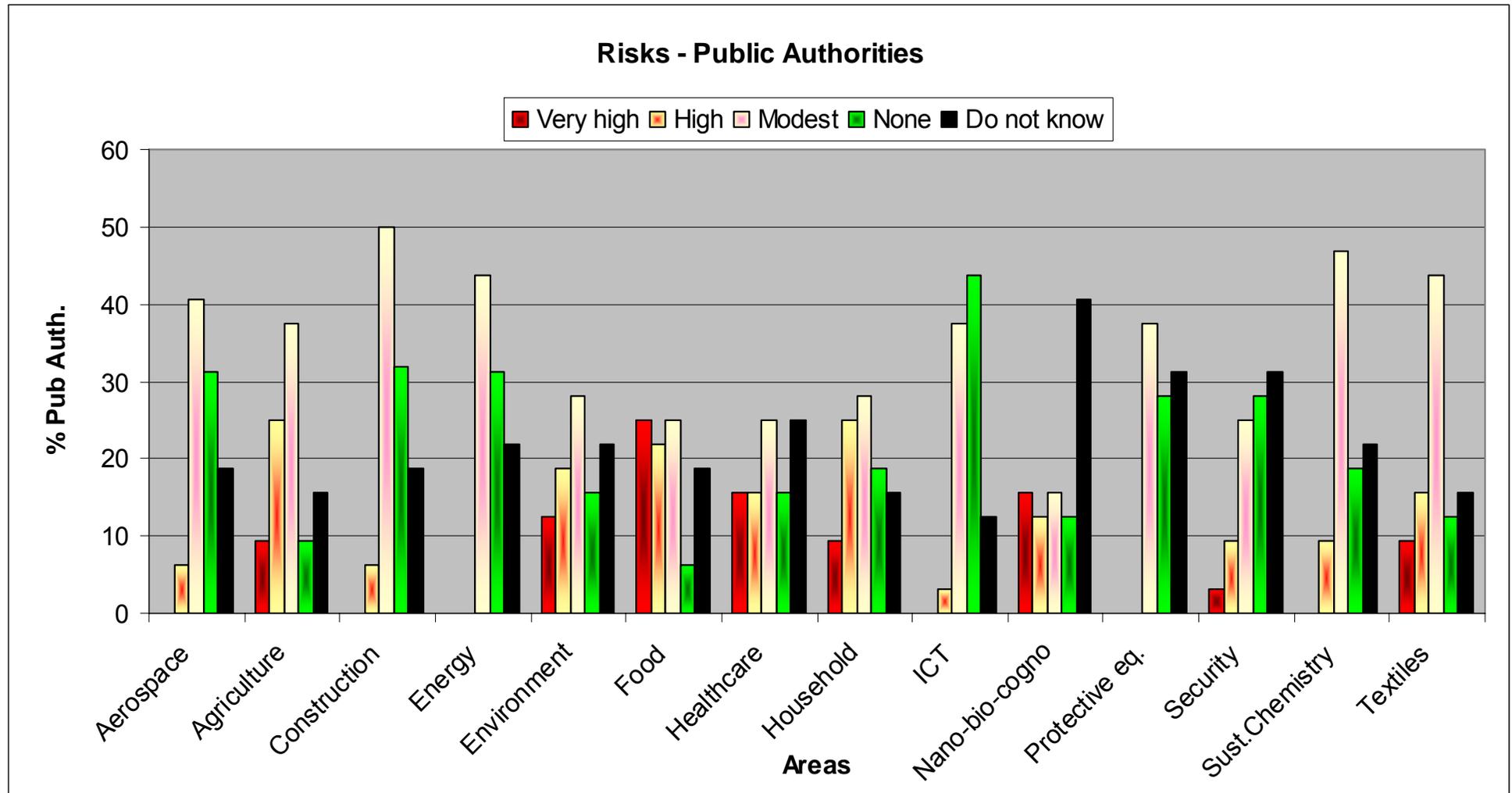




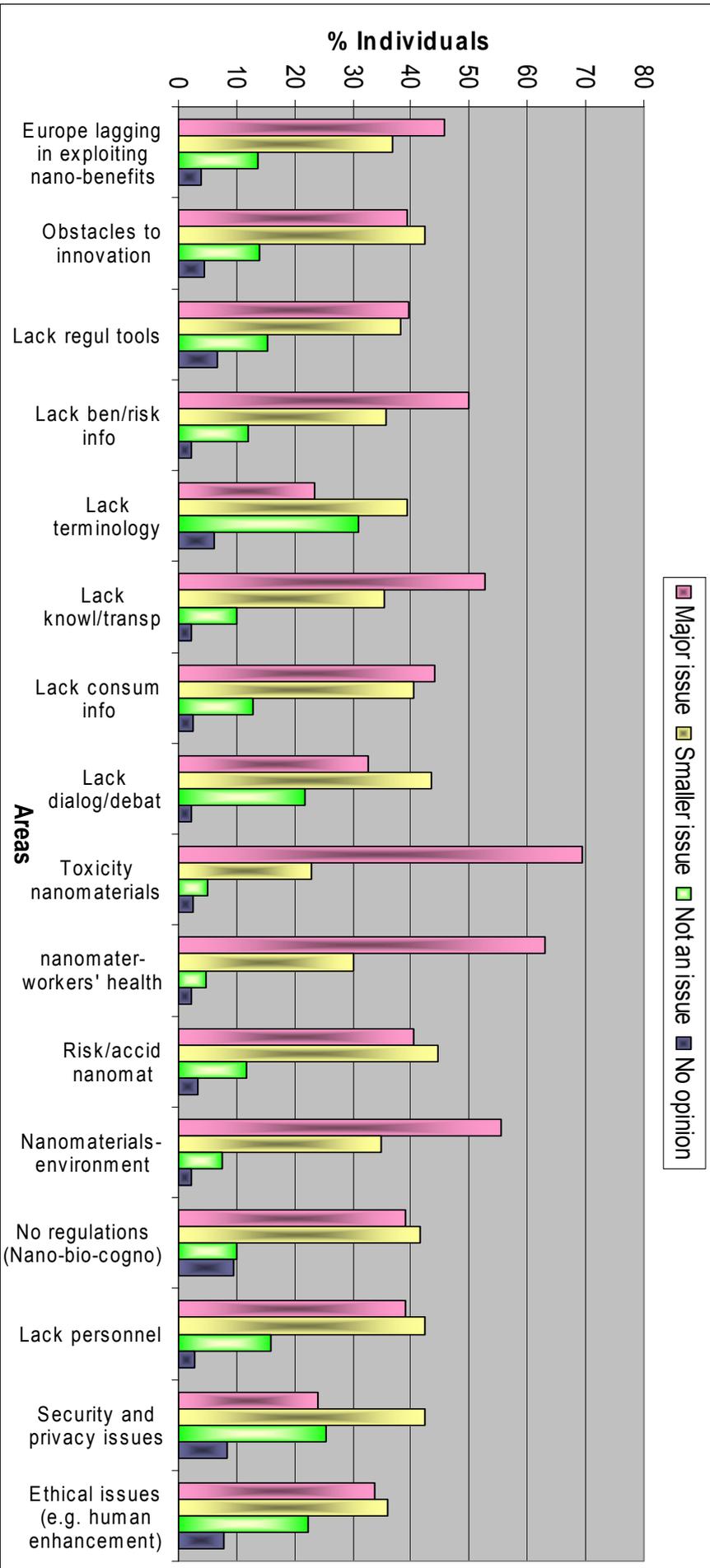




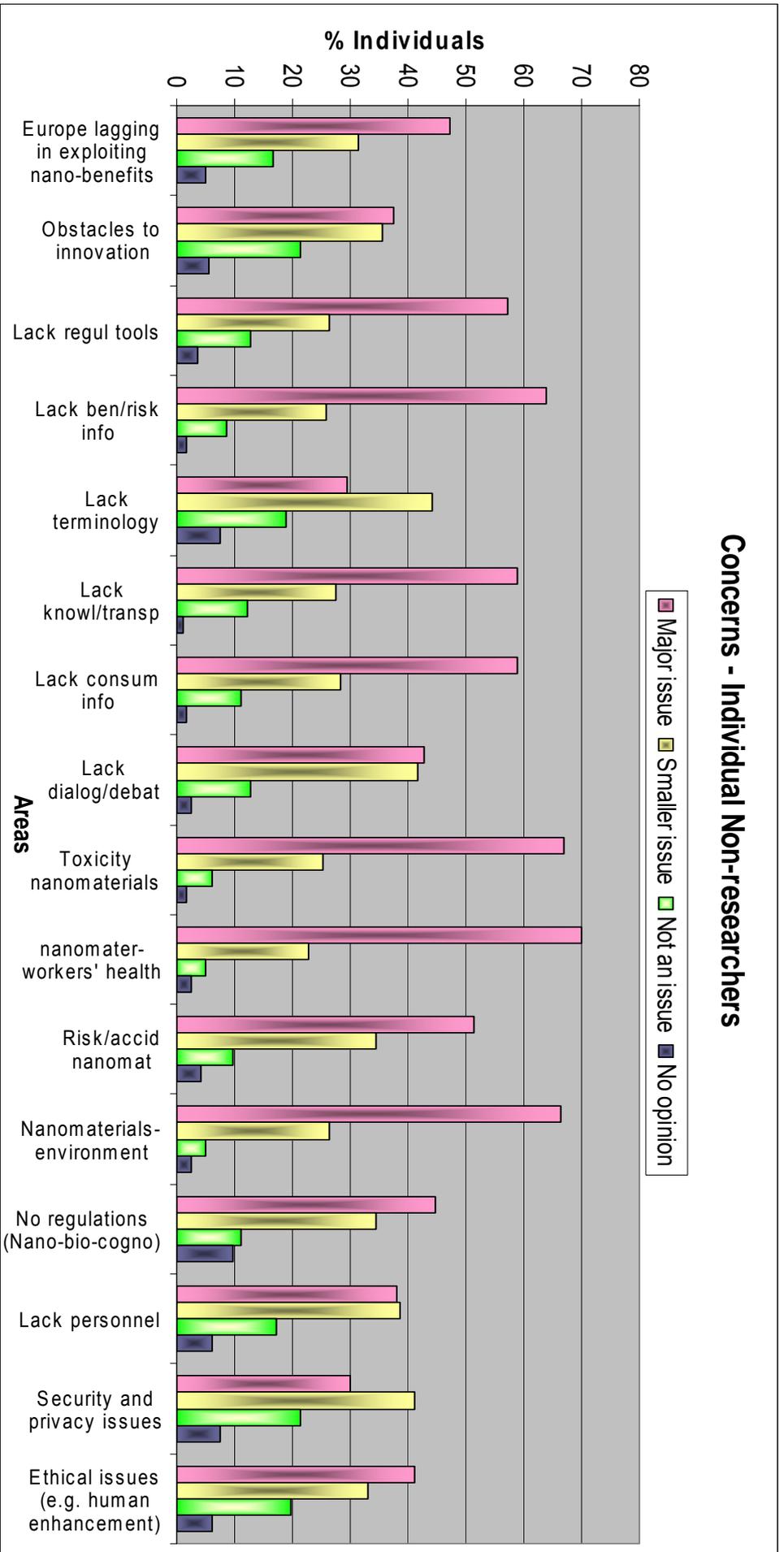




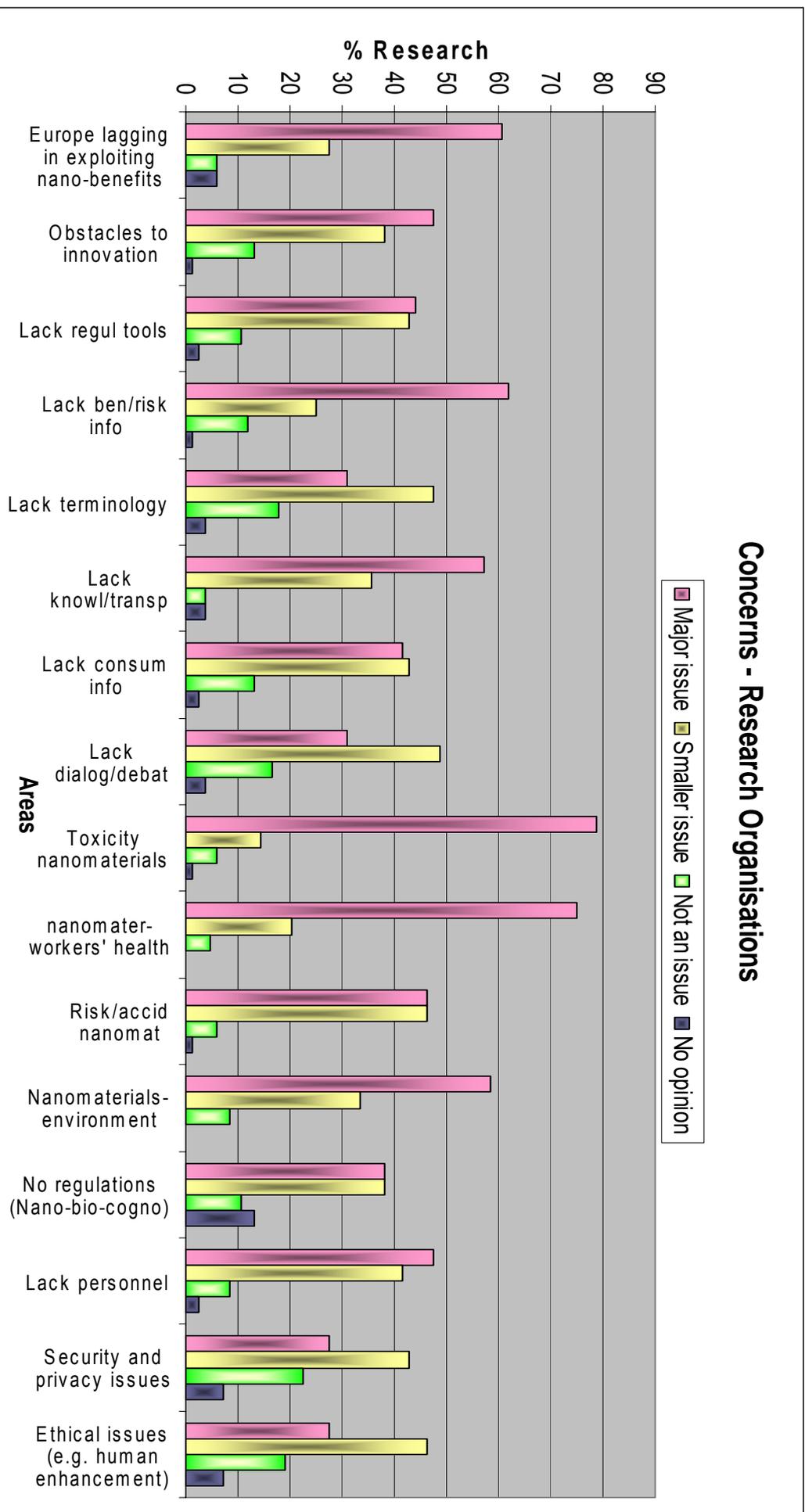
Concerns - Individual Researchers



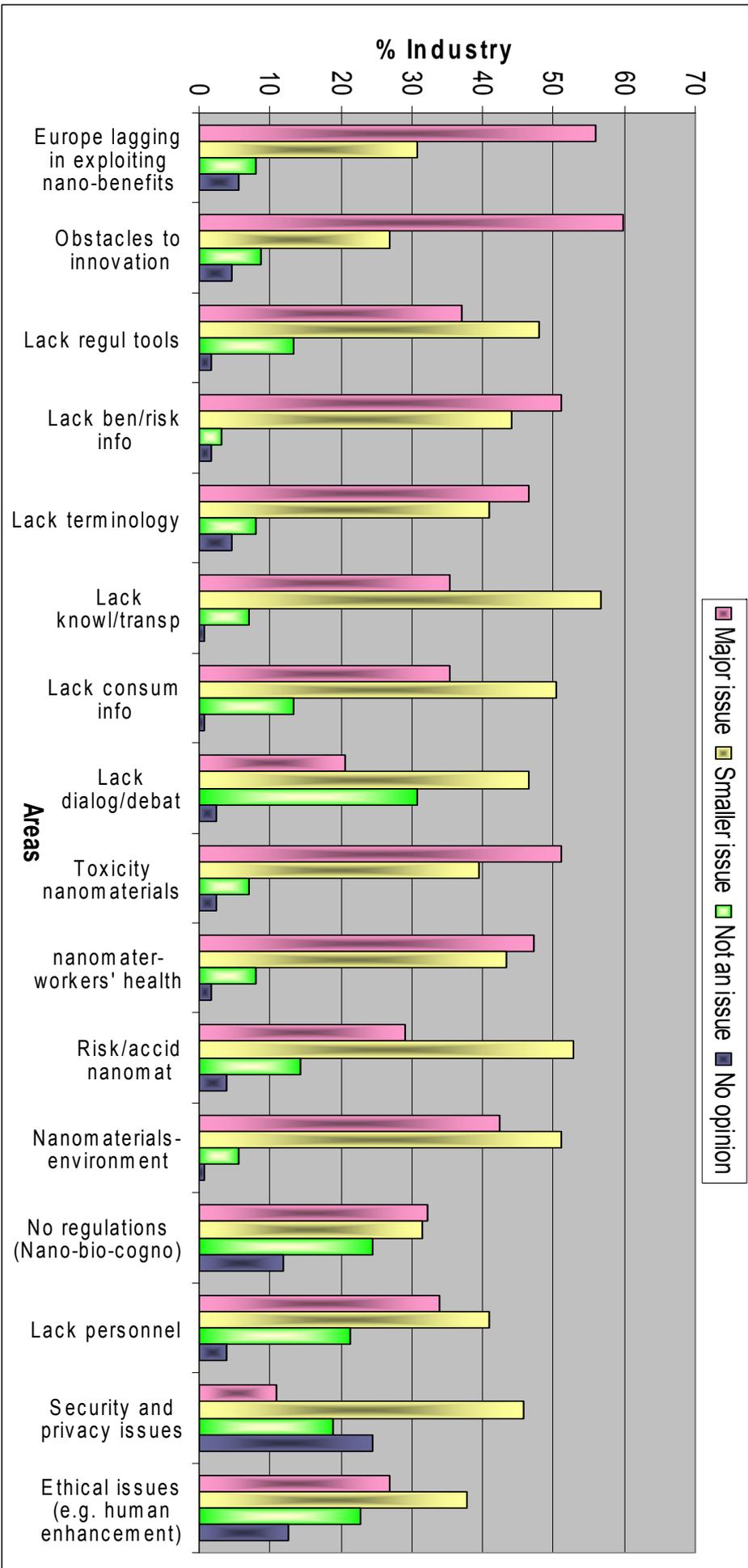
Concerns - Individual Non-researchers



Concerns - Research Organisations



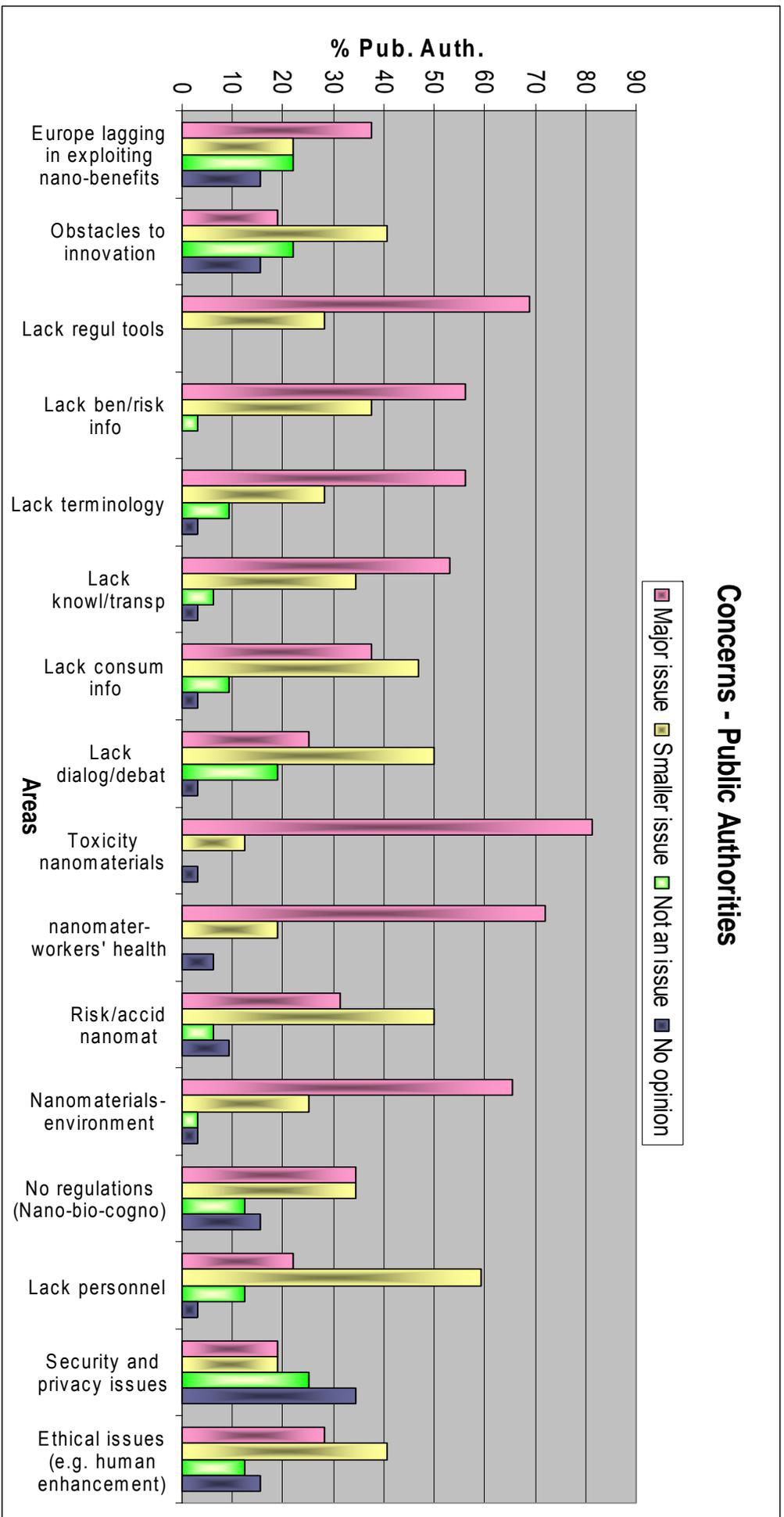
Concerns - Industry

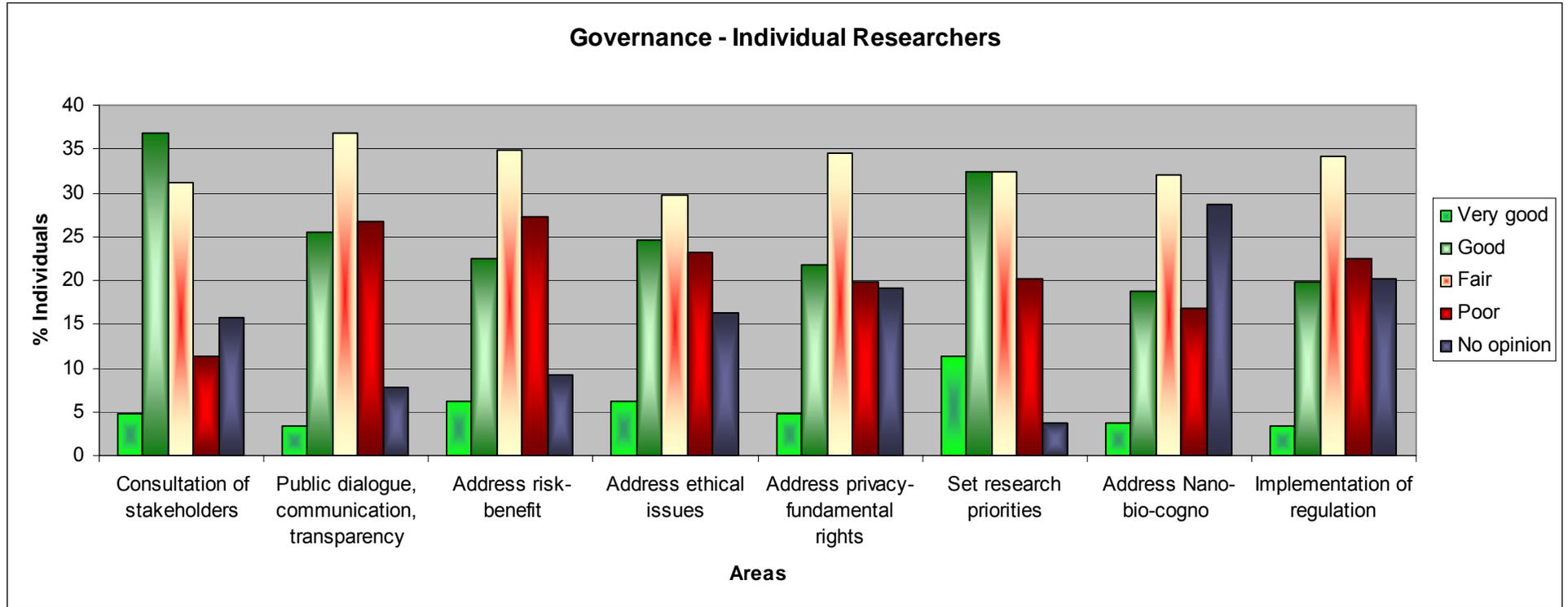


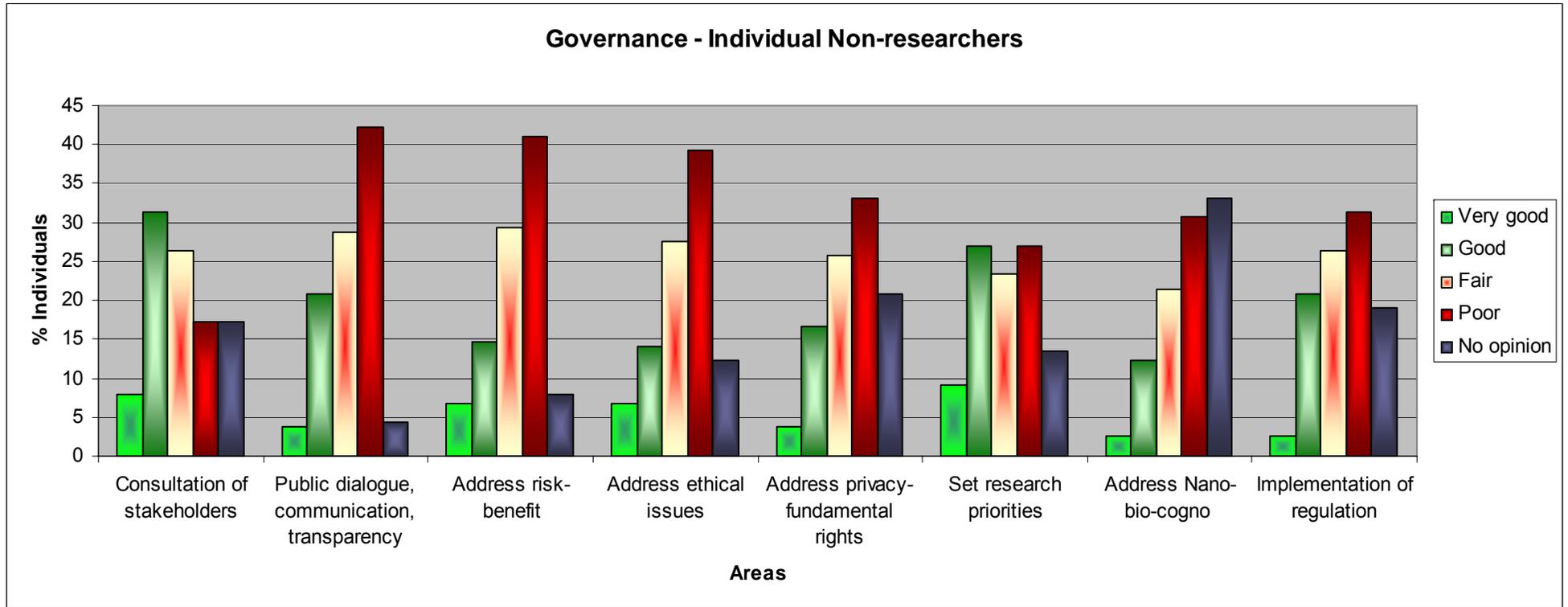
Concerns - NGOs



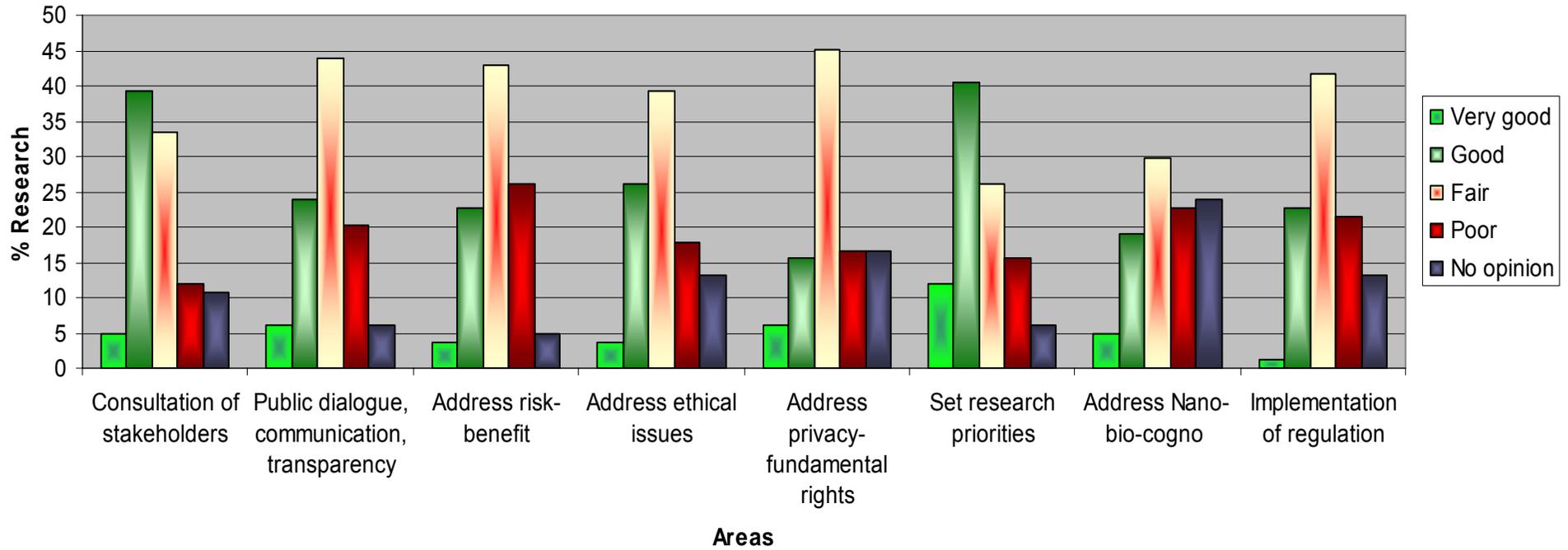
Concerns - Public Authorities

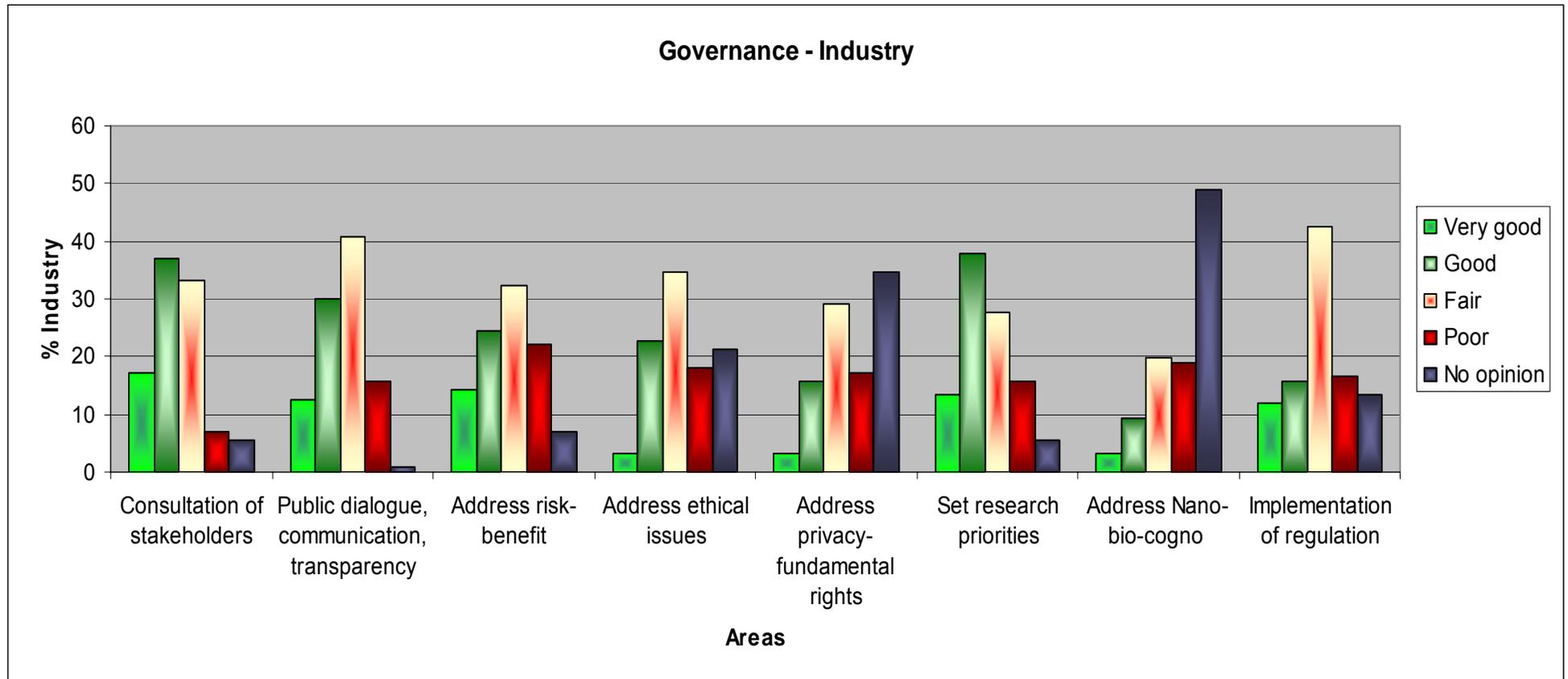


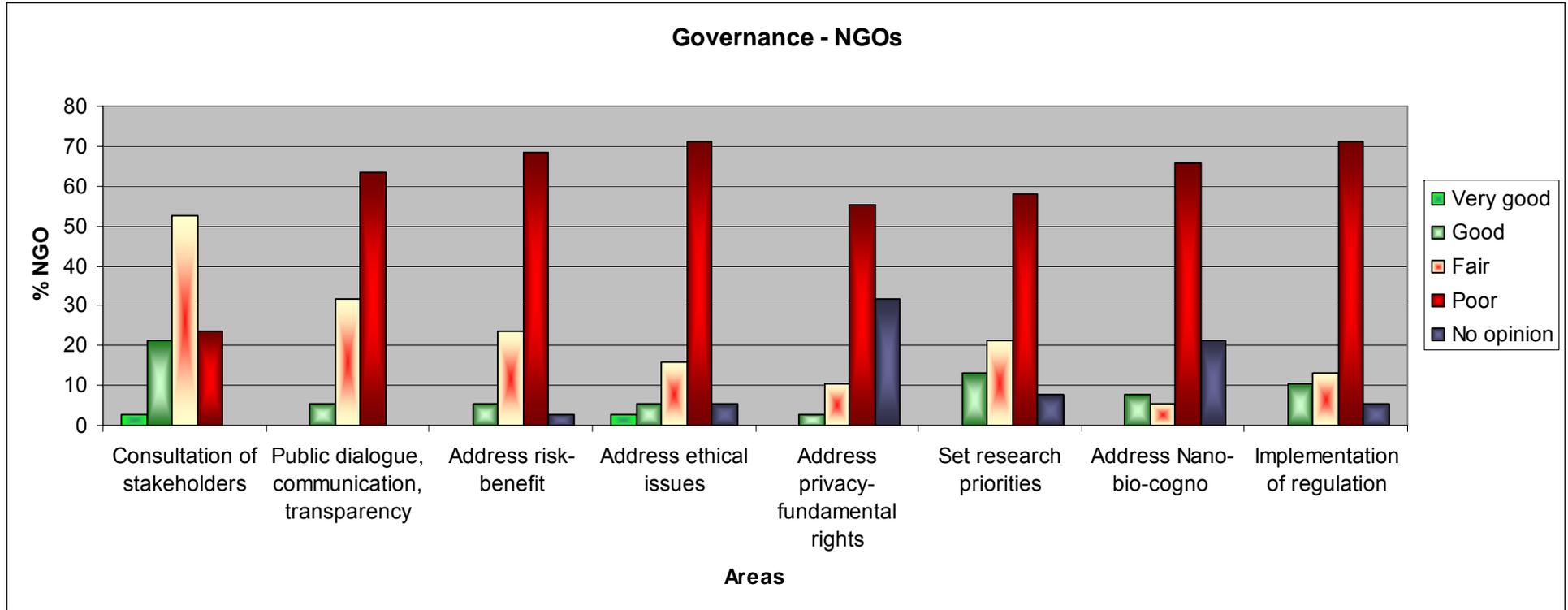




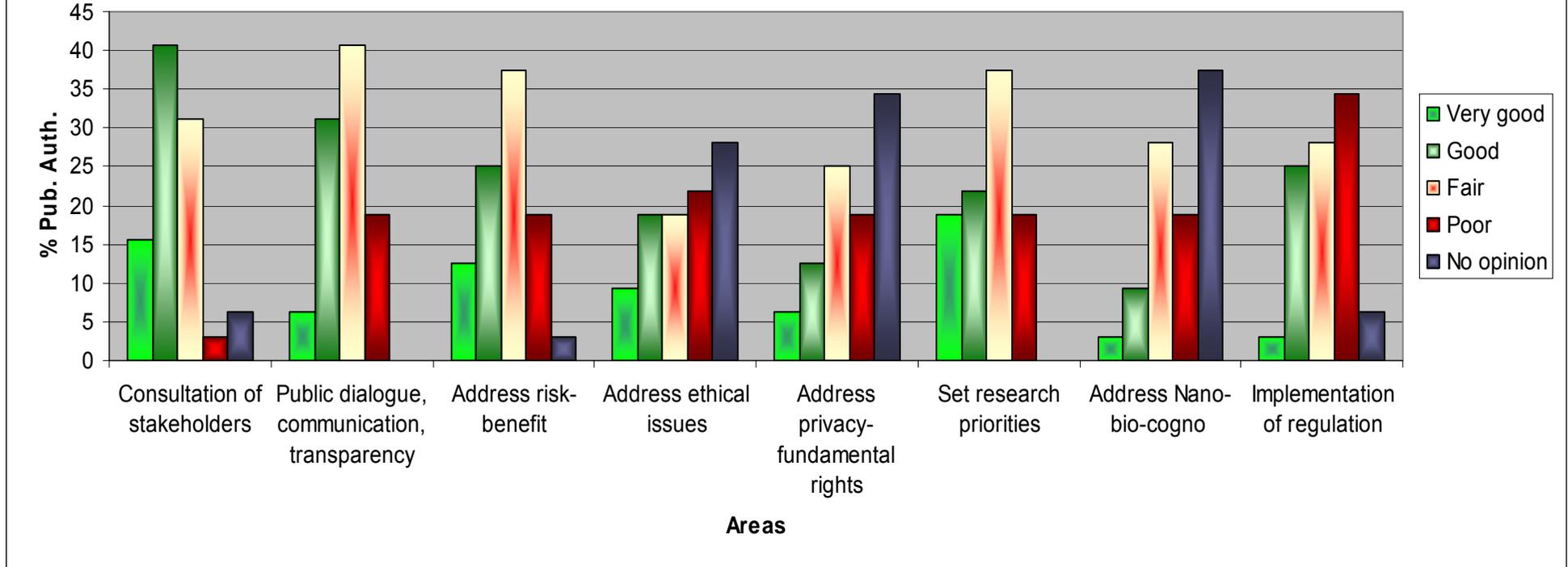
Governance - Research Organisations

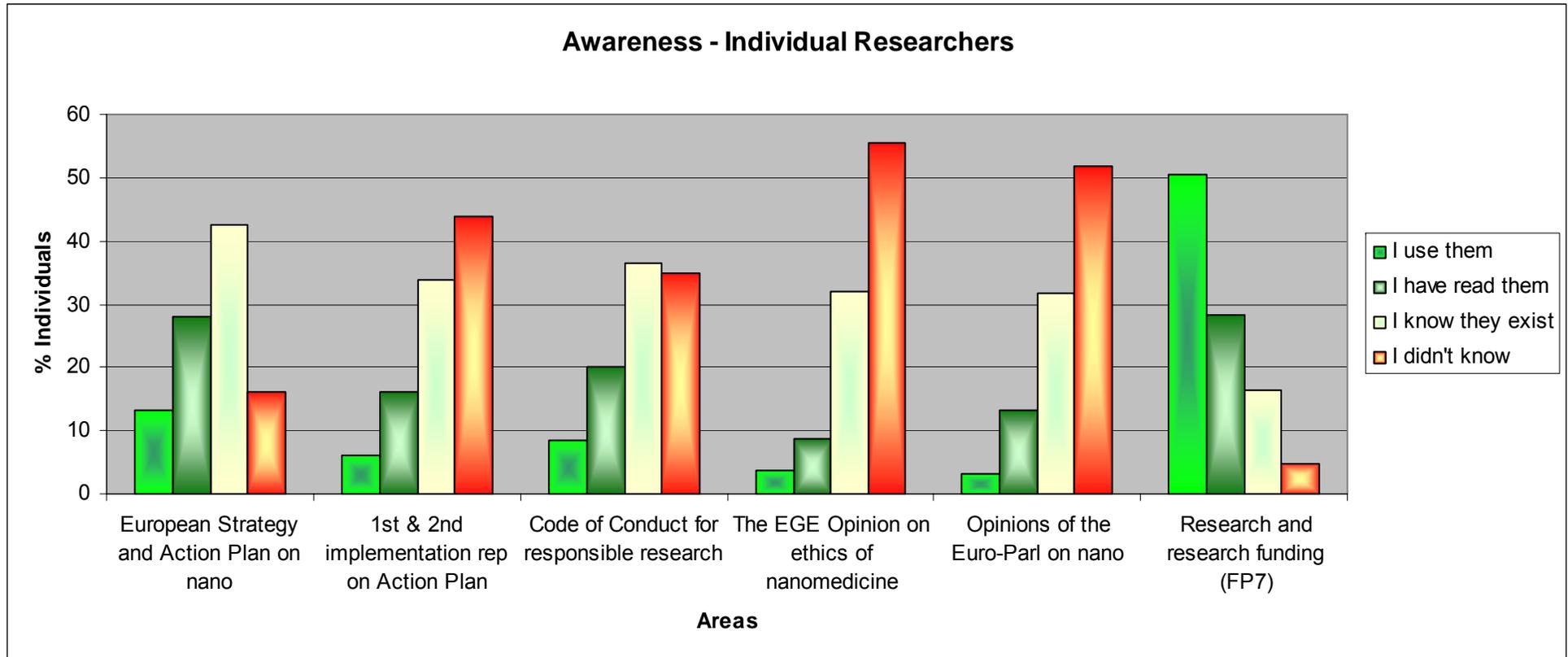


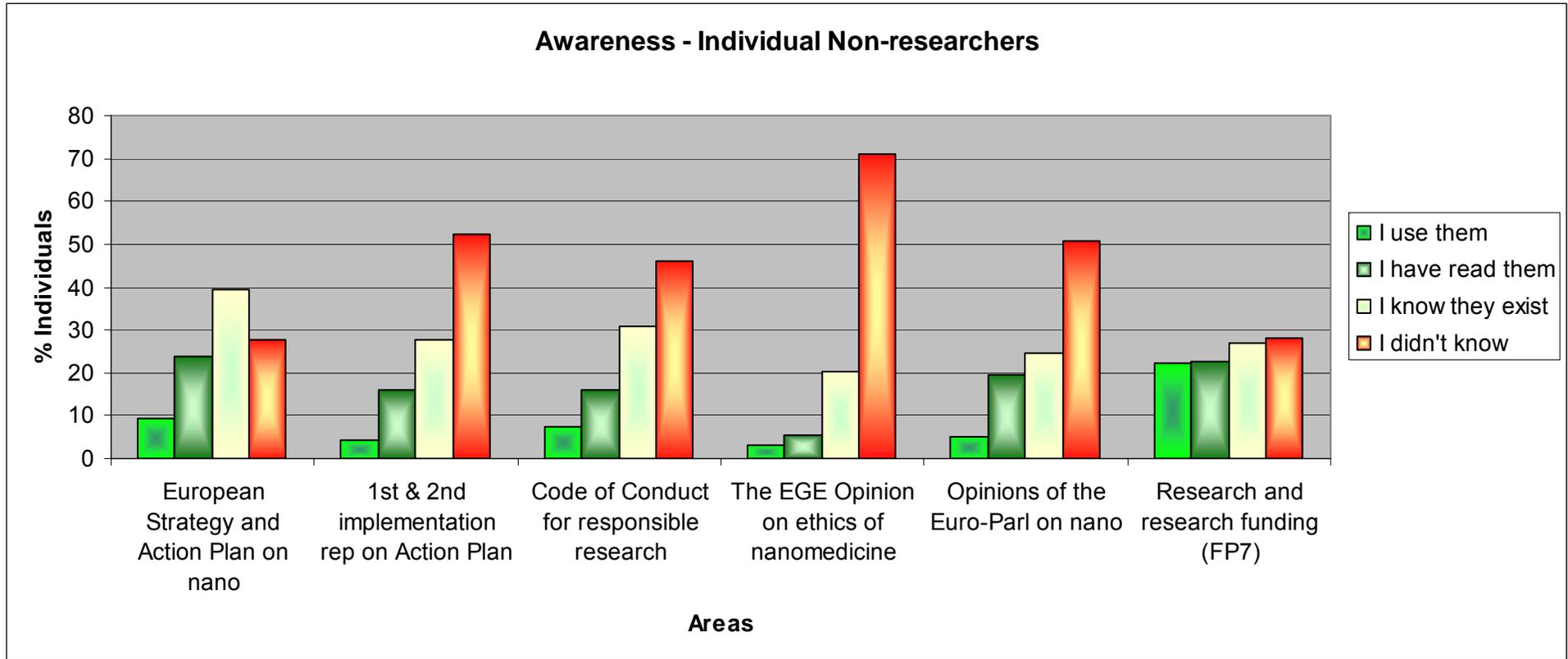


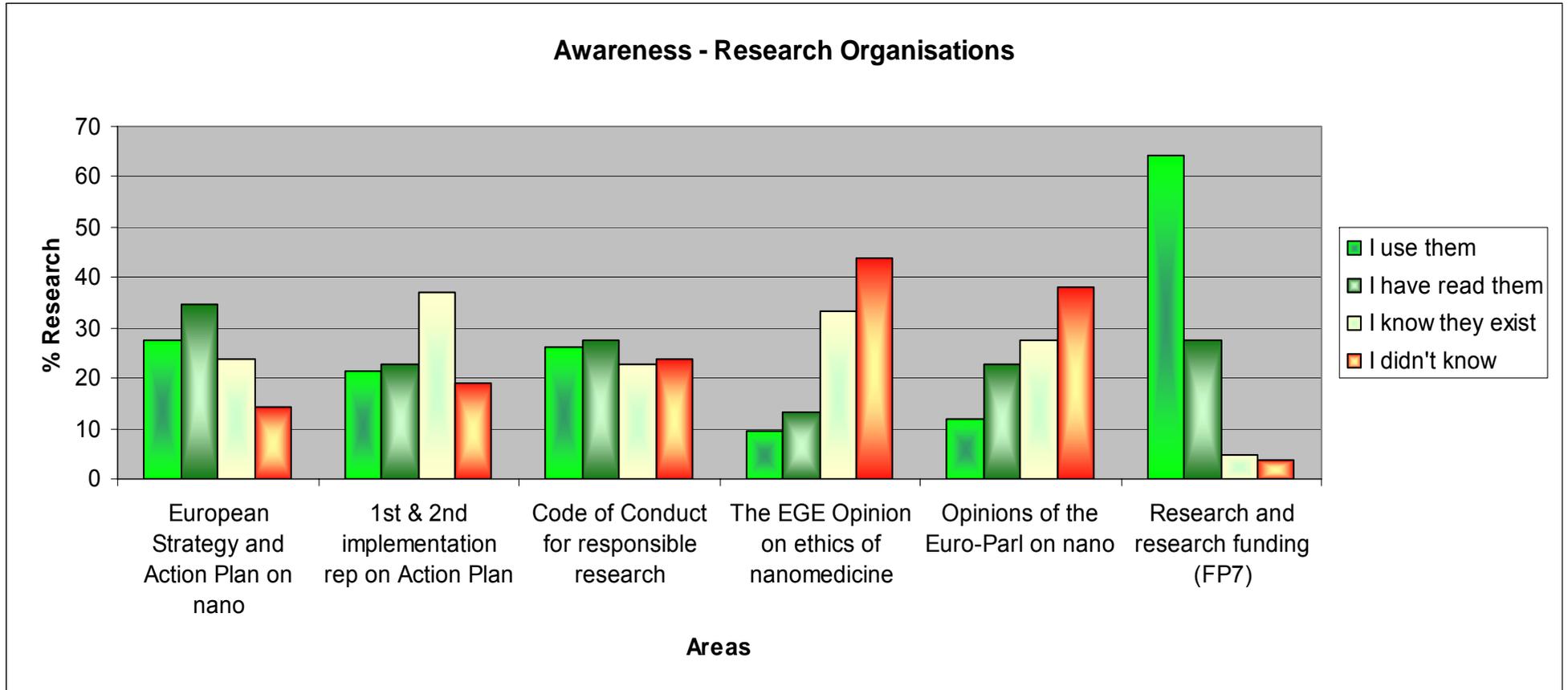


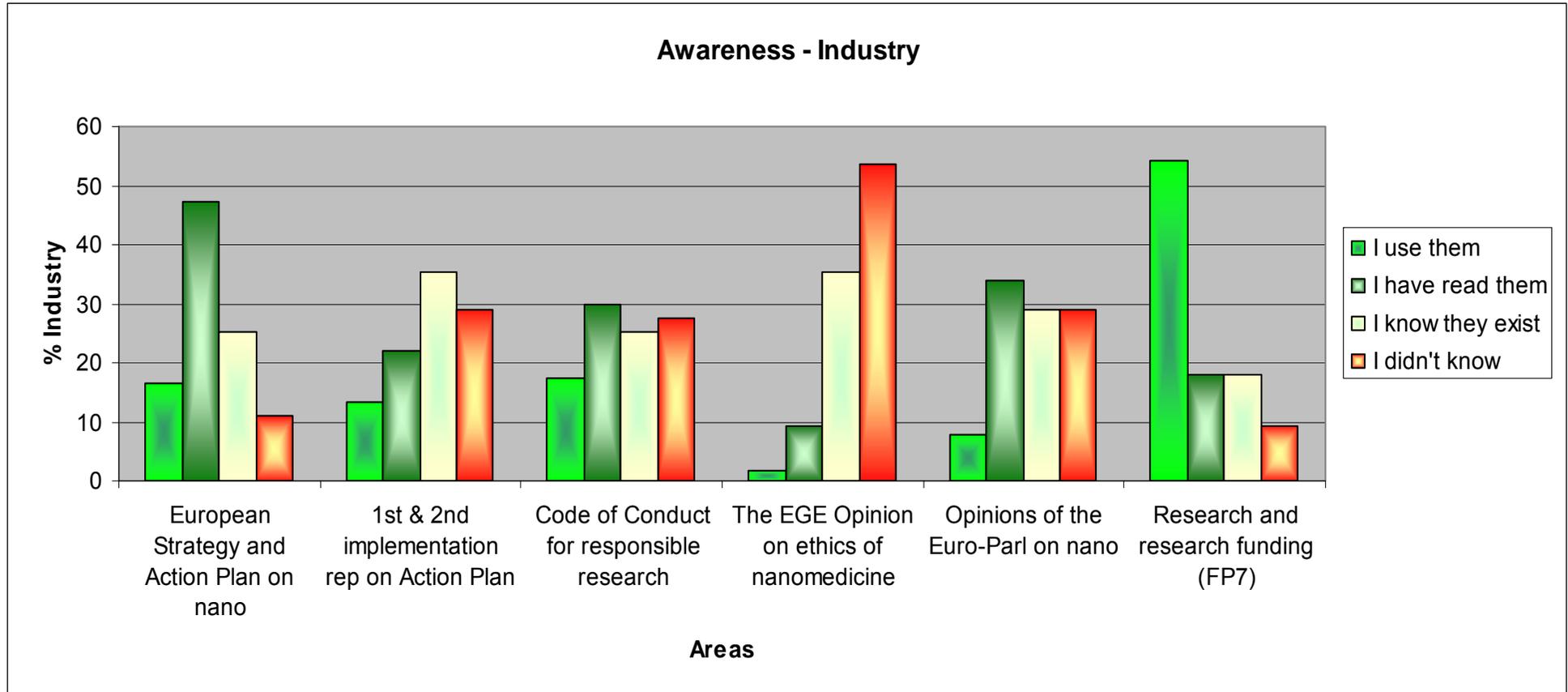
Governance - Public Authorities

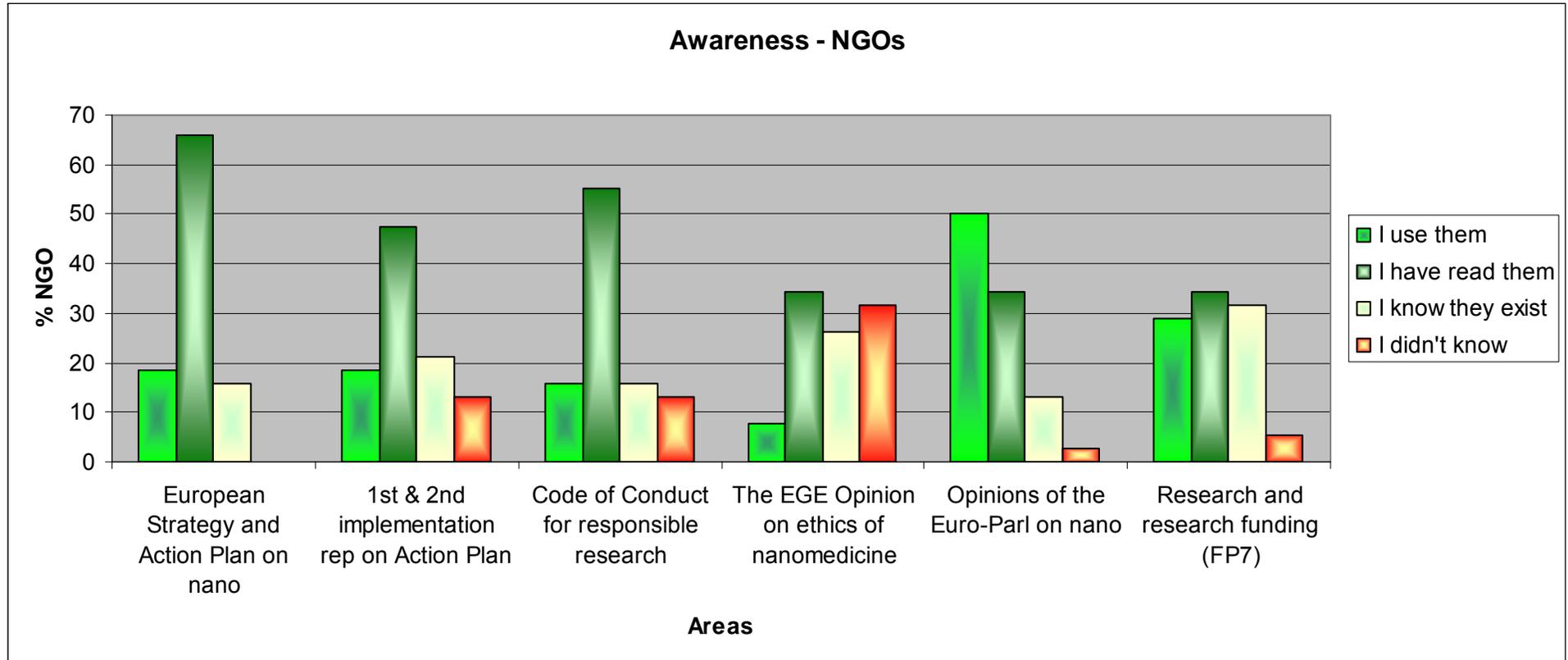


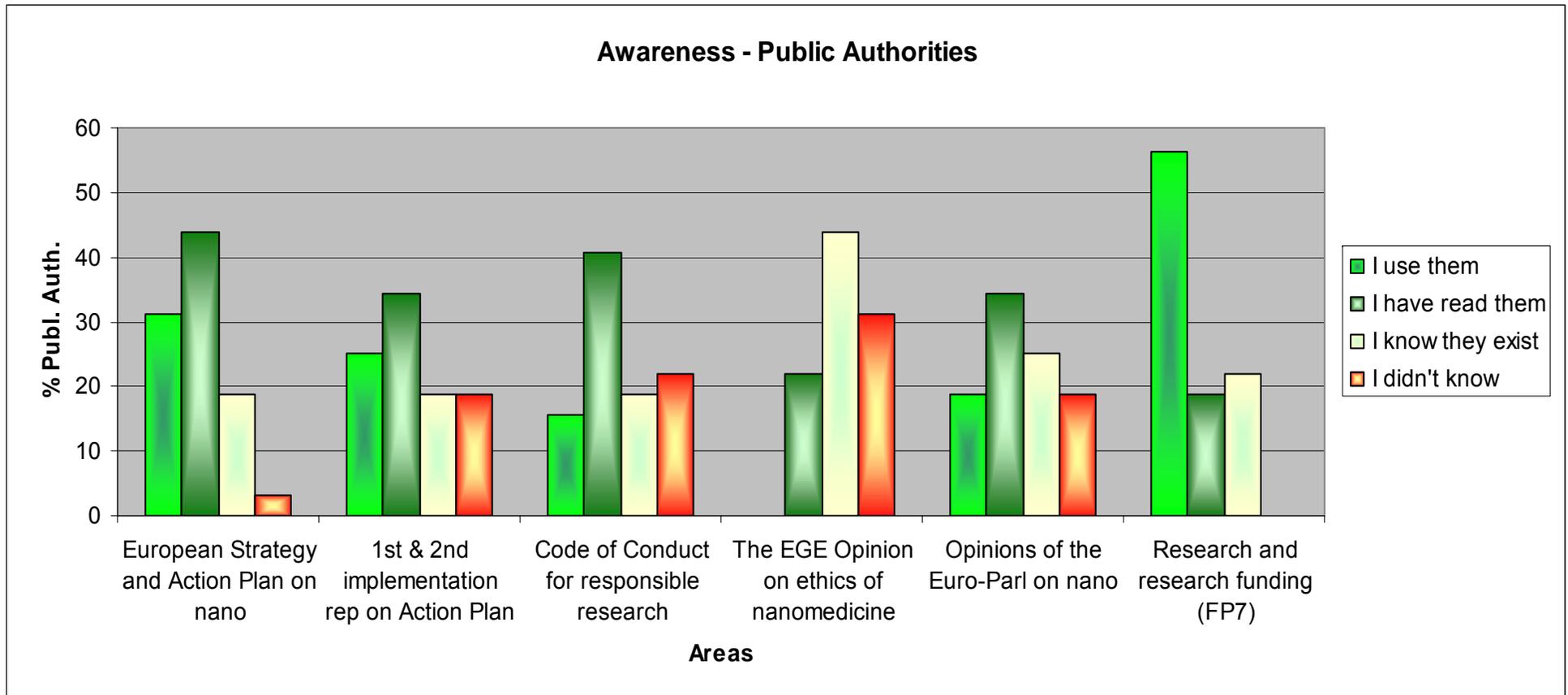


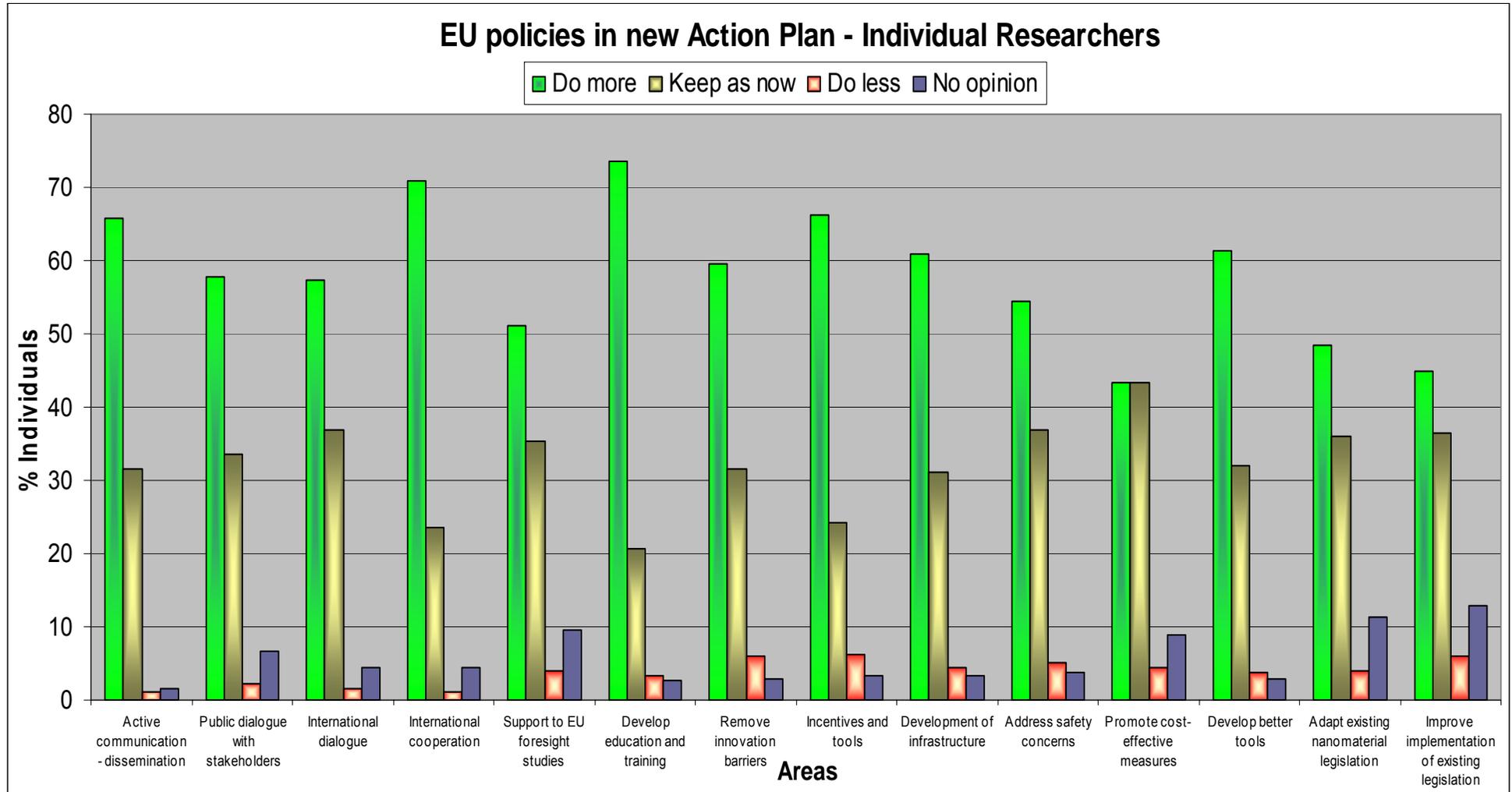


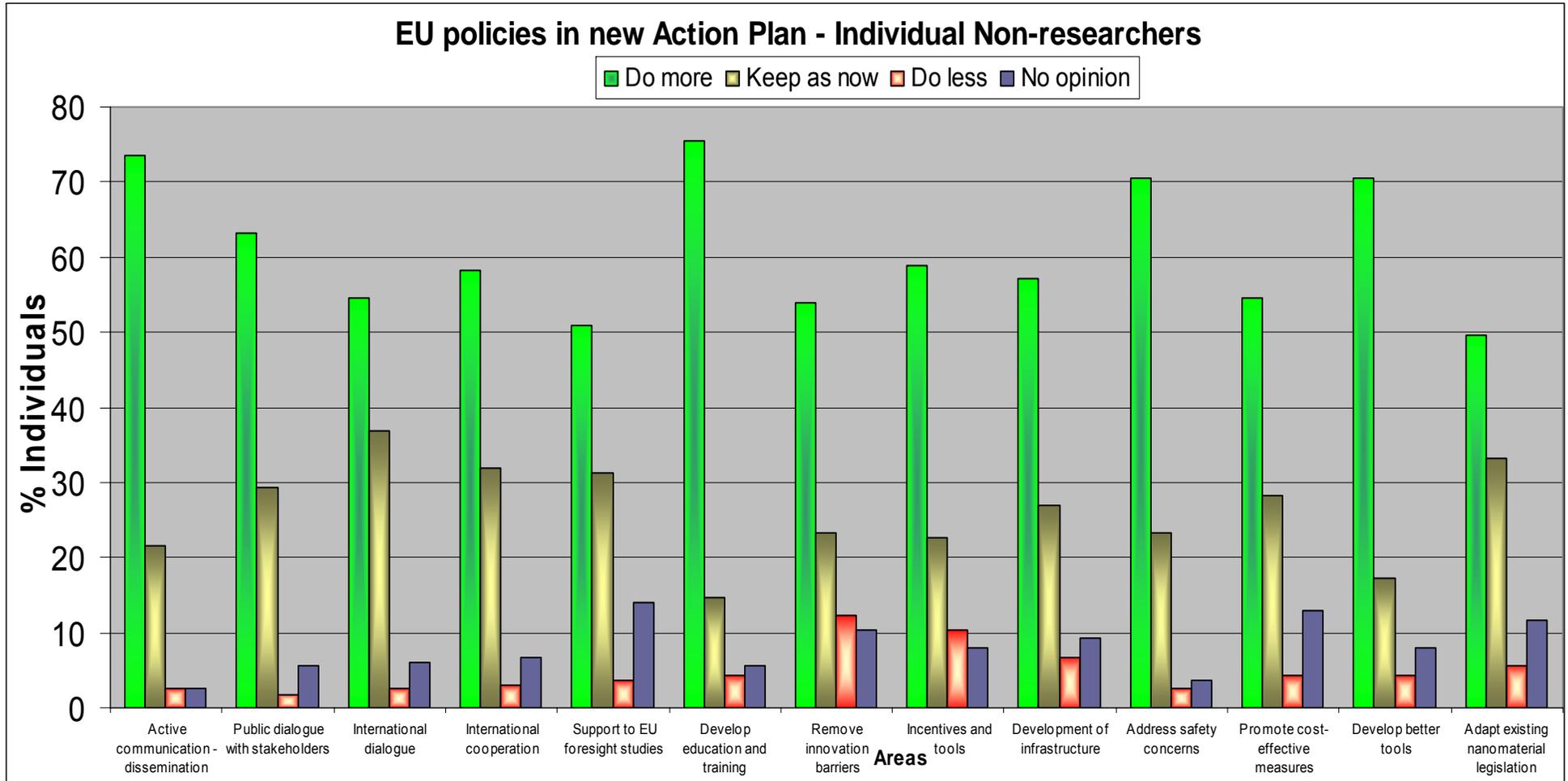


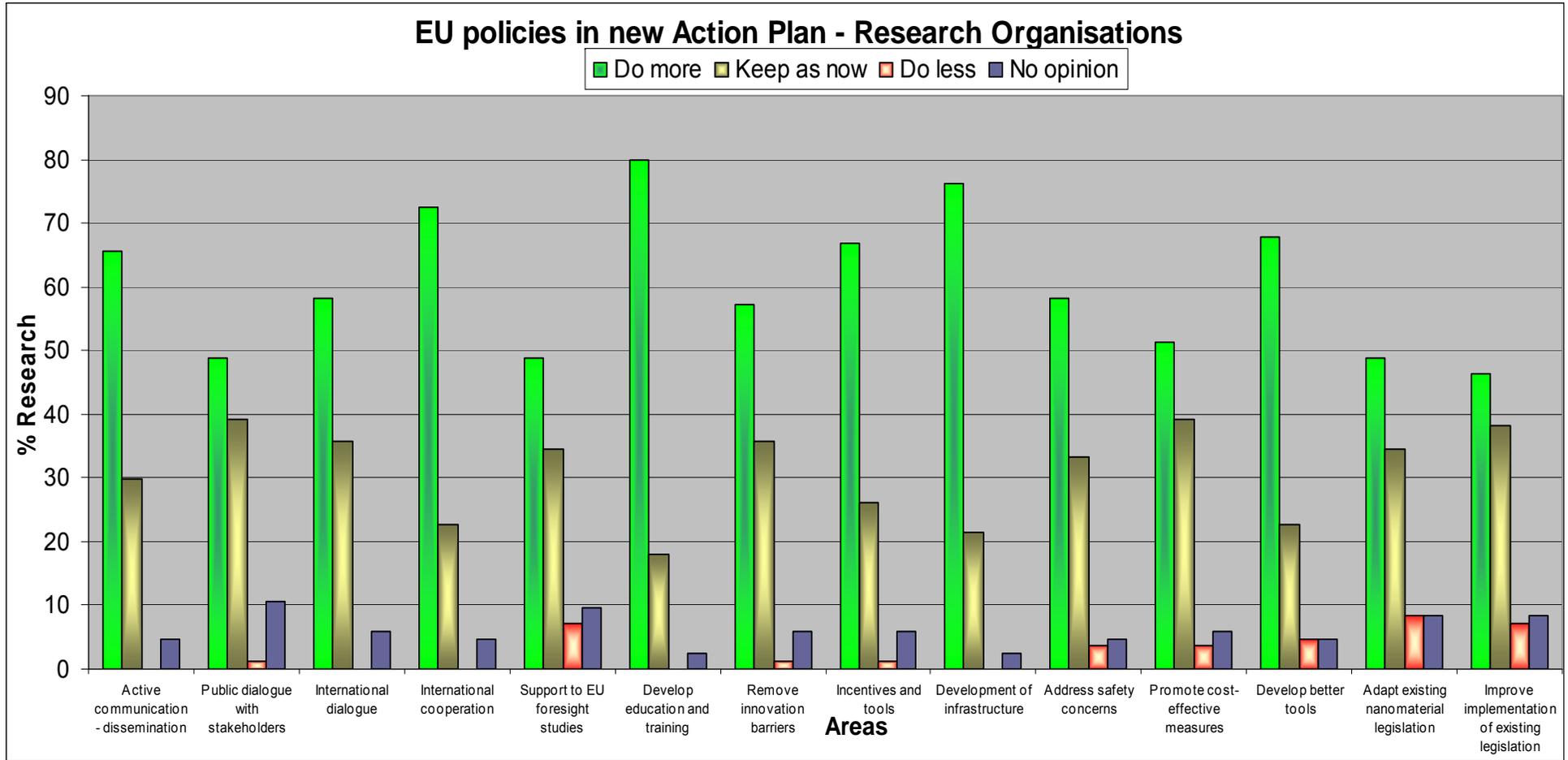


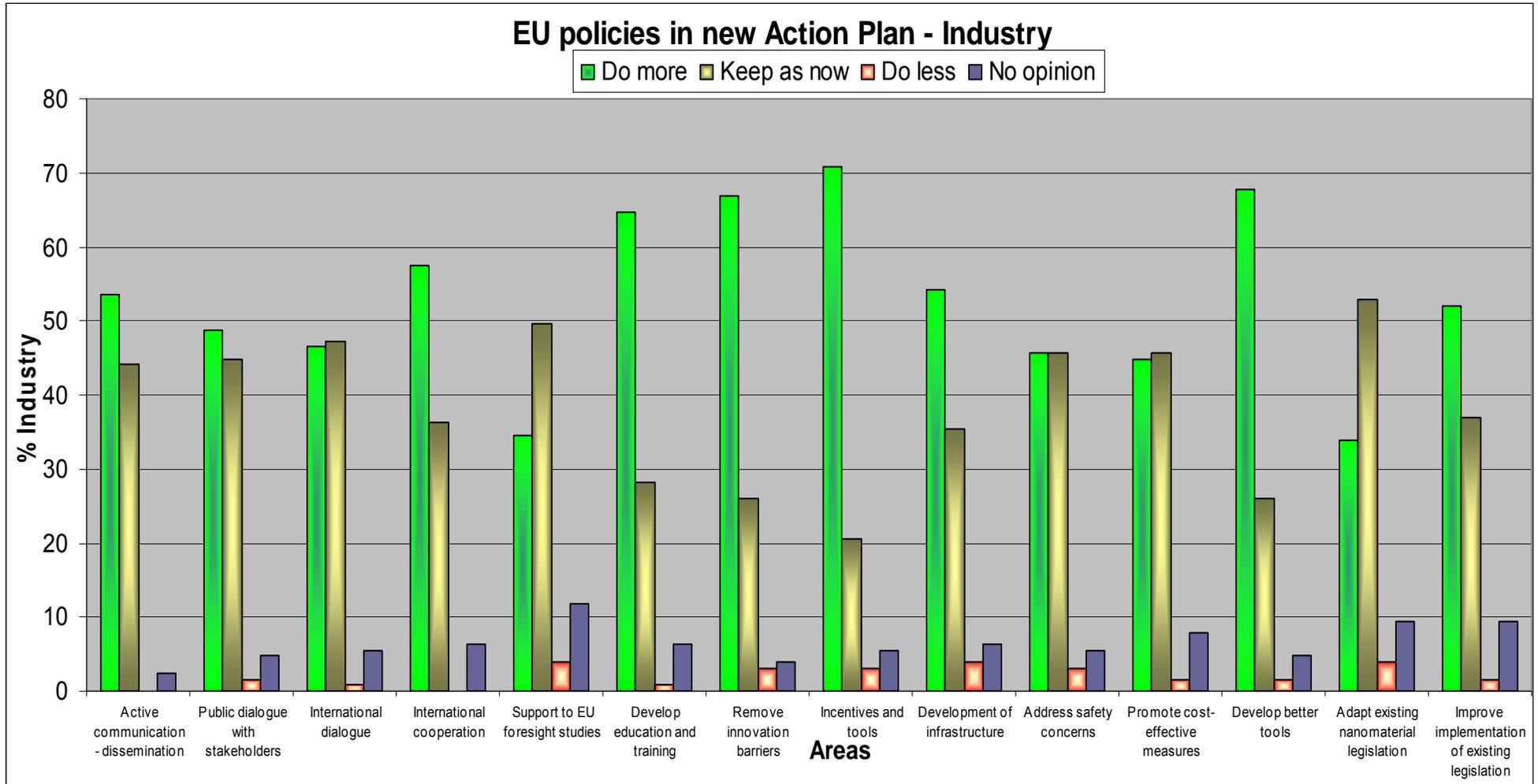


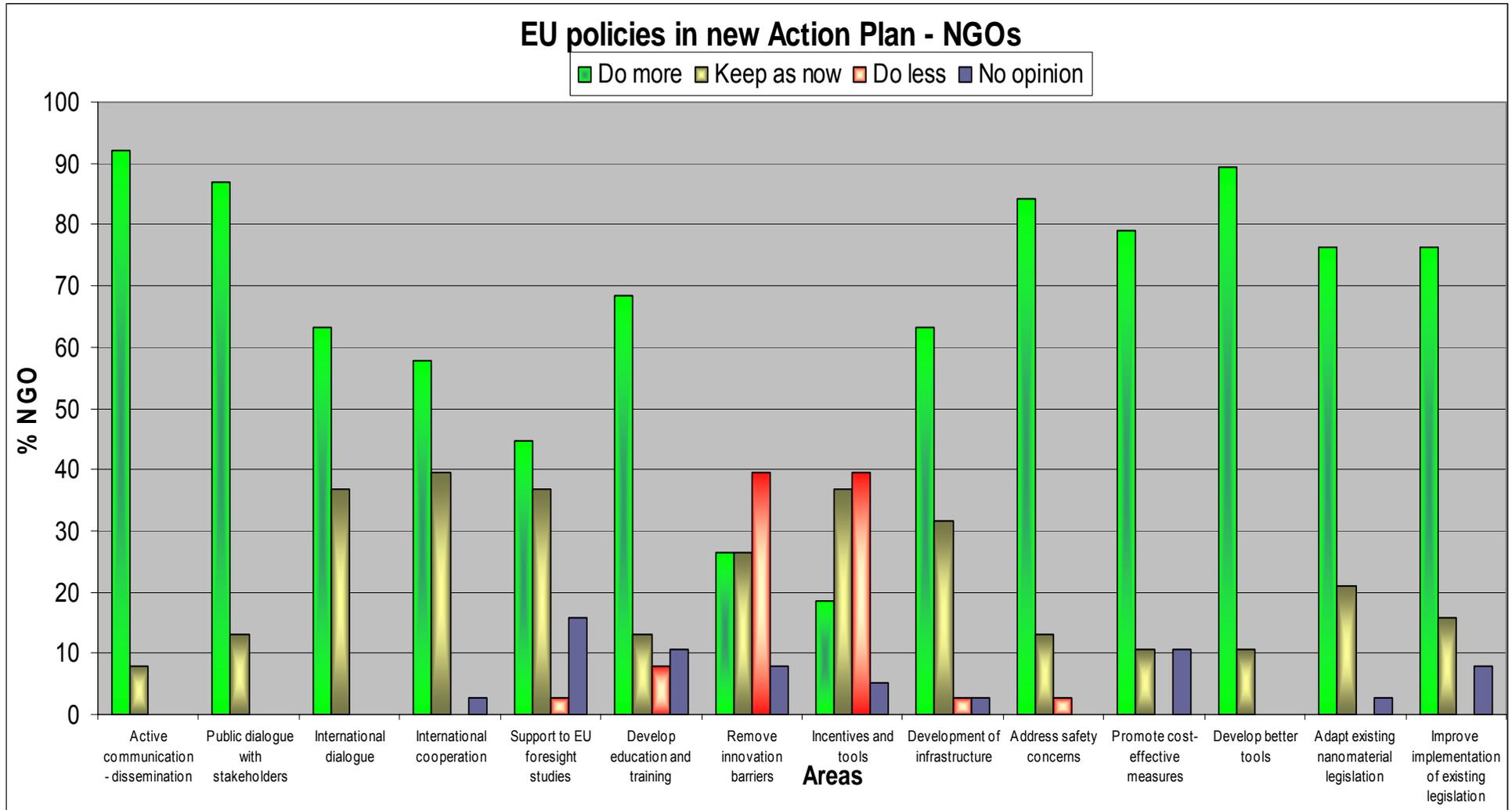


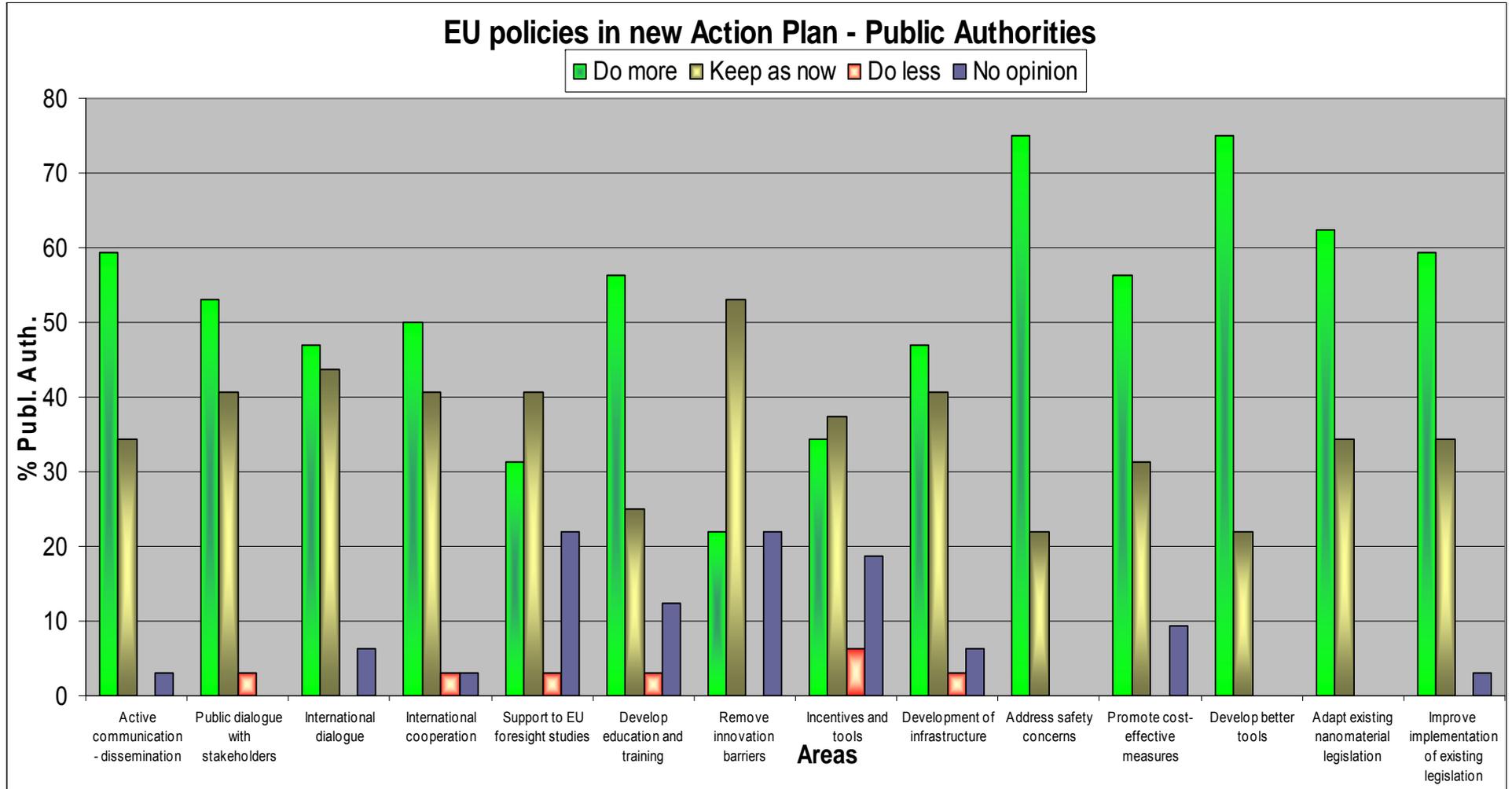


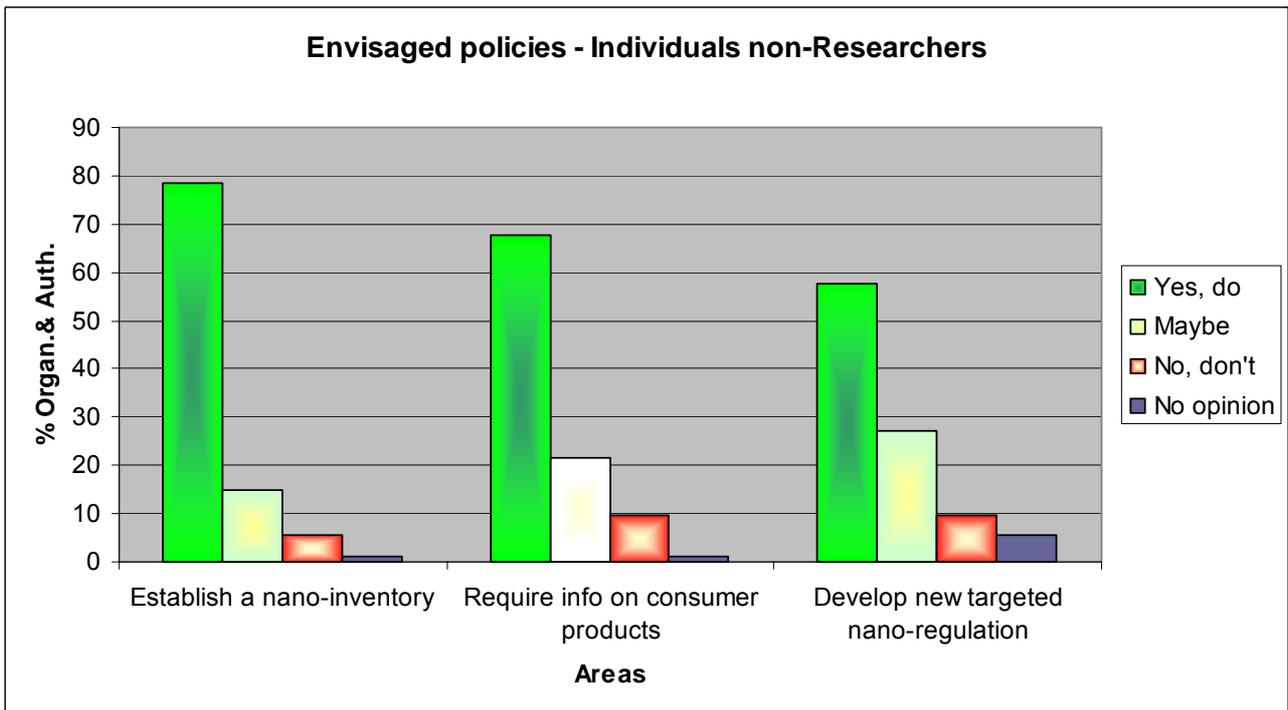
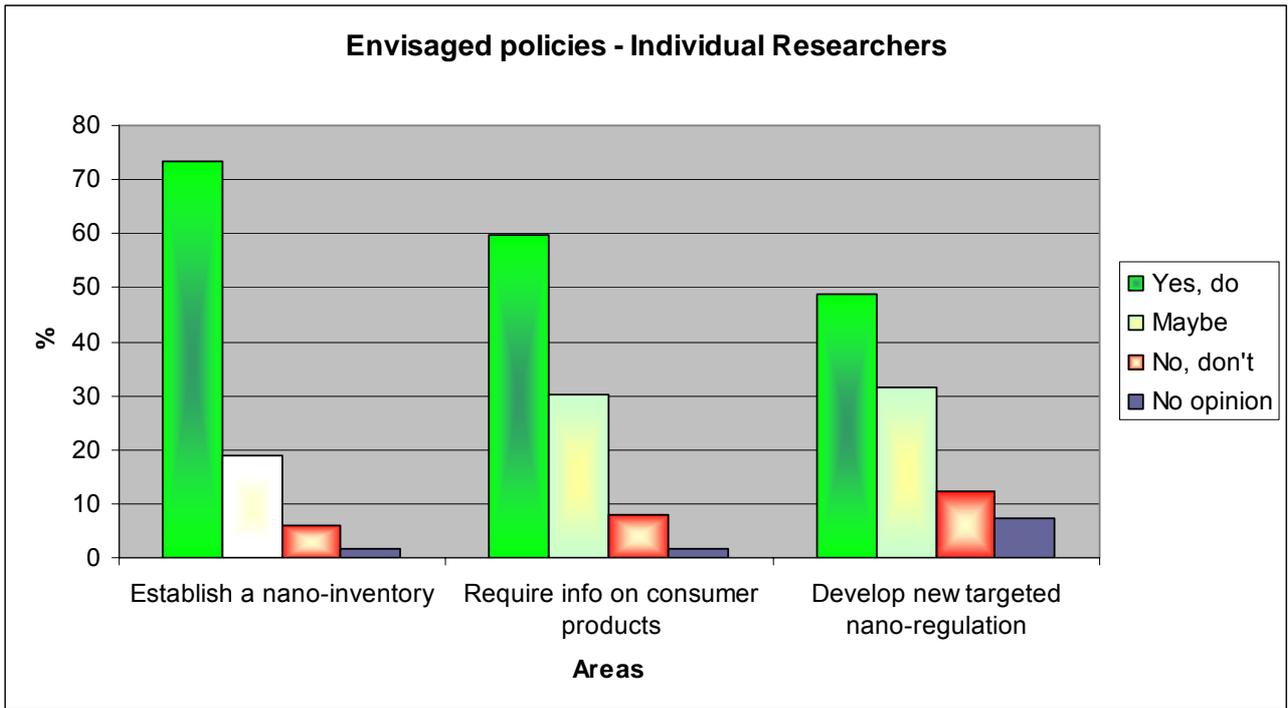


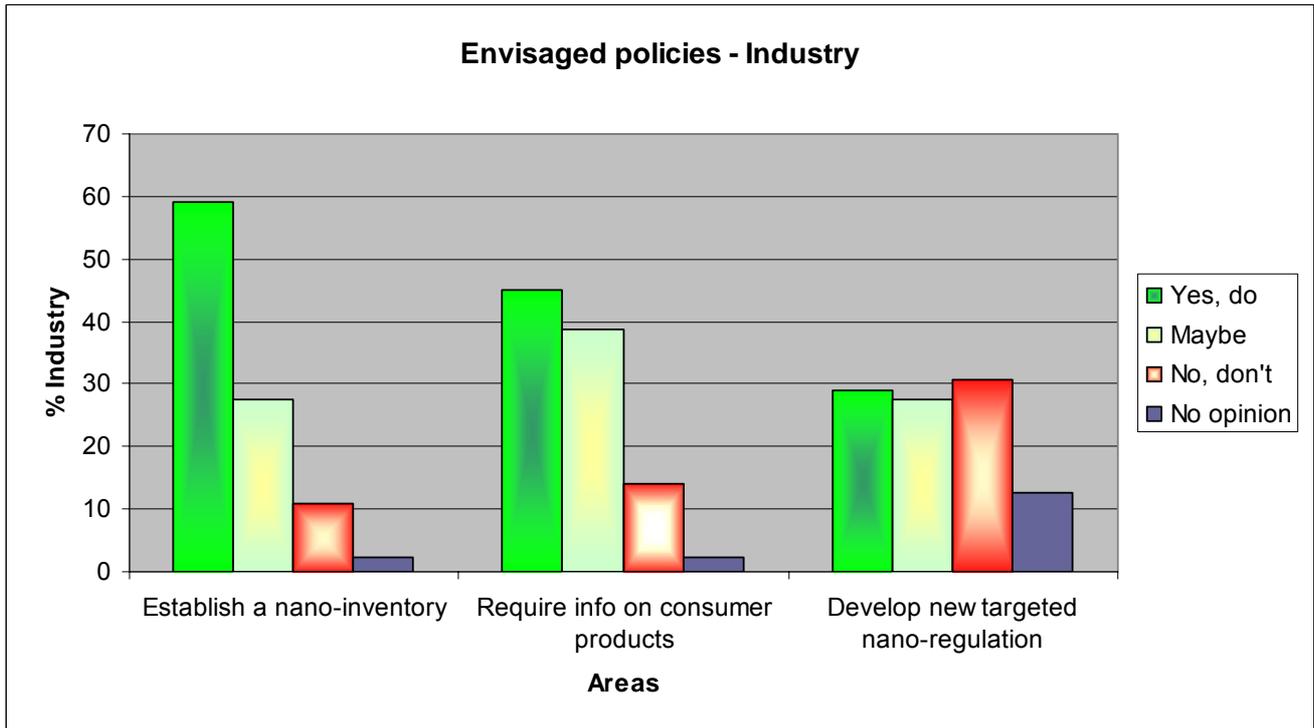
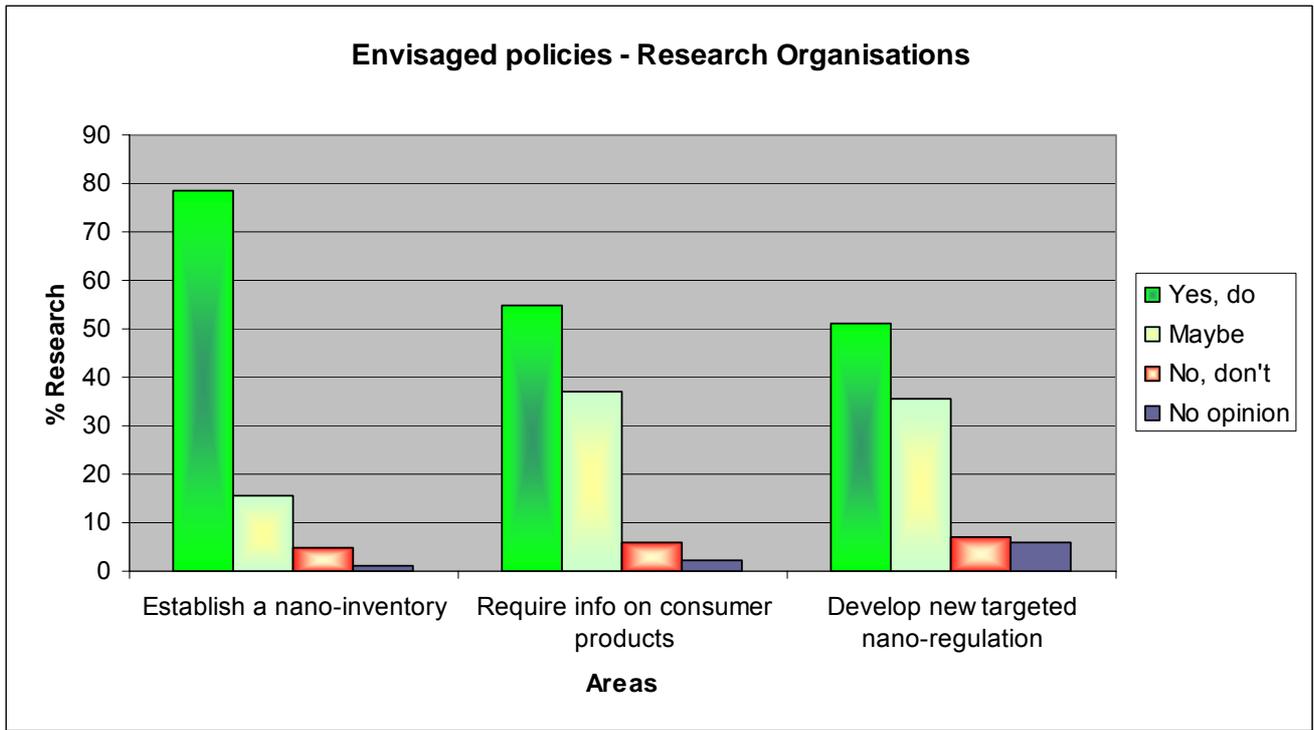


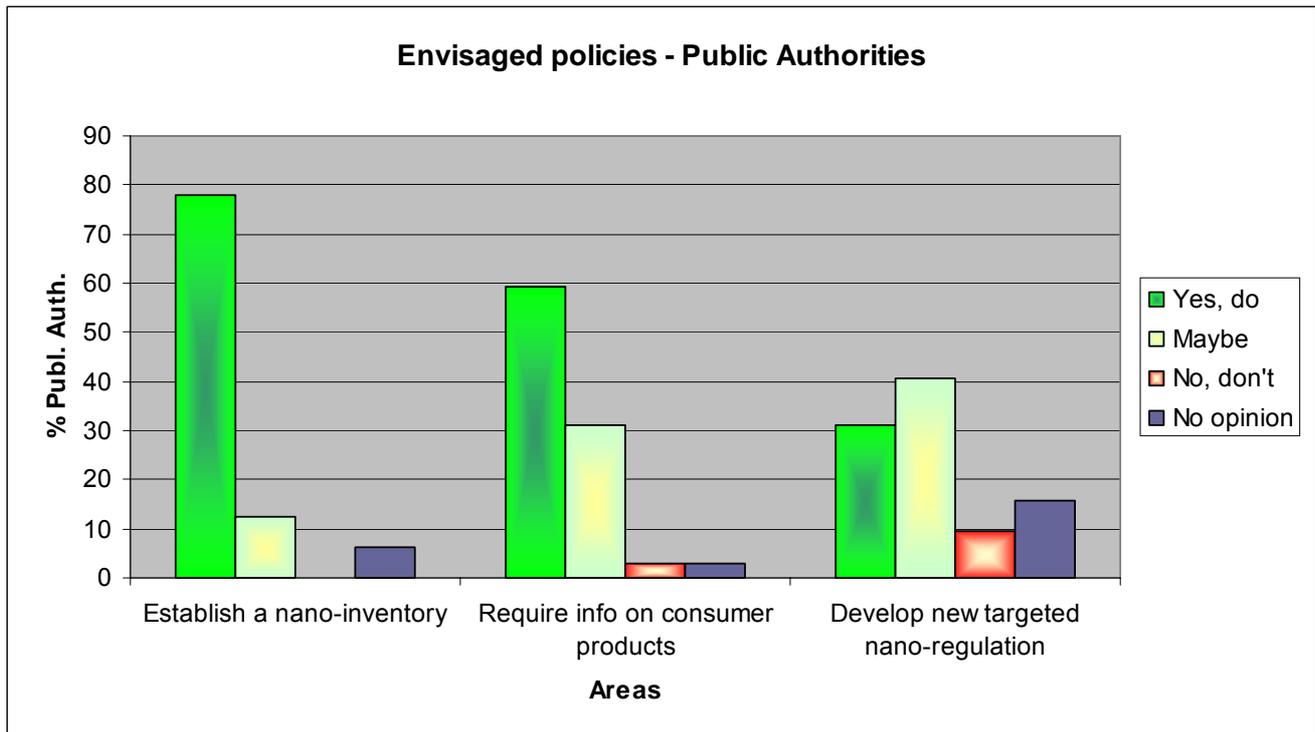
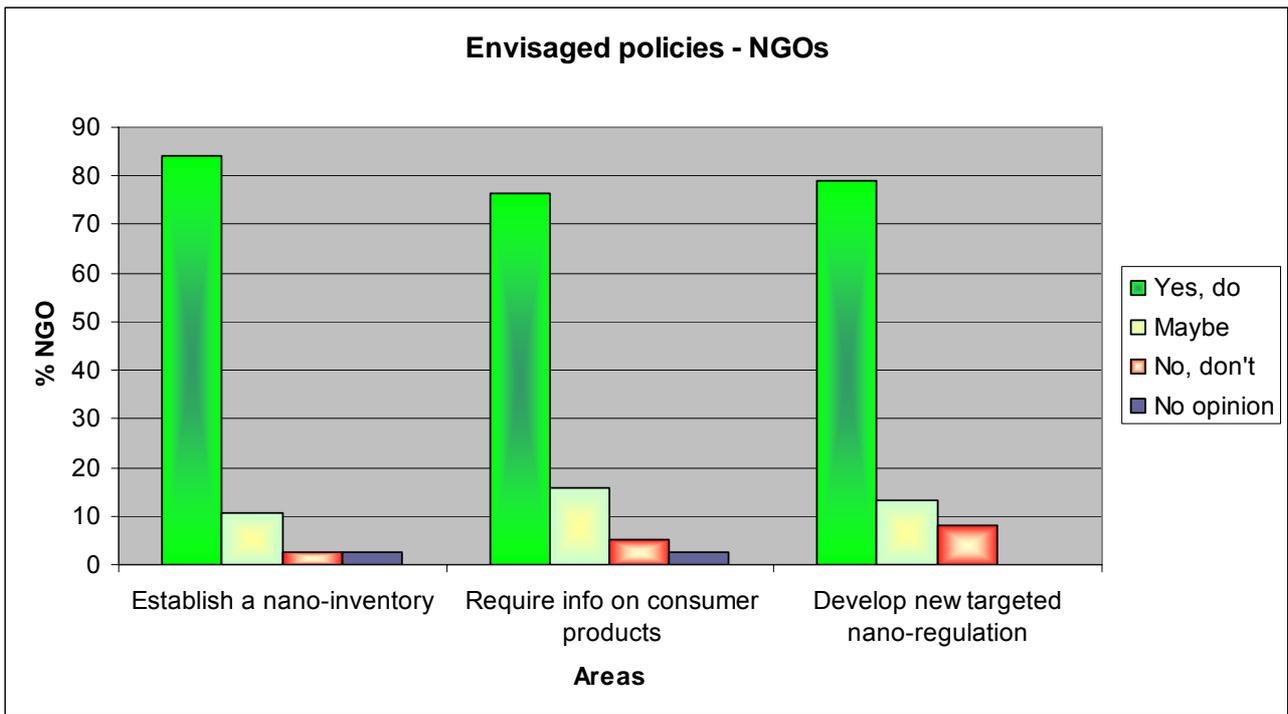


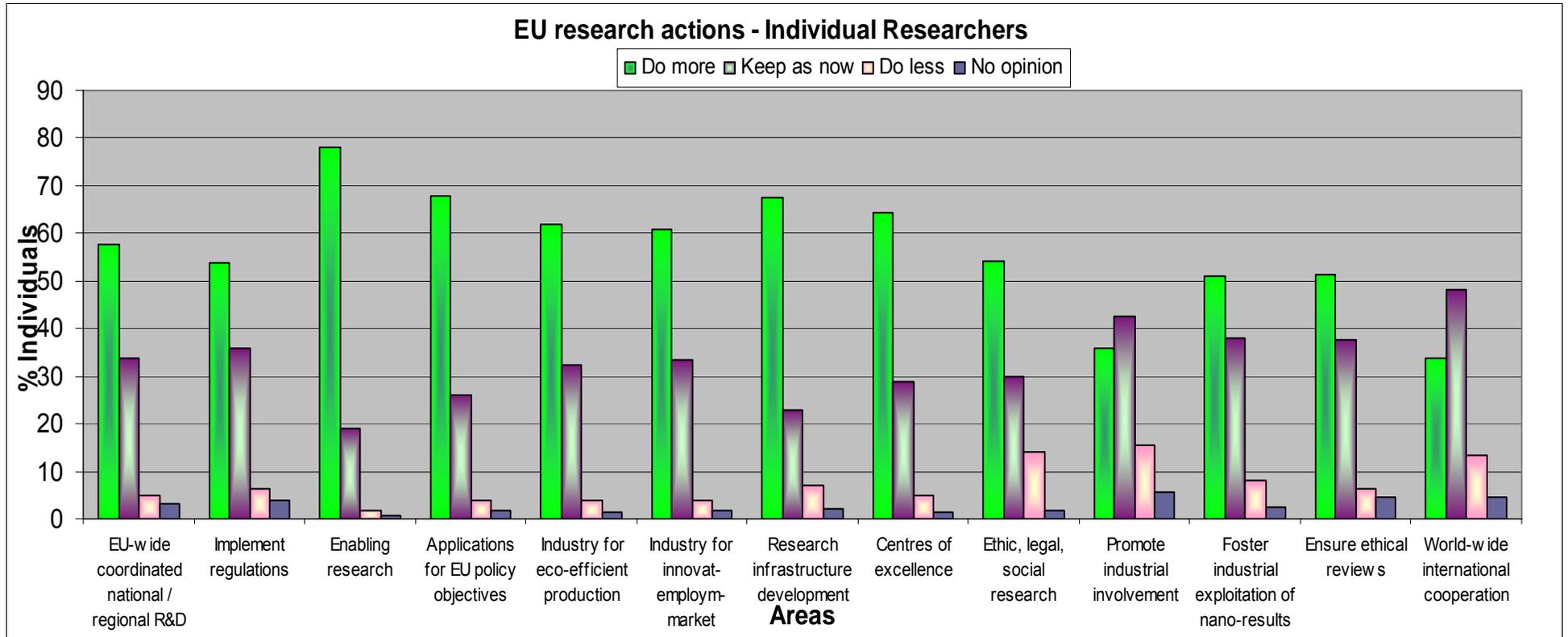


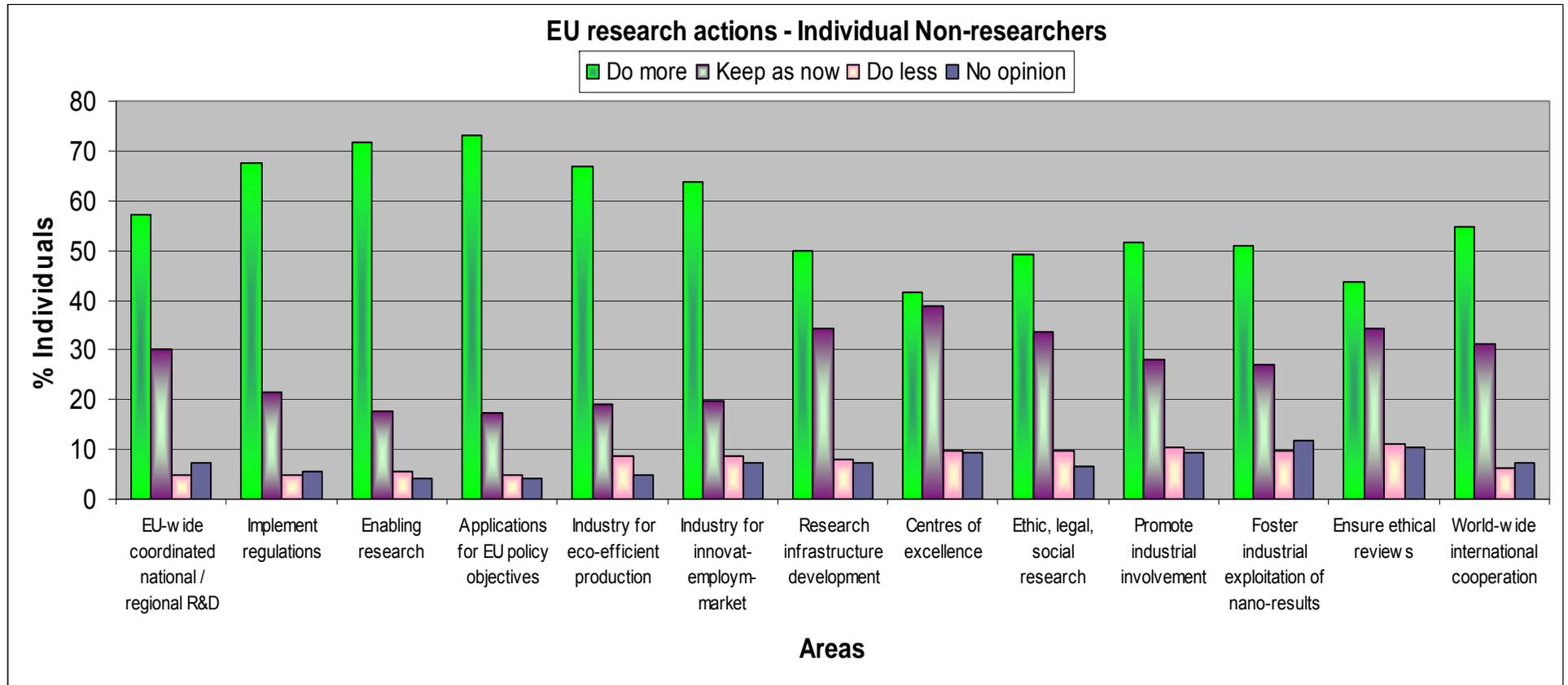


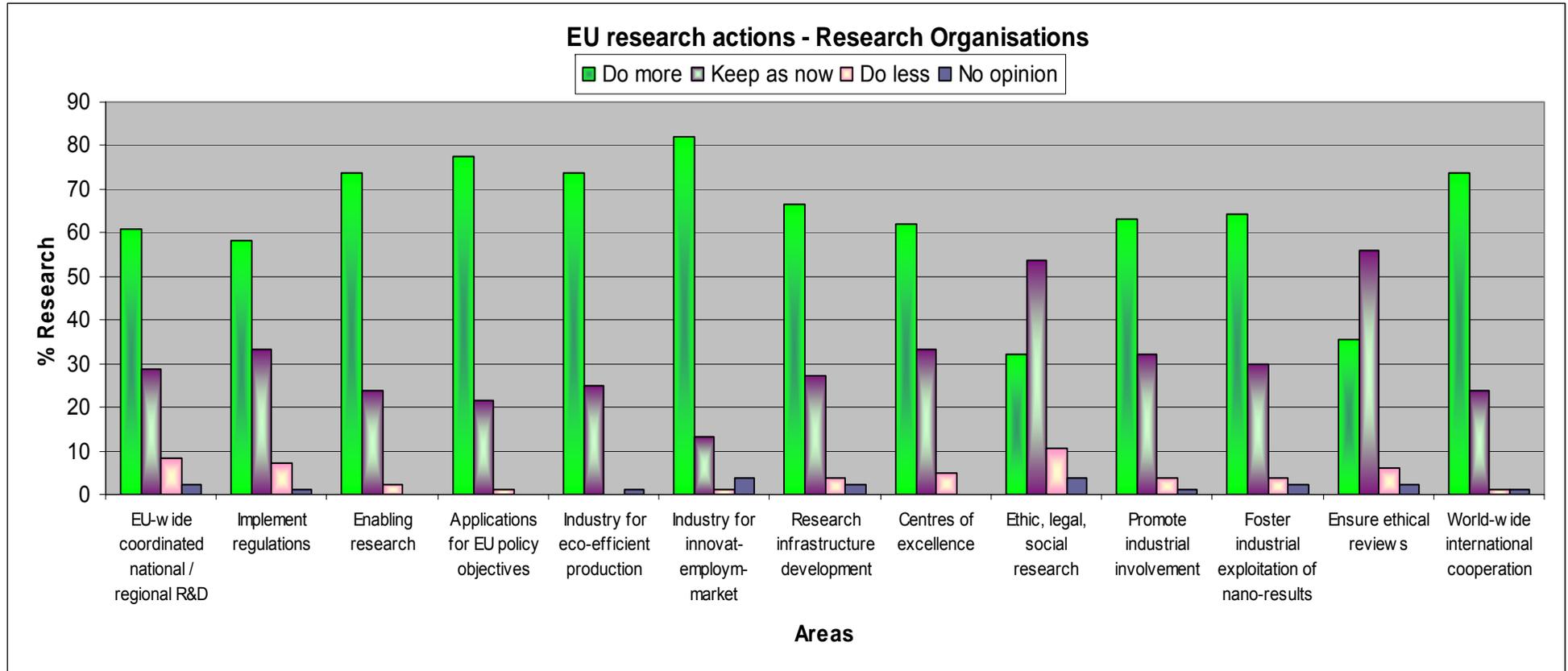


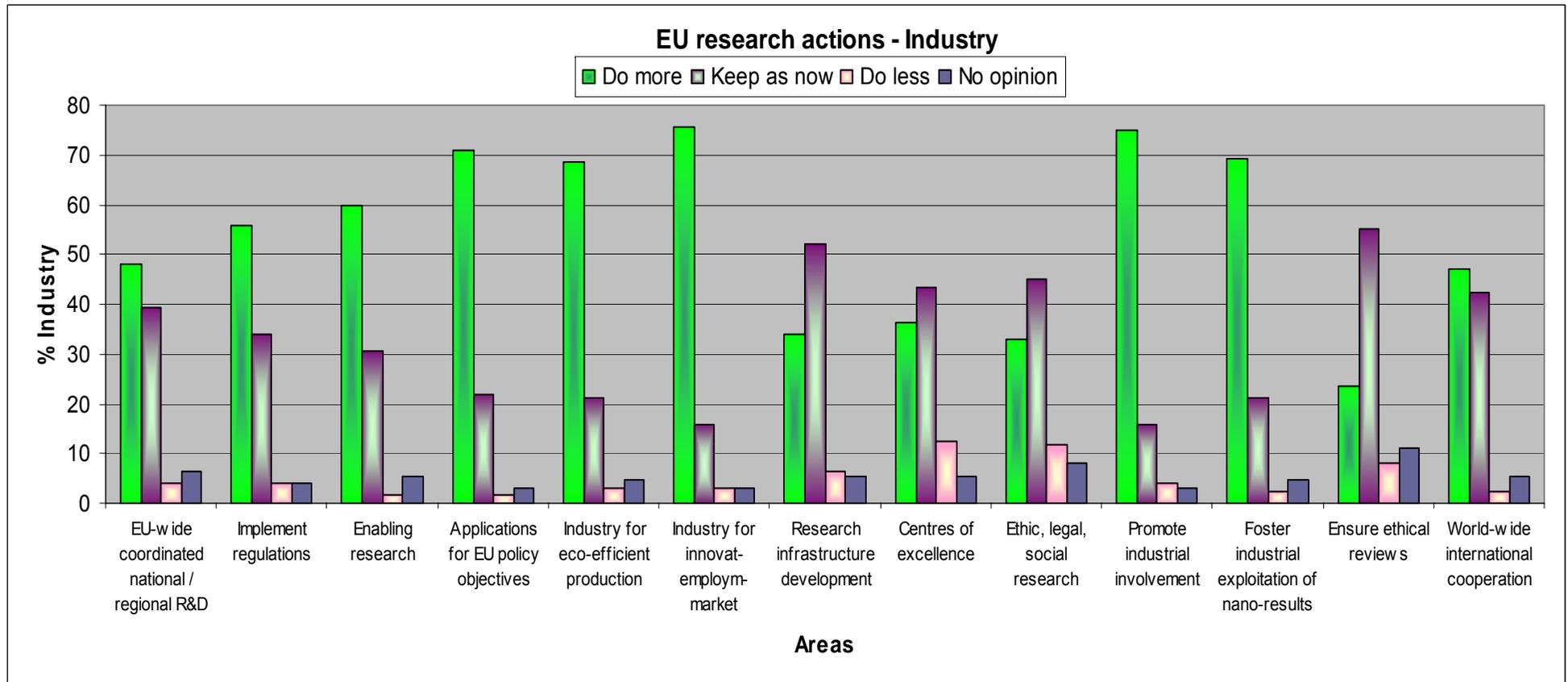


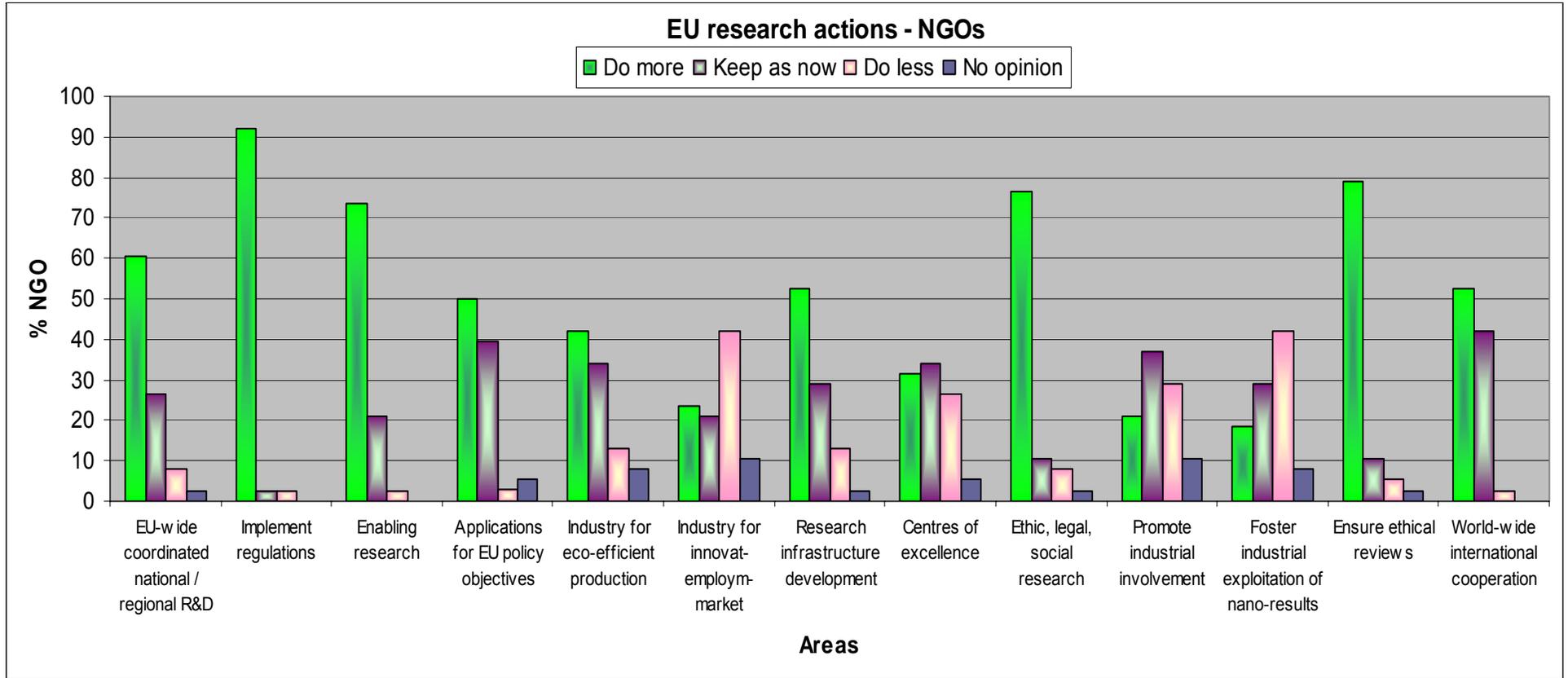


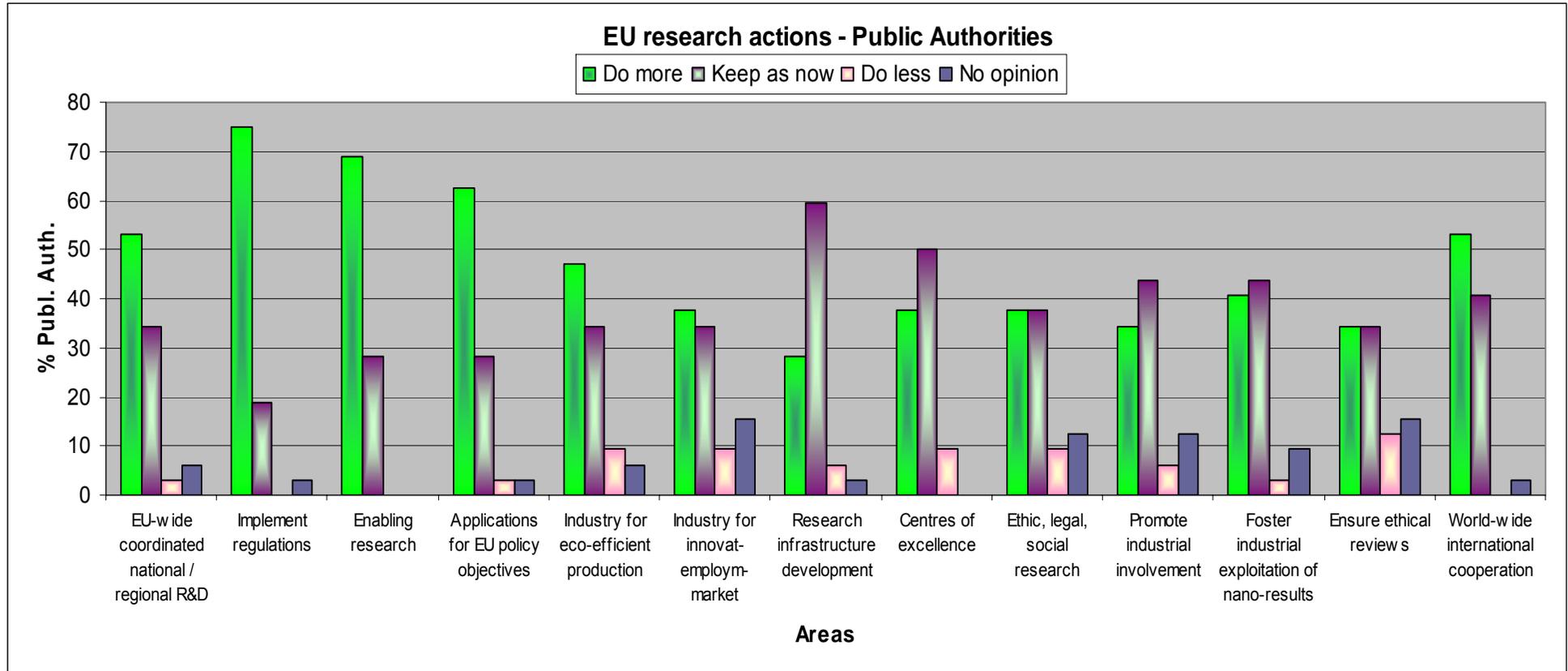












Annex III: Respondents list

Name of respondents – Public authorities*

*listed per type and in alphabetical order

Authority involved in market authorization	BAM (Federal Institute for Materials Research+Testing) - Germany
Authority involved in market authorization	European Food Safety Authority - Italy
Authority involved in market surveillance	Food and Consumer Product Safety Authority - Netherlands
Authority involved in research policy	Academy of Finland
Authority involved in research policy	Afsset - France
Authority involved in research policy	Federal Institute for Risk Assessment - Germany
Authority involved in research policy	Foundation for Fundamental Research on Matter (FOM) - Netherlands
Authority involved in research policy	Fundação para a Ciência e a Tecnologia (FCT) - Portugal
Authority involved in research policy	Instituto de Salud Carlos III - Spain
Authority involved in research policy	Ministry of Higher Education, Science and Technology - Slovenia
Authority involved in research policy	Project Management Juelich - Germany
Authority involved in research policy	State Secretariat for Education and Research – Switzerland
Authority involved in research policy	Tekes, Finnish Funding Agency for Technology and Innovation
Centralized authority	Belgian Coordination Committee for International Environmental Policy (CCIEP)
Centralized authority	Enterprise Ireland FP7 Group
Centralized authority	Institut National de Police Scientifique - France
Centralized authority	Max Rubner-Institut - Germany
Centralized authority	Ministry of Economy, Energy and Tourism, Bulgaria
Centralized authority	Ministry of Environment and Water - Hungary
Centralized authority	Parliamentary Group DIE LINKE in German Federal Parliament
Centralized authority	Science Foundation Ireland
Centralized authority	The Health Council of the Netherlands
Decentralised, regional authority	City of Leiden
Decentralised, regional authority	Denizli Special Provincial Administration
Regulatory authority	Federal Environment Agency - Germany
Regulatory authority	Food Safety Authority of Ireland
Regulatory authority	Health & Safety Authority - Ireland
Regulatory authority	National Food Administration - Sweden
Regulatory authority	The Danish Environmental Protection Agency
Regulatory authority	Tukes -safety technology authority of Finland

Name of respondents – Organisations*

*listed per type and in alphabetical order

Association of companies	Detergent and cleaning products	A.I.S.E.; International Association for Soaps, Detergents and Maintenance Products
Association of companies	Nanotechnologies	AIRI/Nanotec IT - Nanotec IT, a division of AIRI - Italian Association for Industrial Research
Association of companies	Chemicals	Cefic
Association of companies	chemicals	Chemical Industries Association
Association of companies	umbrella organisation food industry	CIAA
Association of companies	Pulp and paper	Confederation of European Paper Industries
Association of companies	mechanical	CONFINDUSTRIA BELLUNO DOLOMITI
Association of companies	Specialty food ingredients	ELC - Federation of EU Specialty Food Ingredients Industries
Association of companies	colorants	ETAD

Association of companies	chemical/employers' association	European Chemical Employers Group (ECEG)
Association of companies	multi-sectoral	European-American Business Council
Association of companies	metal	federación empresarial metarlugica valenciana
Association of companies	FOOD & DRINKS	FEDERACIÓN ESPAÑOLA DE INDUSTRIAS DE ALIMENTACIÓN Y BEBIDAS
Association of companies	Chemical	Federchimica
Association of companies	Metals & engineering	FIMECC Ltd.
Association of companies	food industry	FNLI
Association of companies	Cheical Industry	German Chemical Induytry Association
Association of companies	nanomaterials	NANOfutures Romania
Association of companies	Nanotechnology	Nanotechnology Industries Association aisbl
Association of companies	Organisation of the collection and recycling of used packaging	PRO EUROPE s.p.r.l.
Association of companies	High-tech	TechAmerica Europe (formerly AeA Europe)
Association of companies	Chemicals	The Swedish Plastics & Chemicals Federation
Association of companies	MACHINE TOOLS	UCIMU-SISTEMI-PER PRODURRE
Association of companies	PAINTS	UNIFAP
Association of companies	Chemical Industry	VCI - Verband der chemischen Industrie e.V.
Association of companies	Microtechnologies	VDMA Micro Technology
Manufacturing or trading company involved in nanotechnologies		AB ANALITICA SRL
Manufacturing or trading company involved in nanotechnologies		ALTANA AG
Manufacturing or trading company involved in nanotechnologies		APC Composite AB
Manufacturing or trading company involved in nanotechnologies		BASF SE
Manufacturing or trading company involved in nanotechnologies		Bayer AG
Manufacturing or trading company involved in nanotechnologies		Bayer Technology Services GmbH
Manufacturing or trading company involved in nanotechnologies		Biocroi Ltd
Manufacturing or trading company involved in nanotechnologies		Cellix Limited
Manufacturing or trading company involved in nanotechnologies		Center of Applied Nanotechnology (CAN) GmbH
Manufacturing or trading company involved in nanotechnologies		CILAS
Manufacturing or trading company involved in nanotechnologies		Cochlear Research and Development Limited
Manufacturing or trading company involved in nanotechnologies		COLOROBIA ITALIA S.p.A.
Manufacturing or trading company involved in nanotechnologies		Complex Fluid Simulations GmbH
Manufacturing or trading company involved in nanotechnologies		Du Pont de Nemours International S.A.
Manufacturing or trading company involved in nanotechnologies		Encapson
Manufacturing or trading company involved in nanotechnologies		European Tyre and Rubber Manufacturers' Association
Manufacturing or trading company involved in nanotechnologies		Evonik Degussa GmbH
Manufacturing or trading company involved in nanotechnologies		Fluidinova, Engenharia de Fluidos, S.A:
Manufacturing or trading company involved in nanotechnologies		GENERAL ELECTRIC
Manufacturing or trading company involved in nanotechnologies		Guerbet
Manufacturing or trading company involved in nanotechnologies		Henkel AG & Co. KGaA
Manufacturing or trading company involved in nanotechnologies		Hewlett-Packard
Manufacturing or trading company involved in nanotechnologies		Hill-Rom company
Manufacturing or trading company involved in nanotechnologies		HISTOCELL
Manufacturing or trading company involved in nanotechnologies		Huntsman Polyurethanes
Manufacturing or trading company involved in nanotechnologies		IBS Precision Engineering
Manufacturing or trading company involved in nanotechnologies		IMS Nanofabrication AG
Manufacturing or trading company involved in nanotechnologies		Innovnano Materials Avançadps, S.A.
Manufacturing or trading company involved in nanotechnologies		KERABEN Grupo, S.A.
Manufacturing or trading company involved in nanotechnologies		Lake Chemicals and Mienrals Ltd
Manufacturing or trading company involved in nanotechnologies		LIMO Lissotschenko Mikrooptik GmbH
Manufacturing or trading company involved in nanotechnologies		MagnaMedics Diagnostics BV
Manufacturing or trading company involved in nanotechnologies		MBN nanomaterialia spa
Manufacturing or trading company involved in nanotechnologies		Medipol SA
Manufacturing or trading company involved in nanotechnologies		Merck KGaA
Manufacturing or trading company involved in nanotechnologies		Millennium Inorganic Chemicals Thann SAS

Manufacturing or trading company involved in nanotechnologies	Nanobiotix
Manufacturing or trading company involved in nanotechnologies	Nano-H S.A.S.
Manufacturing or trading company involved in nanotechnologies	NanoPhos SA
Manufacturing or trading company involved in nanotechnologies	NanoSys GmbH
Manufacturing or trading company involved in nanotechnologies	Nanovector srl
Manufacturing or trading company involved in nanotechnologies	NEOS SURGERY S.L.
Manufacturing or trading company involved in nanotechnologies	Nikon Metrology NV
Manufacturing or trading company involved in nanotechnologies	NIL Technology ApS
Manufacturing or trading company involved in nanotechnologies	Novartis International AG
Manufacturing or trading company involved in nanotechnologies	Oxford Instruments Plasma Technology
Manufacturing or trading company involved in nanotechnologies	Robert Bosch GmbH
Manufacturing or trading company involved in nanotechnologies	Royal DSM N.V.
Manufacturing or trading company involved in nanotechnologies	Sirius International
Manufacturing or trading company involved in nanotechnologies	Solvay
Manufacturing or trading company involved in nanotechnologies	Stobbe Tech A/S
Manufacturing or trading company involved in nanotechnologies	TEandM- Tecnologia e Engenharia de Materiais, SA
Manufacturing or trading company involved in nanotechnologies	Technovár Ltd.
Manufacturing or trading company involved in nanotechnologies	Tethis
Manufacturing or trading company involved in nanotechnologies	The Oricter & Gamble Company
Manufacturing or trading company involved in nanotechnologies	Trion Tensid AB
Manufacturing or trading company involved in nanotechnologies	Verband der deutschen Lack-und Druckfarbenindustrie e.V.
Manufacturing or trading company involved in nanotechnologies	XEPTAGEN SPA
Manufacturing or trading company not involved in nanotechnologies	Afvalenergiebedrijf
Manufacturing or trading company not involved in nanotechnologies	Arcelik A.S.
Manufacturing or trading company not involved in nanotechnologies	Comau
Manufacturing or trading company not involved in nanotechnologies	Environics Oy
Manufacturing or trading company not involved in nanotechnologies	Ferroperm Piezoceramics A/S
Manufacturing or trading company not involved in nanotechnologies	Lanxess AG
Manufacturing or trading company not involved in nanotechnologies	Megatech Industries Amurrio S.L.
Manufacturing or trading company not involved in nanotechnologies	METRO Group
Manufacturing or trading company not involved in nanotechnologies	Nabaltec AG
Manufacturing or trading company not involved in nanotechnologies	REPSOL
Manufacturing or trading company not involved in nanotechnologies	Resiquimica, Resinas Quimicas, S.A.
Manufacturing or trading company not involved in nanotechnologies	SAATI spa
Manufacturing or trading company not involved in nanotechnologies	Sealed Air Corp.

Non-Governmental Organisations (NGOs)*

*listed per type and in alphabetical order

Non-Governmental Organisation	Altroconsumo
Non-Governmental Organisation	ANEC
Non-Governmental Organisation	Austrian Federal Chamber of Labour, Consumer Policy Department
Non-Governmental Organisation	BEUC, The European Consumers' Organisation
Non-Governmental Organisation	Bulgarian Organization for Standardization (BDS)
Non-Governmental Organisation	Bund für Umwelt und Naturschutz Deutschland (BUND) e.V. - Friends of the Earth Germany
Non-Governmental Organisation	Center for International Environmental Law (CIEL)
Non-Governmental Organisation	CONSMERS' ASSOCIATION OF KAVALA
Non-Governmental Organisation	DECHEMA
Non-Governmental Organisation	Deutscher Tierschutzbund - German Animal Welfare Federation
Non-Governmental Organisation	EU-Environmental bureau
Non-Governmental Organisation	Euro Coop
Non-Governmental Organisation	European Environmental Bureau
Non-Governmental Organisation	European Genetic Alliances' Network
Non-Governmental Organisation	European Society for Biomaterials
Non-Governmental Organisation	Forbrugerrådet
Non-Governmental Organisation	Foundation Animalfree Research
Non-Governmental Organisation	France Nature Environnement
Non-Governmental Organisation	Friends of the Earth Australia Nanotechnology Project
Non-Governmental Organisation	Gesellschaft Deutscher Chemiker e.V.
Non-Governmental Organisation	Health and Environment Alliance
Non-Governmental Organisation	Institut Européen pour la Gestion Raisonnée de l'Environnement

Non-Governmental Organisation	Institut Maçonique européen de la Grande loge féminine de France
Non-Governmental Organisation	Inter-Environnement Wallonie
Non-Governmental Organisation	KEPKA - Consumers' Protection Center
Non-Governmental Organisation	Mediterranean Information Office for Environment, Culture and Sustainable Development (MIO-ECSDE)
Non-Governmental Organisation	National Assotiation for Consumer Protection in Hungary
Non-Governmental Organisation	People for the Ethical Treatment of Animals
Non-Governmental Organisation	Proefdiervrij: Dutch Society for Replacement of Animal Testing
Non-Governmental Organisation	SEPANSO
Non-Governmental Organisation	Stichting Natuur en Milieu
Non-Governmental Organisation	TechnoStart GmbH
Non-Governmental Organisation	Test-Achats, association belge des consommateurs
Non-Governmental Organisation	VIVAGORA
Non-Governmental Organisation	Which?
Non-Governmental Organisation	Women in Europe for a Common Future

Trade Unions*

*listed per type and in alphabetical order

Trade Union	European Trade Union Institute - Belgium
Trade Union	National Farmers' Union - UK

Research Institutes or Higher Education Institutes*

*listed per type and in alphabetical order

Research institute or Higher education institute	AIMEN Technology Centre
Research institute or Higher education institute	Asociación de Investigación de la Industria Textil -AITEX
Research institute or Higher education institute	CEA: Commissariat à l'Energie Atomique et aux Energies Alternatives
Research institute or Higher education institute	Center for NanoScience (CeNS), LMU Munich
Research institute or Higher education institute	center for solid state physics and new materials
Research institute or Higher education institute	Center of Competence for Microsystem Engineering in Life Sciences FH Jena
Research institute or Higher education institute	Centralny Instytut Ochrony Pracy - Państwowy Instytut Badawczy (CIOP-PIB)
Research institute or Higher education institute	Centre for Business Relationships, Accountability, Sustainability and Society (BRASS)
Research institute or Higher education institute	CENTRE FOR RESEARCH IN CERAMICS AND COMPOSITE MATERIALS
Research institute or Higher education institute	Centro Tecnológico de Miranda de Ebro
Research institute or Higher education institute	Delft University of Technology
Research institute or Higher education institute	Deutsch-Franzoesisches-Forschungsinstitut Saint Louis
Research institute or Higher education institute	European Research institute of Catalysis a.i.s.b.l.
Research institute or Higher education institute	Forschungsgesellschaft für Pigmente und Lacke e.V.
Research institute or Higher education institute	Fraunhofer Institute for Mechanics of Materials
Research institute or Higher education institute	FUNDACION CIDETEC
Research institute or Higher education institute	Fundacion LEIA - CDT
Research institute or Higher education institute	Ghent University
Research institute or Higher education institute	Ghent University - Department of Textiles
Research institute or Higher education institute	Hohenstein Institute
Research institute or Higher education institute	I3N/FSCOSD-Institute for Nanostructures, Nanomodelling and Nanofabrication
Research institute or Higher education institute	Ilmenau University of Technology, Institute of Biomedical Engineering and Informatics
Research institute or Higher education institute	IMEC
Research institute or Higher education institute	INCIE ICPE-CA
Research institute or Higher education institute	INERIS
Research institute or Higher education institute	INSIS "System and Enineering Science" Institute of CNRS- france
Research institute or Higher education institute	Institute of Photonic Technology - Germany
Research institute or Higher education institute	Institut National des Sciences Appliquées de Lyon
Research institute or Higher education institute	Institute for Sustainable Development, Slovenia
Research institute or Higher education institute	Institute of electronics, Bulgarian Academy of Sciences
Research institute or Higher education institute	Institute of Materials and Technology, Dalian Maritime University

Research institute or Higher education institute	Institute of Metal Science, Bulgarian Academy of Sciences, Sofia, Bulgaria
Research institute or Higher education institute	Institute of Molecular Recognition and Technological Development - Spain
Research institute or Higher education institute	Institute of Occupational Medicine - UK
Research institute or Higher education institute	Instituto de Engenharia Biomédica
Research institute or Higher education institute	Instituto Tecnológico del Embalaje, Transporte y Logística
Research institute or Higher education institute	Istituto di Ricerche Farmacologiche "Mario Negri"
Research institute or Higher education institute	Italian National Research Council
Research institute or Higher education institute	IVAM UvA BV
Research institute or Higher education institute	Laboratory of Analytical Chemistry – University of Crete, Greece
Research institute or Higher education institute	Lehrstuhl für Verbundwerkstoffe
Research institute or Higher education institute	LEITAT Technological Center
Research institute or Higher education institute	Linnaeus University
Research institute or Higher education institute	Lunds Universitet
Research institute or Higher education institute	MEC, Cardiff University
Research institute or Higher education institute	National Aerospace Laboratory NLR - Netherlands
Research institute or Higher education institute	National Institute for Research and Development in Microtechnologies - Romania
Research institute or Higher education institute	National Institute of Materials Physics - Romania
Research institute or Higher education institute	National Research and Development Institute for Nonferrous and Rare Metals - Romania
Research institute or Higher education institute	Nederlandse Organisatie voor toegepast-natuurwetenschappelijk onderzoek TNO
Research institute or Higher education institute	Netwok of Excellence in Functional Biomaterials, National University of Ireland, Galway
Research institute or Higher education institute	Partnership for European Research in Occupational Safety and Health (PEROSH)
Research institute or Higher education institute	Politecnico di Torino
Research institute or Higher education institute	POP en Materiales Avanzados y Nanotecnologías, UAM
Research institute or Higher education institute	Profactor GmbH
Research institute or Higher education institute	re: liability (oxford) ltd
Research institute or Higher education institute	RESCOLL
Research institute or Higher education institute	SEMAT/UM
Research institute or Higher education institute	SRI - BAS
Research institute or Higher education institute	SRI-BAS
Research institute or Higher education institute	SRI-BAS, Bulgaria
Research institute or Higher education institute	St Petersburg Electrotechnical University LETI
Research institute or Higher education institute	Stichting Dienst Landbouwkundig Onderzoek, Institute Food and Biobased Research
Research institute or Higher education institute	STUVA
Research institute or Higher education institute	Tampere University of Technology
Research institute or Higher education institute	Te.Far.T.I. University Center for Pharmaceutical Technologies
Research institute or Higher education institute	TEKNIKER
Research institute or Higher education institute	The Research Development National Institute for Textile and Leather Bucharest
Research institute or Higher education institute	Triniry College Dublin
Research institute or Higher education institute	TU Kaiserslautern
Research institute or Higher education institute	Universidad de Zaragoza (Spain)
Research institute or Higher education institute	Università degli Studi di Modena e Reggio Emilia
Research institute or Higher education institute	Universitätsklinikum Wuerzburg
Research institute or Higher education institute	Universite Catholique de l'Ouest
Research institute or Higher education institute	University of Antwerp
Research institute or Higher education institute	University of Barcelona
Research institute or Higher education institute	University of Cologne, Science faculty
Research institute or Higher education institute	University of Palermo
Research institute or Higher education institute	university of perugia
Research institute or Higher education institute	University Paris Sud 11, Orsay
Research institute or Higher education institute	Veneto Nanotech S.C.p.A.
Research institute or Higher education institute	VTT Technical Research Centre of Finland
Research institute or Higher education institute	Wroclaw University of Technology, Faculty of Microsystem Electronics and Photonics

Other Organisations*

*listed per type and in alphabetical order

Research funding organisation	Agence Nationale de la Recherche
Consultancy	Alcon Advies BV
Toxicology and REACh Consultant	ALLOTOXCONSULTING
Consulting company in the field of plastics and composites	ATOUTVEILLE
Charity	Cancer Prevention & Education Society - UK
innovation management company	Dando and colucci limited
Manufacturing of Household appliances (partially involved in nanotechnologies)	Electrolux Italia SpA
Flame retardancy consultancy	Fire and Environment Protection Service - Germany
	Institut national de la consommation - France
Research oriented SME	Integrated Resources Management Company ltd
UN Organization	International Centre for Science and High Technology of UNIDO
Consultancy company with regulatory, R&D and online business media activities	Ionline
Consultancy	Laroche Conseil
An association of higher education institutions	League of European Research Universities (LERU)
	Management Effective Concepts
Nano- and Biotechnology Cluster, non-profit association	NanoBioNet
Standardization	NEN
Consultancy in field of Nanotechnology	NMTC (Nano- and Microtechnology Consulting)
Manufacturing of equipment for Oil & Gas production	Nuovo Pignone S.p.A.
National Metrology Institute of Germany	Physikalisch-Technische Bundesanstalt (PTB)
company providing software services	Process Relations GmbH
church	Protestant Church in Germany (Evangelische Kirche in Deutschland - EKD)
Think tank	Responsible Nano Forum - UK
Association of chemical societies	The European Association for the Chemical and Molecular Sciences (EuCheMS)
Patient Organisation	Vlaams Patiëntenplatform
Austrian Federal Economic Chamber	Wirtschaftskammer Österreich

Annex IV: Comments for questions 2, 9 and 11 of the questionnaire

QUESTION 2 (Opinion on nanotechnology - other)	
Respondent* *in alphabetical order	Comment
Belgian Coordination Committee for International Environmental Policy (CCIEP)	None of the mentioned answers corresponds to our opinion: BE is aware of potential benefits of nanotechnology, but at the same time wants to see its development suitably regulated in order to avoid negative impacts on health, environment and the society
Foundation Animal free Research	We are concerned that nanotechnologies can lead to an increase in animal experiments - both in fundamental research (nanomedicine) and in safety/efficacy testing of nanomaterials/nanoproducts. We are especially concerned that a dedicated, target-oriented goal to prevent such an increase in animal use has not yet been implemented. However, if promoted accordingly, nanotechnologies could contribute to improving the scientific applicability of non-animal test methods and thus prevent animal testing. [See additional input as a part of this report]
Glaenzer, Jan	NT offer great benefits, but only when risks are evaluated parallel to the products and applications
Management Effective Concepts	The influence of "small parts" as well in nanotechnology as in social development.
Proefdiervrij: Dutch Society for Replacement of Animal Testing	We believe that nanotechnology plays a very important role in developing alternatives towards animal experiments. On the other hand we are afraid for an increase of animal testing, which is currently already taking place in order to investigate the health effects of nanoparticles.
Protestant Church in Germany (Evangelische Kirche in Deutschland - EKD)	The high potential of nanotechnologies for economic growth, research and industry has to be weighed against potential risks for health and environment by taking into account the precautionary principle.

QUESTION 9 (New envisaged EU policy actions related to Nanotechnologies – Other)	
Respondent* *in alphabetical order	Comment
A.I.S.E.; International Association for Soaps, Detergents and Maintenance Products	Concerning information and labelling: websites should also be taken into account as a mean to provide information.
AIRI/Nanotec IT - Nanotec IT, a division of AIRI - Italian Association for Industrial Research	Support standards, best practices/soft law measures. In case of an inventory, need for clear view of the purpose: what to cover, how to be used, what to report (not to duplicate REACH data collection)
Alcon Advies BV	Promote industrial use/application of nanotechnology
Altroconsumo	The existing legislation needs to be adapted. More evaluations on risk assessment and exposure to nanotechnologies are needed
ANEC	Existing regulation needs to be adapted; mandatory reporting scheme
Bayer AG	Some questions are not explicit enough. Question 5 asks about concerns, however the answers are related to "issues". For example the workers' safety is a major issue for Bayer, but not a major concern
Bayer Technology Services GmbH	Balanced dialogue of benefits and risks
Belgian Coordination Committee for International Environmental Policy (CCIEP)	The first policy to implement is an exposure mitigation. Nanomaterials not included in a matrix and having not well understood risks should be avoided before a full risk assessment is available
BEUC, The European Consumers' Organisation	The existing legislation needs to be adapted
Bund für Umwelt und Naturschutz Deutschland (BUND) e.V. - Friends of the Earth Germany	BUND supports EEB's additional comments in its document responding to this consultation (available at http://www.eeb.org/index.cfm/activities/industry-health/nanotechnology/) [also available as a part of this report]
Cefic	For an inventory, there is a need for a clear view of the purpose of the inventory, what to cover, how to use and what to report in order to not repeat data collection done through REACH.
Chemical Industries Association	Reporting scheme of some nature provided certainty of definition of nanomaterial, it is pan European, reporting of data is not burdensome and protection of companies intellectual properties
CILAS	Develop new specially targeted regulation for workers in firms manufacturing or using nanoparticles

CONSMERS' ASSOCIATION OF KAVALA	See EEB's demands in its document responding to the public consultation (available at http://www.eeb.org/index.cfm/activities/industry-health/nanotechnology/). [also available as a part of this report]
dando and colucci limited	More support for collaborations with groups in other developed countries
Delft University of Technology	Reduce costs of and/or provide funding for regulatory conformity, and especially for SMEs
Deutscher Tierschutzbund - German Animal Welfare Federation	Aim at replacement of animal experimentation for risk assessment of nano materials, promote and develop alternatives to animal experimentation for risk assessment of nanomaterials. [See further input as a part of this report]
Du Pont de Nemours International S.A.	If an inventory is considered, important to clarify what audience, what purpose and what information. Would an inventory not overlap/duplicate with REACH?
Electrolux Italia SpA	Encourage nanotech-related patent applications to ensure EU competitiveness. Promote nanotech patents exploitation (licensing, start-ups, etc...)
Encapson	Inform the public in an understandable manner on the potential of nanotechnology
Enterprise Ireland FP7 Group	Specific dialogue with the public to provide up to date information on the safety aspects and effects
EU-Environmental bureau	See EEB's demands in its document responding to the public consultation (www.eeb.org/index.cfm/activities/industry-health/nanotechnology) [available as a part of this report]
European Chemical Employers Group (ECEG)	For an inventory, there is need for a clear view of the purpose of the inventory, what it should cover, how it should be used and what to report in order to not repeat data collection already done.
European Environmental Bureau	EEB also submits a fuller response to the consultation since the questions did not allow nuanced response. It will be sent to the Commission and put on our website in the nanotechnology section [available as a part of this report].
European Trade Union Institute	Develop an inventory of workers exposed to nanomaterials either in the production of the product and all along its life cycle and waste management. The minimization of risks of manufactured nanomater
Evonik Degussa GmbH	Regarding an inventory, there is need for clear guidance on what and who will be reportable to assure that data collection already done through REACH is not duplicated.
Federchimica	There is need for a clear view of the purpose of the inventory, what it should cover, how it should be used and what to report in order to not repeat data collection already done through REACH and CLP.
Fire and Environment Protection Service	Promote research on nanocomposites in fire safety
Food Safety Authority of Ireland	Educate politicians and regulators in general to the potential risks and benefits of nanotechnology. All decisions/opinions should be attributed to verifiable science, ethics etc
Forbrugerrådet	The existing legislation needs to be adapted
Foundation Animalfree Research	Implement target-oriented strategy to develop non-animal test batteries for nanomaterial safety testing. Promote research on non-animal test methods in fundamental nanomedical research. [See additional input as a part of this report]
France Nature Environment	Case by case regulation for MNT needed; moratorium on MNT for food, health care products and textiles in contact with the skin
Friends of the Earth Australia Nanotechnology Project	2000 characters is too small to express any relevant opinion [See further input as a part of this report]
Fundação para a Ciência e a Tecnologia (FCT)	Reinforce enabling research in order to potentiate the emergence of new NTs in the medium to long term.
GENERAL ELECTRIC	Establish terminology and regulatory framework(s) that work for all stakeholders.
German Chemical Industry Association	Public and discuss results and outcomes on safety research of EU COM projects
Health and Environment Alliance	Set a standard definition of nanomaterials for all EU, place a moratorium on new uses & placing on market until sufficient health and environmental safety tests are developed & applied to all uses now
Henkel AG & Co. KGaA	Focus on implementation of existing regulations, like REACH, not on setting up new regulations, treatment of nanomaterial as chemical substance
IBS Precision Engineering	Develop an industry related innovation program and demand tools to measure both technical and commercial results
INSIS "System and Engineering Science" Institute of CNRS- France	INSIS is developing a GLOBAL "moral contract" between researches and Society. No need of a focus on NANO
Institut Européen pour la Gestion Raisonnée de l'Environnement	Limit yourselves to checking that the precautionary principle is properly applied - give some financial help to research
Institute of Occupational Medicine	The key issue is to ensure that nanotechnology issues are dealt with adequately through existing regulations such as REACH
Instituto de Salud Carlos III	Establish regulations for the use of nanomedical tools for early diagnosis by the population (Negative Effects on their lifestyles if they are performed outside professional clinical supervision)

lonline	Develop world market reports on market potentials and trends of nanotech products available for EU business players
Italian National Research Council	Improve research activity on nano-manipulation and nano-dispersion
IVAM UvA BV	Establish governance plan for making uncertainties acceptable for risk management
MagnaMedics Diagnostics BV	List of best-practices guidelines in production and handling of nanomaterials
Management Effective Concepts	Development of strategy, working tools and education as a solid base for as well nanotechnology as for social development also called as societal marketing.
MBN nanomaterialia spa	For an inventory, there is need for a clear view of the purpose of the inventory in order to not repeat data collection already done through REACH. Acknowledge nano is covered by REACH and CLP
Mediterranean Information Office for Environment, Culture and Sustainable Development (MIO-ECSDE)	The precautionary principle approach should be adopted before producing and introducing nano-materials in the market for consumer use.
Merck KGaA	Wait on results / outcomes of the currently running EHS projects on national and european level
METRO Group	The term "nano" shall not be used if the product doesn't content nanoobjects, e.g. IPod Nano or Mascara with "Nano Brush"
Millennium Inorganic Chemicals Thann SAS	Potential value of a reporting scheme (mandatory /voluntary) if all following are met: Definition uncertainty resolved, Purpose clear, Pan-European, not burdensome(no duplication of REACH),IP protected.
NANO futures Romania	Develop new specific tools to enhance technology transfer in the field of nanomaterials and nanotechnologies
Nanotechnology Industries Association aisbl	Conduct & update a gap-analysis of (eco)toxicology data on nanomaterials (in collaboration with OECD WPMN and industry); set FP7/FP8 research spending to address gaps, & publically discuss the results.
National Research and Development Institute for Nonferrous and Rare Metals	Better address to mass production of nanomaterials, with emphasis of chemical processes.
Novartis International AG	Hazard evaluation of nano-materials/particles
Parliamentary Group DIE LINKE in German Federal Parliament	Regulate the dissemination of nano-scaled silver in textiles and surface materials and checks possible limitation to health and hospital products and surfaces
People for the Ethical Treatment of Animals	Safety assessment should be done using human-relevant, non-animal based methods.
Proefdiervrij: Dutch Society for Replacement of Animal Testing	Promote development of animal free testing techniques. Prevention of animal testing. Research data collected through animal testing should be shared by companies, to avoid duplication
Profactor GmbH	Do more for "manufacturing technologies"
Protestant Church in Germany (Evangelische Kirche in Deutschland - EKD)	A legally binding Code of Conduct covering nanomaterials and their products at all stages of their life cycle: research, development, production, use and disposal
Royal DSM N.V.	For an inventory, there is need for clear guidance what needs to be reported. Do not repeat data collection already done through REACH. Acknowledge nano is covered by chemical legislation REACH & CLP
Sirius International	Promote application research for nano technology as a new industry branch (employment, innovation, development)
Solvay	For an inventory, there is a need for clear view of the purpose of the inventory, what it should cover, how it should be used and what to report in order to not repeat data collection already done
SRI-BAS	Need for uniform standards for nanomaterials
Stichting Dienst Landbouwkundig Onderzoek, Institute Food and Biobased Research	Do not support all nano-activities, but focus on key issues for the EU: sustainable energy production and electronics
Te.Far.T.I. University Center for Pharmaceutical Technologies	Nanomedicine improvement, mainly to reduce side effects of drugs and to improve patients compliance
Technovár Ltd.	Should enlarge the knowledge of nanoparticles in higher education.
Test-Achats, association belge des consommateurs	The existing legislation needs to be adapted. More evaluations on risk assessment and exposure to nanotechnologies are needed.
The Procter & Gamble Company	Will need a clear definition and a clear set of criteria for nanotechnology to be able to make any kind of meaningful decisions about additional regulatory oversight.
Trinity College Dublin	Create predictive model for human, environment and population risk exposure
University of Cologne, Science faculty	Avoid any form of overregulation: only address general responsibility of manufacturers and consumers
University of Palermo	For an inventory, there is need for a clear view of the purpose of the inventory, what it should cover, how it should be used and what to report in order to not repeat data collection already done through REACH. Acknowledge nano is covered by chemical legislation REACH and CLP

VCI - Verband der chemischen Industrie e.V.	Public and discuss results and outcomes on safety research of EU COM projects.
VIVAGORA	Strengthen the citizens capacity to clarify useful and useless purposes/ Avoid electronic watching
Which?	Public database for consumers of nano products; Mandatory reporting scheme
Wirtschaftskammer Österreich	Develop and promote strategies on global level
Women in Europe for a Common Future	Require toxicity data disclosure for all nanoparticles manufactured or purchased before entering the EU market including a thorough estimation of the expected exposure - independent of their volume.
Wroclaw University of Technology, Faculty of Microsystem Electronics and Photonics	Controlling of mismatched or false using of the phrase "nano" in science, production and marketing

QUESTION 11 (Other suggestions - comments)	
Respondent* *in alphabetical order	Comment
A.I.S.E.; International Association for soaps, detergents and maintenance products	A key enabler of information, dialogue, regulation and trust is clarity on what nanotechnologies, nanomaterials, nanoparticles, etc. mean. Until the issue of terminology is resolved, consumer information and dialogue cannot happen in a coherent and meaningful way, and trust cannot be built.
A.I.S.E.; International Association for soaps, detergents and maintenance products	For an inventory, there is need for a clear view of the purpose of the inventory, what it should cover, how it should be used and what to report in order to not repeat data collection already done through REACH. Acknowledge nano is covered by existing legislation including General Product Safety Directive, REACH and CLP
ALTANA AG	We appreciate stakeholder consultations by the EU. However we felt that some of the questions leave too much room for interpretation to really express our opinion. So we want to emphasize some aspects that are important from our point of view: Nanomaterials are nothing new. For nanoplates we do not think that further research is necessary because they will not have a potential to cross biological membranes. There should be a uniform procedure for risk evaluation. From our point of view the question of adequacy of assessment methods testing nanomaterials should more consequently consider OECD's statement that the existing methods are applicable in principle. Industry supports, pays for a lot of studies on the risk of various nanomaterials. We do not have the impression that the results are acknowledged. General experience is: "if industry pays stakeholders believe, the results are influenced". So EU should pay more studies maybe with financial support by industry. So please support us in the communication also of positive results of studies. We understand that stakeholders want improved legislation as to nanomaterials. We think a reasonable modification of REACH is appropriate.
Altroconsumo	We urge for the future Action Plan to: <ul style="list-style-type: none"> • Carefully and objectively assess the risks and true benefits posed by the use of nanotechnologies and nanomaterials to human health, safety and the environment; • Urgently address the main consumers' concerns such as the lack of knowledge and transparency about products on the market containing nanomaterials and the lack of proper consumer product information; • Put in place a pro-active governance approach at EU level by developing specific nano-regulations and better implementing existing ones to provide a high level of safety for consumers; • Increase the pace of revision of existing regulations in order to meet the specific characteristics of nanotechnologies and nanomaterials • Develop new policy actions aimed at establishing a mandatory reporting scheme for the notification of the use of nanomaterials and a public inventory of nanomaterials which are used in consumer products; • Increase and support funding for research regarding health, safety and environmental aspects of nanotechnologies and nanomaterials; • Set up a long-term societal dialogue in order to increase consumer awareness and knowledge about nanotechnologies and nanomaterial
ANEC	Carefully and objectively assess the risks and true benefits posed by the use of nanotechnologies and nanomaterials to human health, safety and the environment

APC Composite AB	Though our world will have to reduce the use of materials coming from fossil oil we will have to more and more develop materials coming from renewable resources. Our knowledge level today tells us that these renewable resources not can fulfil all technical and/or physical properties that the "old" materials have got. But by using different nanomaterials we can make the materials coming from renewable resources "good enough" or even sometimes better in some applications. This is very important if we would like to have a European industry that is competitive to the Asian or American Industry, we have to develop materials coming from renewable resources that are good enough to build our future vehicles, houses, bridges, ships and so on with!!!
BAM (Federal Institute for Materials Research + Testing)	Establish a new kind of former SM&T programme for Nanotechnology measurement techniques
BASF SE	BASF welcomes the European Commission's initiative to develop a New Action Plan for Nanotechnology, addressing the technological and societal challenges and describing the European Union's nanotechnology policy of the next five years. We appreciate the opportunity to contribute to it.
Bayer AG	<p>Key to sustainable innovation in Europe are:</p> <p>1/ Applications addressing societal challenges: Fields related to energy, protection of resources and health have all the potential to benefit from nanotechnology.</p> <p>2/ Safe use over the life's cycle: Bayer welcomes the Commission's initiative to expand the safety research on nanomaterials. In this respect the question of adequacy of assessment methods testing nanomaterials should more consequently consider OECD's statement that in general the existing methods are appropriate for investigating the health effects of nanomaterials, needing some additional consideration on the phys.-chem. characterisation. Our goal is to ensure that Bayer products are handled both safely and with concern for the environment at every stage of the products' life cycles. This can be achieved by developing nanomaterials under the core principles and commitments of the chemical industry's Responsible Care® Global Charter.</p> <p>3/ Promote dialogue: We believe that societal acceptance is essential for technological innovation. Bayer supports platforms that promote dialogue about the benefits as well as the concerns of nanotechnology with civil society in a climate of openness</p>
Belgian Coordination Committee for International Environmental Policy (CCIEP)	This is an answer on behalf of BE as member state, through the CCIEP. Regarding question 3: economical benefits must be distinguished from health social and environmental benefits, and answers to such a question cannot be given without a life-cycle analysis, as well as a comparison to existing technologies, alternatives, and appropriate technologies. When talking about benefits, the beneficiaries must always be identified. Regarding question 4: The proposed answers are mixing risks for society, environment and health. Our answers are for environment and health, and are based on the fact that nanomaterials in a matrix are probably less dangerous than free particles. A very large degree of uncertainty is to be associated to our answer, due to the knowledge gaps associated with the nanomaterials risks. Regarding question 7 none of the following important opinions were listed: EFSA: "The potential risks arising from nanoscience and nanotechnologies on food and feed safety"; SCCP "Safety of nanomaterials in cosmetic products"; SCENIHR "The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies
BEUC, The European Consumers' Organisation	<p>Under the 2010-2015 Nano Action Plan, the EU should:</p> <ul style="list-style-type: none"> • Carefully and objectively assess the risks and true benefits posed by the use of nanotechnologies and nanomaterials to human health, safety and the environment; • Urgently address the main consumers' concerns such as the lack of knowledge and transparency about products on the market containing nanomaterials and the lack of proper consumer product information; • Put in place a pro-active governance approach at EU level by developing specific nano-regulations and better implementing existing ones to provide a high level of safety for consumers; • Increase the pace of revision of existing regulations in order to meet the specific characteristics of nanotechnologies and nanomaterials • Develop new policy actions aimed at establishing a mandatory reporting scheme for the notification of the use of nanomaterials and a public inventory of nanomaterials which are used in consumer products; • Increase and support funding for research regarding health, safety and environmental aspects of nanotechnologies and nanomaterials; • Set up a long-term societal dialogue in order to increase consumer awareness and knowledge about nanotechnologies and nanomaterials.

Bund für Umwelt und Naturschutz Deutschland (BUND) e.V. - Friends of the Earth Germany	BUND supports EEB's additional comments in its document responding to this consultation (available at http://www.eeb.org/index.cfm/activities/industry-health/nanotechnology/) [also available as part of this report]
Cancer Prevention & Education Society	New technologies should not be introduced without proper Public Debate and independent safety evaluation free of commercial and political interference
CEA: Commissariat à l'Energie Atomique et aux Energies Alternatives	CEA develops nanoscience and nanotechnologies towards their applications in energy, health, and communication technologies sciences. Nanoscience and nanotechnologies offer tremendous opportunities in energy sciences, saving of natural resources, health care and ICT. CEA develops nanoscience and nanotechnologies in a responsible way, dedicating a strong effort to nanosafety, life-cycle management, toxicology and ecotoxicology of nanomaterials, education, ethical aspects and public dialogue. From the CEA point of view, one should not create a specific regulation for nanotechnologies as a whole but consider the different fields of application of those enabling technologies, because it is the appropriate place where to handle the different issues of societal importance. The points CEA considers as particularly important that a global European 2010-2015 action plan for nanoscience and nanotechnology be established, encompassing their different aspects and being quite ambitious. Specific comments on the questionnaire: some questions are ambiguous in our opinion. We did not address them (answers by no opinion or don't know). [See further input as part of this report]
Cellix Limited	My overview of this situation is that we cannot hope to plan and implement legislative strategies until we understand nanomaterials in their different environments. Many excellent facilities exist and much excellent research is being done; however there appears to be a complete lack of co-ordination between researchers/centres in sharing their results on these nanomaterials in a central European database.
Center for International Environmental Law (CIEL)	CIEL is highly concerned that this consultation is inadequate to allow meaningful input. We submitted additional information as a separate doc to complement and relativise our answers. It was sent directly by Email to Mr Tokamanis, Mr. Vandendriessche, Ms. Suominen, Ms. Van-Neck, Mr. Kirmizidis (DG RTD);, Mr. VanDerZandt and Laursen (DG Env); Ms Puolamma and Mr. Berkelmans (DG Entr) Mr Martin and Garkov (DG Sanco).In summary of the information mentioned above, CIEL invites the EU Commission to: Urgently adopt a wide definition of nanomaterials; Review and amend all relevant EU legislation to ensure safety of all applications of nanomaterials as well as ensuring adequate implementation of these; Further integrate Sustainability criteria in the assessment of nanotechnology in all EU governance mechanisms; Strictly apply the REACH "no data, no market" principle to nanomaterials; Involve the public in a broad sense by developing more democratic decision-making instruments; Prioritise research funding in favour of eliminating the knowledge gaps on environmental and health impacts; Please refer to the full document attached as part of this report .
Centre for Business Relationships, Accountability, Sustainability and Society (BRASS)	A strategic lead from the Commission is necessary as it is difficult for Member States to act alone in regulating nano. The fact that existing regulations cover nano offers little indication of their actual ability to afford adequate protection. Recent initiatives to improve implementation are welcomed, however we urge the Commission to encourage further efforts to adapt current regulations. This need not entail the adoption of nano-specific legislation, but it ought to include the production of supporting guidance documents, standardised procedures and collaboration on data-sharing and testing between companies. Information disclosure is key. The extent to which nano-labelling enables consumers to make informed choices may be limited unless it is embedded in a wider programme of public engagement. Such a programme needs to build on efforts at upstream engagement already undertaken in the UK and elsewhere, but must also take note of criticisms made of these programmes. Research has indicated that trust in and acceptance of new technologies depends on factors which cannot be reduced to a perceived preponderance of benefits over risks, e.g. transparency and regulatory capacity.
Chemical Industries Association	Our members are committed to Responsible Care, which is the global chemical industry's environmental, health, safety and security (EHSS) initiative to drive continuous improvement in performance across all its activities. It achieves this objective by meeting and going beyond legislative and regulatory compliance, and by adopting cooperative and voluntary initiatives with government and other stakeholders.
CIAA	R&D teams are monitoring the scientific research and potential applications where nanotechnology may be used.
Comau	Nanotechnology is one of the new technological frontiers in terms of both product and process developments. The enabling technologies, such as new production processes of new material and product that will arise from basic research requires a great boast to implement the new achievements.
CONSUMERS' ASSOCIATION OF KAVALA	See EEB's comments in its document responding to the public consultation (available at http://www.eeb.org/index.cfm/activities/industry-health/nanotechnology/) [also available as part of this report]

Dando and colucci limited	Do not cancel the framework programmes. this is a competitive advantage that has not been effectively exploited yet
Delft University of Technology	Promote technology transfer between research institutions and industry, especially SMEs, and especially by facilitating personnel exchanges and reducing European Patent filing and maintenance costs
Du Pont de Nemours International S.A.	Consultation process appreciated. As the questions are closed questions the options of answers are not always adequate as they limit the possibility to reflect an opinion which is not always black or white such as suggested in the options. Thank you for your attention.
ELC - Federation of EU Specialty Food Ingredients Industries	This questionnaire is difficult to answer to because it is too general. There are so many diverse potential applications of nanotechnologies that it is often impossible to give a "one fits all" response to most questions. Should the consultation be targeted by application sectors instead of a hotchpotch going from nanofiltration of water to nano-medicines, the responses would likely be more robust, hence more useful.
Electrolux Italia SpA	This questionnaire was filled by a research team involved in nanotech-related projects. Hence it represents the common feeling of this team and cannot be considered as the official position of the company (Electrolux) on nanotechnology. Questions that mix the technology with ethical aspect are difficult to answer. It is believed that EU must invest many recourses to ensure its competitiveness in exploiting nanotechnologies benefits
Encapson	Europe should strive to be a leader in nanotechnology. Every stimulation in this area is therefore more than welcome
Environics Oy	Develop technologies and methods to control and detect the possible misuse of medicines (toxics) encapsulated in nanoparticles
EU-Environmental bureau	See EEB's demands in its document responding to the public consultation (www.eeb.org/index.cfm/activities/industry-health/nanotechnology) [also available as part of this report]
Euro Coop	With reference to the first question (opinion on nanotechnologies): consumer cooperatives are not against technology and the progress of science, but they require this progress to be safe when it comes to changes that affect consumers' health and the environment; they also call for other aspects to be taken into account, such as ethics.
Eurocommerce	The full document can be found at: http://www.eurocommerce.be/media/docs/Food/positionpaper/EuroCommercePositionpaperonNanotechnology26February2010.pdf
European Environmental Bureau	EEB also submits a fuller response to the consultation since the questions did not allow nuanced response. It will be sent to the Commission and put on our website in the nanotechnology section. [also available as part of this report]
European Trade Union Institute	Please see additional feedback as part of this report .
European Tyre and Rubber Manufacturers' Association	In case of creation of an inventory (nanomaterials/products or others), there is a need for a clear view of its purpose: what should be covered, how it should be used and what should be reported in order to avoid repeating data collection already done for instance through REACH. Additionally, official inventories should be based on scientific proves on the presence and type of nanomaterials in products.
Evonik Degussa GmbH	Regulation: In EVONIK' view any potential value of databases or registers on nanoproducs will significantly overlap with existing statutory mandatory information requirements within REACH-regulation and GHS / CLP as well as with well established rapid information system for consumer products (RAPEX). Thus we would like to challenge, that public databases on products making use of nanotechnology may bring any additional value assessing nanomaterials safety. EVONIK welcomes the activities of the Commission to explore possible adaptations of the existing chemical regulation REACH in order to improve the principle coverage of Nanomaterials which could be facilitated by adjustments of the technical guidance documents. The question of adequacy of the existing OECD Test Guidelines to identify possible effects of Nanomaterials has been assessed by OECD with the result that existing methods are applicable in principle, needing some adjustment on the level of physico-chemical characterization of the test material, sample preparation and dosimetry.
Fire and Environment Protection Service	One important topic is the use of nanotechnologies and nanomaterials for promoting fire safety in building, transportation, electrical engineering & electronics, furniture and textiles. The use of conventional flame retardant systems, which may be harmful to humans and the environment, can be reduced or completely substituted by nanosystems, which may also help to optimize other mechanical, physical and chemical properties of materials and products. In addition, new nanosystems would enhance the sustainability of products and help to better protect humans and the environment against catastrophic fires.
FNLI	Supporting research is probably best done via universities
Food Safety Authority of Ireland	JRC capacity should be upgraded to be Commission's own centre of excellence for nanotechnology

Forbrugerrådet	We call for: clear definitions of nanomaterials and nanotechnologies as the lack of definitions leads to legal uncertainties and hampers the development of regulatory requirements; the precautionary principle to be applied in the field of nanotechnologies; the safety of nanomaterials to be assessed by knowledgeable independent scientific committees before they can be used in consumer products with which consumers come in direct, close or regular contact or in products leading to discharges to the environment; adequate safety and risk assessment methodologies taking account of all characteristics of nanomaterials; existing European legislation relevant to nanotechnologies to be adapted in order to safeguard consumer health and safety, as well as the environment. legal safety requirements to be adapted or established (eg. limit values for certain nanomaterials in products) and standardisation to be only used to establish test methods and other technical specifications; increased transparency about the use of nanomaterials and labelling of consumer products containing nanomaterials in particular products with which consumers come in direct, close or regular contact; effective participato
Foundation Animal free Research	For legal, ethical & scientific reasons, the EU Nanotechnology Action Plan should set the goal to implement a non-animal testing strategy for nanomaterial testing and set a target date to meet this goal. If proper consensus for a total ban on animal experiments cannot be achieved yet, at least moderately & severely distressful animal experiments should be banned. As a further minimum requirement, in vivo experiments should not be conducted in research fields where the ethical implications of the products aimed for have not yet been accepted publicly. It is totally unacceptable if animal experiments are performed in research fields that are later abandoned for ethical reasons. Appropriate regulations should be implemented clarifying under which circumstances animal experimentation must not take place. An authorisation procedure should be implemented in the field of nanotechnology research, in which an independent committee weighs the indispensability of the respective animal experiment against expected benefit of project and its overall research goal - taking into account: severity of experiment, availability of alternative methods & scientific/ethical aspects of expected products. [See additional input as part of this report]
Foundation for Fundamental Research on Matter (FOM)	In EU-policy at the moment the focus is on support and effort for applied and industrial research, and ethical, health and safety issues. In our view for Europe's competitive position it should be equally important to ensure adequate support for basic research.
Friends of the Earth Australia Nanotechnology Project	Again, our additional information is 9 pages not 1200 characters, this is ridiculous! [See further input as part of this report]
Fundação para a Ciência e a Tecnologia (FCT)	Nanotechnologies cover a very wide spectrum of technologies and applications. Each of these is at a different stage of development, from fundamental research to the market in some cases. RTD policy in Nanotechnologies must insure that all of these stages are properly supported, enabling immediate but also medium and long term applications, which could be those presenting the highest potential for becoming disruptive technologies.
GENERAL ELECTRIC	Views expressed pertaining to the needs to enhance existing, or establish new, regulatory paradigms and harmonized terminology are intended to cut across all related vertical legislations. For example, the answers to the question herein are not just related to REACH.
German Chemical Industry Association	VCI welcomes the European Commission's initiative to develop a New Action Plan for Nanotechnology, addressing the technological and societal challenges and describing the European Union's nanotechnology policy of the next five years. We appreciate the opportunity to contribute to it. Given innovation friendly framework conditions nanotechnology will become the key to innovation in many industrial sectors. VCI is convinced that nanotechnology will contribute to the European Union's sustainability goals, improve citizens' quality of life and boost industrial competitiveness in Europe
Health and Environment Alliance	The primary focus of EU research should be to deal with the environment and health impacts of existing uses of nanotechnologies where immediate and long term risks to public health may have been incurred from applications in consumer products with little or no real gain in functionality or added value.
Hewlett-Packard	We would appreciate the availability of an appropriate set of definitions applicable to the 'area' of nanotechnology.
Hill-Rom company	Before inserting nanomaterials in consumer products, the first priority is to understand and well know the (positive and negative) impacts of nanomaterials on the human population and the Environment.
IBS Precision Engineering	Nanometrology as key issue to close the gap between scientific research and commercialisation

IMEC	It is important to see Joint Programming as a process, not as an instrument. It is an evolutionary process where countries and regions gradually take coordinated initiatives regarding the allocation of their budgets for research and innovation, and which allows for countries, regions, and cities variable participation. Ideally national programmes will be lined up and budgets of publicly-funded research programmes will be pooled. The initiatives within the Joint Programming should be linked to the nominated Grand Challenges, but need to be based on excellence and variable geometry, on flexibility and voluntarism. In addition, there should be room for both strategic basic research and result-driven research within the Grand Challenges. Smaller countries or regions encounter specific challenges and problems with instruments based on co-funding schemes, especially with the article 171 and 169 initiatives. Due to differences in country size and differences in budget limits, unfair competition occurs at the level of (big) organisations in different Member States in the public-private partnerships as they are today (JTIs) and in the public-public partnerships.
INSIS "System and Engineering Science" Institute of CNRS- france	Do the same for other new fields...
Institut Européen pour la Gestion Raisonnée de l'Environnement	Support research on the potential risks for health and environment
Institut Maçonique européen de la Grande loge féminine de France	Before responding to this enquiry, I didn't know that Europe had an Action Plan related on nanotechnology matters; public opinion is not aware of these strategic developments whereas it will be a major issue in life within next years : for health and economic in Europe, Europe must inform citizens and encourage nanotechnology researches and industries. The nanotechnologies issues (economic and health) should main matters in Education for next generations
Institut national de la consommation	There is a strong need for a harmonized definition of nanotechnologies at an international level. Public information should be one of the main concerns of the EU policy including adequate training to consumers and environmental organisations. There is a strong need to allow the general public access to a European inventory of nano products, including information on healthy, safety and environmental aspects.
Institute of Metal Science, Bulgarian Academy of Sciences, Sofia, Bulgaria	Better support for national and regional centres dealing with nano-fundamental scientific and technological studies;
Institute of Occupational Medicine	Whilst many of the potential risks within question 4 have been checked as modest, it is necessary to take into account and manage potential exposures to nanomaterials, both within the occupational setting and to end users of those products manufactured. A proportionate approach to evaluation and management of the potential risks associated with nanotechnologies is key to realising its benefits.
Integrated Resources Management Company lted	Define the meaning of the terminology/ parameters/indicators of what is meant by "a new sustainable social market economy and a smarter greener economy" (for example, what does new sustainable mean exactly: assessing how much we need and using only what we need, and then negotiating to extract it from where it makes 'economic and sustainable sense" to make it smarter??) And set up an viable land accounting system to make it green?
KEPKA - Consumers' Protection Center	We acknowledge that nanotechnologies have a potential to offer benefits in particular to consumers and the environment. They could be used to improve the resource and energy efficiency of appliances, the storage capacity and loading time of batteries, lead to new medical treatment opportunities or products of better performance. However, these technologies and materials may also present new risks which have never been evaluated. We are therefore concerned about the increasing number of products containing nanomaterials which are already and will be sold on the EU market without having been subject to a proper safety assessment. This paper aims at presenting the consumer point of view on nanotechnologies and nanomaterials. We call for: clear definitions of nanomaterials and nanotechnologies, precautionary principle to be applied, safety of nanomaterials to be assessed, adequate safety and risk assessment methodologies, existing European legislation relevant to nanotechnologies to be adapted, legal safety requirements to be adapted or established, increased transparency about the use of nanomaterials and labelling of consumer products containing nano, effective participatory process.

League of European Research Universities (LERU)	<p>The League of European Research Universities has consulted its members for feedback on a LERU vision on the consultation 'Towards a strategic nanotechnology action plan (SNAP) 2010-2015'. As a limited number of member universities replied, and their responses varied quite often, it is not possible for LERU to give a correct univocal response on the questions of the consultation. Therefore the answers given are a weighed representation of the responses LERU received. A document was sent to Mr. Tokamanis in which the responses from the LERU universities are explained in more detail.</p> <p>[Find this document as part of this report].</p> <p>This document does more credit to the different responses LERU received from its members and we therefore hope you will use the document to understand LERU's vision. For more information or to receive another copy of the document, please contact Laura Keustermans at the LERU Office.</p>
Linnaeus University	Disseminate nanotechnology competence to smaller universities and regions some distance away from big cities. Otherwise, there is a severe risk that the depopulation of such regions may accelerate. It is important to take advantage of nanotechnology in existing industries with a long history in a certain region and to foster collaborations with these industries and local universities. It is also important to foster innovation by small focused projects rather than by huge centres. Whereas the latter have some advantages they may not always be optimal for creativity since high degree of specialization may make the researchers more like employees in an industry than independent researchers.
MagnaMedics Diagnostics BV	Make integral research projects
Management Effective Concepts	As mentioned before, integration and connection of the nano-approach within a broader approach. I do have info about New Tools for Effective Leadership and Education Economical, Ecological and Social Modelling and Evaluation. To start an activity it's important to assess the Strategic Position of the existing (political economical, societal, ecological) organization. An internationally oriented innovative policy should be based upon a clear strategy, a contribution to solid societal relations and a well known history. A Strategic project and assessment models will be available and can be explained.
MBN nanomaterialia spa	Supports the intermediate integration of nano to goods and final application
Mediterranean Information Office for Environment, Culture and Sustainable Development (MIO-ECSDE)	<ol style="list-style-type: none"> 1. Nano-research and technical application should be driven by real societal needs and priorities and based on ecological, social and sustainable development considerations and not on the 'marketability' of products only. 2. Research and testing is needed to provide a scientific basis for policy frameworks to deal with uncertainties and risks of nanotechnologies. In particular, there is an urgent need for additional toxicological and ecotoxicological studies, tests and protocols (all still very limited) to elucidate health and environmental impacts, as it has been shown that the ones available (targeted to bulk chemicals and substances) might not be suitable for the assessment of nano-risks. 3. Public research programs need to play an important role in providing greater incentives and encouragement for nanotechnologies that support sustainable development and do not endanger humanity's well-being in the long-term. 4. The existing imbalance in funds allocated to nanotech research needs to be corrected so that impact assessment and minimization and not only application come high in the agenda. Research into the potential hazards of nanomaterials should keep pace with new development
Merck KGaA	The Association of the German chemical industry (VCI) welcomes the EU Com's initiative to expand the safety research on nanomaterials. The VCI will continue its activities prioritizing relevant topics in safety research. Furthermore the intention of the COM to contribute to the development of educational infrastructure is welcomed. The COM's intention to use technological development in nanotechnologies to strengthen the competitiveness of the EU is also welcomed. The EU COM may focus its activities in shaping the political framework conditions and dialogue activities nanotechnology applications in the field of energy supply and energy efficiency, protection of environment and resources, and health. The discussion of the suitability of existing chemical regulation on nanomaterials is well acknowledged and will be supported by the VCI; but it should be stressed that any adjustment should stick to the level of technical documents. From the viewpoint of the VCI the question of adequacy of assessment methods testing nanomaterials should more consequently consider OECD's statement - within its activities around the sponsorship program on representative nanomaterials, that the existing
Millennium Inorganic Chemicals Thann SAS	We consider the risk of nanotechnologies to be modest overall but point out that some nanomaterials such as ultrafine TiO ₂ have been manufactured and used to the benefit of society for several decades and for these there is good evidence that the risks are low or none.
NANOfutures Romania	Involve more in consultation and decision process the new entered countries

Nanotechnology Industries Association aisbl	<p>Include: (a) specific targets, measurable against milestones and deliverables, (b) increased strategic research planning in collaboration with industries, (c) stronger collaboration with international fora, in order to avoid trade issues and to maximise the outcome of research and development work, (d) creation of common definitions regarding terminology, nomenclature and categorization, (e) strengthen efforts in the development of potential hazard and exposure data, as well as the relevance of 'conventional' (eco)toxicology tests, (f) consider establishment of a centre of excellence at the EU level, in order to collect, interpret and manage all the results/information generated at the EU level. This dedicated centre would be very helpful by providing appropriate advice to each stakeholder, (g) combine risk assessment considerations with risk management practicalities, (h) continue to drive risk assessment and management mainly based on a case-by-case approach where the precautionary/proportion principle is adjusted according to expert's advices; for all of the above: seek specific collaborations with OECD WPMN, OECD WPN, ISO, and Members States.</p>
NEN	Improve balance between nanoscience and legislation development
Novartis International AG	<p>1) clear definition/classification of nanotechnology to be the basis for any benefit-risk assessment and necessary policy; 2) proactively engage stakeholders and interested parties in discussion (e.g. like STRATA group); 3) establish an ongoing, proactive technology assessment process to continuously evaluate risk-benefit of nanotechnology based on most updated scientific knowledge</p>
Parliamentary Group DIE LINKE in German Federal Parliament	<p>Stop distribution of substances and products containing uncombined and soluble nanoparticles until a final risk-assessment comes into life; Stop the distribution of food, food additives, food packages and cosmetics containing nano-scaled substances until a final risk-assessment for each substance comes into life. Reinforce the standardisation of methods of nano-assessment and of toxic screenings. Initiate a fund for long-time studies in risk assessment to co finance the research by the means of private enterprises that benefit from research support on nanotechnologies. Be aware of a possible Nano-Divide: High cost of nano-research might deepen the gap with regard to access to medicine etc. between poor and rich people as well as countries. Therefore demand societal cost-performance ratio within EU-funded research into applications. Increase support for research on life cycle of nano-products. Support risk-assessment without private partners.</p>
People for the Ethical Treatment of Animals	Old test methods are inadequate for nanomaterials. Novel, high-throughput, in vitro and in silico-based methods need development, validation, and implementation.
Physikalisch-Technische Bundesanstalt (PTB)	<p>In order to make full use of the potential of nanotechnology in Europe, developments along the following directions should be followed and supported by the EC from the point of view of a metrology institute: - Further standardization of terminology in the field of nanotechnology is necessary and should be followed internationally - The positive impact as well as the potential risk of nano-enabled products has to be determined on the basis of a scientifically sound interpretation of the results of suitable measurement methods - Each measurement result has to be used and interpreted together with its associated measurement uncertainty - In nanometrology, the science of measurement in nanotechnology, the small dimensions of nano-objects often challenges existing measurement methods and sometimes the measurement uncertainties are rather large - New methods and reference standards should therefore be developed, targeting at reduced measurement uncertainty and improved traceability of measurement results to internationally accepted standards (SI system) - Such an improved measurement infrastructure (nanometrology system) will support the further development of nanotechnology in Europe</p>
Proefdiervrij: Dutch Society for Replacement of Animal Testing	<p>Proefdiervrij appreciates the opportunity to give input on the formulation of the SNAP. Animal testing is currently taking place in order to investigate the health effects of nanoparticles. Safety evaluation of nanotechnology products differs from present-day risk assessments. As well as the amounts of substance taken in by the body (expressed in weight), other factors of importance in nanotechnology are the shape, the surface properties and the size of the nanoparticle. At this moment, neither in vivo nor in vitro assays are sufficiently developed for a full risk assessment. Therefore, alternative testing methods are called for. In Europe, the so-called '3 R policy' is applicable with regard to animal testing: Replacement, Reduction and Refinement. Why start with animal testing, only to replace those tests later with methods sparing laboratory animals? Nanotechnology offers us a great opportunity for the development of animal free testing techniques. This must be promoted.</p>
Profactor GmbH	More research programs for "manufacturing technologies" !!!

Protestant Church in Germany (Evangelische Kirche in Deutschland - EKD)	As already mentioned above a legally binding Code of Conduct would be necessary to guarantee a safe and sustainable approach to nanotechnologies based on the precautionary principle. The current EU legislation does not cover the relevant risks relating to nanomaterials nor can the protection of health and environment be enhanced alone by improving implementation of current legislation. Therefore more attention should be given to the development of risk assessment and risk management tools in relation to the use of nanomaterials and to collecting the necessary data. Moreover an EU-wide definition of "nanotechnologies" is urgently needed as a prerequisite for a comprehensive regulatory and policy framework of this area taking into account already existing legislation and international standards. Such a legislative framework should be reviewed on a regular basis to ensure that it is adjusted to the current state of scientific knowledge. A Nano-labelling system should be envisaged to ensure transparency and traceability. Communication on risks and benefits of nanotechnologies and participation of civil society in a public debate on nanotechnologies should be fostered.
re: liability (oxford) ltd	Investors and insurers need tools and information related to financial risk management. This is not the same as health and environmental risk though these are influential in financial risk assessment to a small extent. Financial risk assessment will determine the rate at which the benefits of nano tech are felt. Risks under the following headings are needed: regulatory change, quality assurance, public profile, innate risk to human health, innate risk to the environment, advantage, etc. Some of these are unpredictable because of the nature of nano technology.
Royal DSM N.V.	The European SNAP should include: (a) specific targets, measurable against milestones and deliverables, (b) increased strategic research planning in collaboration with industries, (c) stronger collaboration with international fora, in order to avoid trade issues and to maximise the outcome of research and development work; specific collaborations should be sought with the OECD WPMN (on testing strategies, protocol development, information requirement and collation, policy information, etc.), the OECD WPN (on the promotion of benefits of nanotechnologies), ISO (on the development of Technical Reports, Technical Specification, Standards).
SEPANSO	Sometimes it was difficult to answer. I have wondered "What for?"
Solvay	Solvay supports a risk management mainly based on a case-by-case approach where the precautionary/proportion principle is adjusted according to experts' advices
SRI-BAS	1. Creation of international scientific and technological research centres in nanotechnology. 2. Inclusion of these centres in international networks. 3. International educational programs for training specialists in nanotechnology, including businessmen.
Stichting Dienst Landbouwkundig Onderzoek, Institute Food and Biobased Research	The focus should be first on the inventions and then on the safety aspects. We shouldn't kill the baby before its birth. Much industrial research is conducted superficial and universities are far away from the industrial R&D centres to be of help. I have been studying nanocoatings for food packaging for many years and we are still not there. These developments are truly expensive in itself. The EU could focus a group of researchers to specific vital tasks for the future and not letting them deal with the day-to-day nitty-gritty.
Te.Far.T.I. University Center for Pharmaceutical Technologies	Improve Nanomedicine research
TechAmerica Europe (formerly AeA Europe)	The high-tech industry understands the importance of proactive engagement on social, ethical, and EHS issues as we develop sustainable and responsible policies to realize the promised benefits of nanotechnologies, and fully support collaborative efforts for open and public discussions to address the potential risks of this emerging technology. We have contributed for many years to unparalleled advances in miniaturization, performance, and functionality in the field of semiconductor and IT from microprocessors to data centres and have outstanding safety record on the use and application of nanoscience and nanotechnologies. We fully support thoughtful chemical management policies and regulations that are based on sound science. At the same time, it is important to highlight that well-meaning but poorly structured nanoscience and nanotechnologies policies and regulations can have a devastating effect on innovation, blocking advances that can help solve the world's most pressing problems, from poverty to climate change.
Tekes, Finnish Funding Agency for Technology and Innovation	World-wide international cooperation together with member state(s). Pilot project to discover new way to work. INCO era-nets are good example, but call procedure and application preparation are too heavy for funding agencies.
TEKNIKER	This questionnaire is too much focused in nanomaterials. I expect more benefits in other fields of activity than in those related with nanomaterials. For example the expectations created by carbon nanotubes (CNT) have not been fulfilled.

Test-Achats, association belge des consommateurs	<p>We call for: 1) Clear definitions (which lack leads to legal uncertainties and hampers the development of regulatory requirements);</p> <p>2) The precautionary principle to be applied;</p> <p>3) The safety of each materials to be assessed by knowledgeable;</p> <p>4) Independent scientific committees before use in consumer products or in products leading to be discharged into the environment;</p> <p>5) Adequate safety and risk assessment methodologies taking account of all characteristics;</p> <p>6) Existing European legislation relevant to nanotechnologies to be adapted in order to safeguard consumer health and safety, as well as the environment.</p> <p>7) Legal safety requirements to be adapted or established (e.g. limit values for certain nanomaterials in products) and standardisation to be only used to establish test methods and other technical specifications;</p> <p>8) Increased transparency about the use and labelling of consumer products containing nanomaterials in particular products with which consumers come in direct, close or regular contact;</p> <p>9) Effective participatory processes in order to allow citizens to fully engage into decisions impacting their everyday life.</p>
The European Association for the Chemical and Molecular Sciences (EuCheMS)	<p>Costs involved in further developing a specific nanotechnology area may be a limiting factor to application and this should be considered together with benefits and risks in any strategic action plan. Opinions on the risk involved in some areas are often based on the assumption that a higher risk may be acceptable in health care when promising alternatives are missing e.g. in cancer therapy. Transparency in such cases is very crucial if the trust of the public in the industry is to be restored. The distinction between nanostructures/objects and nanotechnologies also needs to be emphasized particularly in communications to the public to remove any confusion. Regarding awareness of the EU documents related to nanotechnologies: There are variations in awareness amongst Member States, amongst institutions within a Member State and even amongst individuals within the same institution or research team. Such variations may be expected. However it would be helpful if EU email alerts to such documents could include a short summary of the document's content. Often some issues are overlooked unintentionally due to the bulk of correspondence coupled to time constraints.</p>
Trinity College Dublin	<p>Encourage the development of European nanotechnology framework where it is compulsory to have a National strategy and a coordinated vision to promote/implement National policies and legislation towards the commercial exploitation of nanomaterials and nanocompounds.</p>
UCIMU-SISTEMI-PER PRODURRE	<p>Involve manufacturing and machining (instrumental goods) in nanotech activities: the actual target is not enough to have a significant impact in manufacturing (where EU is still a competitive entity) and too focused on sectors (aerospace, biotech ICT,..) where non-EU competitors such as China, South Korea, USA, Japan are stronger than us.</p>
UNIFAP	<p>We understand that we need to take care on HSE aspects which were probably neglected in the past. But too much is too much and we are overloaded by European and local legislation which become a severe handicap in international competition mainly for Small and Medium enterprise. Are we sure that chemical industry will survive in next 10 or 20 years? EU seems more and more far</p>
VCI - Verband der chemischen Industrie e.V.	<p>VCI welcomes the EC's initiative to develop a New Action Plan for NT. NT will contribute to the EU's sustainability goals, improve citizens' quality of life and boost industrial competitiveness in the EU. The EC should focus its activities on shaping the political framework conditions and on dialogue activities in NT applications especially in energy supply and energy efficiency, protection of environment and resources, and health. To make use of the technological potential of NT the EC should take care that the acceptance of NT can be enhanced. The question of adequacy of assessment methods for nanomaterials should consider OECD's statement, that the existing methods are applicable in principle, more consequently. Furthermore the German chemical industry would like to challenge that public databases on products making use of nanotechnology may bring additional value assessing nanomaterials safety. Any potential value of databases or registers on nanoproducs will significantly overlap with existing statutory mandatory information requirements within REACH-regulation and GHS / CLP as well as with RAPEX.</p>
VIVAGORA	<p>Support responsible practices within industries and laboratories. Foster capacities to choose the most needed uses.</p>
Women in Europe for a Common Future	<p>WECF does not see a need for additional investment in nanotechnologies, as the current level of financial public support is already very high. WECF warns that there is a risk to distract EU policymakers from investing into available and proven solution to achieve EU policies. Nanotechnology is not the solution to solve every problem. [See further input as part of this report]</p>

<p>Wroclaw University of Technology, Faculty of Microsystem Electronics and Photonics</p>	<p>In my opinion, plenty of results of the so called "basic" research in nanotechnology are consumed by non-EC countries mainly in Asia and North America, while theirs results in the field are being kept classified. China and USA are much better prepared for transfer of R&D effects of "nano" toward consumer and/or military oriented economy. For example: there are plenty of efforts done in nano- materials for electronics (HEMTS, nano-dots, composed ultra thin A2B6/A3B5 semiconductors, nano-powdered optical monocrystalline-like ceramics and other dielectrics which are to be applied out of EC. The same with nanostructurisation of solid-state devices enhancing field tunnelling emission for vacuum nanoelectronics (example of products: flat panels, terahertz electronics, tunable microwave and IR lasers, weapons of XXI century (guns with self-focusing high power free electrons beams), intelligent cool-heat covering, nonweatable surfaces). Beyond discussion is very poor transfer to European industry of effects of nano-science in a life-science area, although there are plenty of examples of the scientific activity in Europe but lack of businesses. I would advice first to precise targets</p>
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Annex V: Comments submitted outside the questionnaire

AmCham EU

American Chamber of Commerce to the European Union
Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium
Telephone 32-2-513 68 92 Fax 32-2-513 79 28

Email: info@amchameu.eu

Secretariat Point of Contact: Christelle Verstraeten - Christelle.verstraeten@amchameu.eu

Telephone 02 289 10 37

The following identifies the core elements that AmCham EU believes should be included in a Nanotechnology Action Plan.

Definition: Agreed definitions and terminology should be developed and based on an **international** consensus (driven by the OECD, ISO) which may be **adapted** to the needs of a specific nano application, where appropriate. For instance, the International Cooperation on Cosmetic Regulations (ICCR) is developing a globally harmonised regulatory definition for cosmetic use of nanotechnology. The definition and scope of further regulatory activity should focus on nanomaterials which are **intentionally manufactured** for specific characteristics not present in the conventionally manufactured materials.

Standardisation: International coordination should build on existing work. Communication: Information should be actively disseminated to the public on benefits/risks to enhance broad understanding and appreciation. The public and all stakeholders should be engaged.

Benefits: Nanotechnology holds great promise across a broad range of applications and some of these benefits are just now starting to be realised. Applications employing nanotechnology are available in medical, pharmaceutical, electronic, energy, agricultural and consumer products. More will be realised as the tools and policies necessary for responsible development become available.

Risk assessment: There is a need for an objective assessment based on **reliable science**. The suitability of existing test methods and guidelines needs to be verified and appropriate methods and guidelines should be collectively adapted or developed as required. Any risk management measures should strike the right balance between ensuring **safety** without stifling **innovation**. Note that a **case-by-case** safety assessment is the current default mechanism to bring a product to the market. Adequate data must exist for each nanomaterial to help determine its safety. Given that many new nanomaterials applications are in development, a broader assessment methodology is imperative and will be supported by an existing database of studies on diverse nanomaterials.

Regulatory framework: Further analysis and stakeholder debate is needed to assess the extent EU REACH regulation is an appropriate instrument to govern nanomaterials. The development of a **Code for Responsible Nanotechnologies** which is favored by some stakeholders may be helpful in providing a reference for regulatory acceptance.

International cooperation: Strong international collaboration is essential to ensuring: appropriate regulatory conditions are developed for safe introduction of nanomaterials; and stimulating innovation in a sector that can bring major economic, health and material benefits. Rapid developments in both the EU and US markets mean that effective **transatlantic** cooperation is essential.

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters.

Aggregate US investment in Europe totalled €1.2 trillion in 2008 and currently supports 4.8 million direct jobs in Europe.

Animalfree Research

Hegarstrasse 9
8032 Zürich
Post Office Box 1766
Phone: +41 44 422 70 70
Fax +41 44 422 80 10
info@animalfree-research.org, www.animalfree-research.org

The Foundation Animalfree Research welcomes the opportunity to contribute to the European Commission's Public Consultation TOWARDS A STRATEGIC NANOTECHNOLOGY ACTION PLAN (SNAP) 2010-2015. We are an independent foundation located in Zurich, Switzerland, dedicated to national and international political and societal opinion making on animal experiments and alternative methods. In this context, Animalfree Research also supports research projects, which promote the replacement or at least the reduction of animal experiments.

Re. Question No. 2 of the Public Consultation: "Which of the following reflects your opinion about nanotechnologies best?"

The opinion of the Foundation Animalfree Research towards nanotechnology cannot be expressed in a simplistic statement. On the one hand, we are concerned that nanotechnologies have the potential to lead to an increase in the use of research animals - both in the areas of fundamental research (such as nanomedicine) and in the area of safety testing of nanomaterials and nanoproducts (e.g. nanotoxicology). We are especially concerned that so far, a dedicated and target-oriented goal to prevent such an increase in animal use from occurring has not been set. Furthermore, we are concerned that animal experiments might be performed for the development of nanotechnological products that turn out to be unrealistic to achieve (nanotechnology 'hype') or that end up being rejected on ethical grounds (e.g. human enhancement devices) - so that the animals would have endured pain, suffering and distress for completely unrealistic and even unethical goals. At the same time, however, we acknowledge that, if promoted accordingly, nanotechnologies could make a contribution towards improving the scientific range of applications of research with non-animal test methods - and thus have the scientific potential to make a contribution towards preventing animal testing.

Re. Question No. 11 of the Public Consultation: "Other suggestions / Comments"

The Foundation Animalfree Research is concerned about nanotechnologies because they have the potential to lead to an increase in animal experimentation – be it in fundamental research (e.g. nanomedicine) or in regulatory testing (e.g. safety and efficacy testing of new nanoproducts) (Sauer, 2009). In consequence, the estimations requested under *Table No. 3* of the Public Consultation are not applicable for elucidating our opinion regarding nanotechnology. As to our estimations made in *Table No. 4*, we are *highly* concerned that *all* areas of possible application of nanotechnological developments have the potential to lead to an increase in animal experimentation.

The Foundation Animalfree Research presumes that the intentions and recommendations for future action spelled out

- in the European Commission's 2nd implementation report to the N&N action plan COM(2009)607fin.
- or in the Commission Staff Working Document SEC(2009)1468 accompanying the 2nd Implementation Report

will form the basis for the European Commission's 2010 - 2015 Strategic Nanotechnology Action Plan. Therefore we would like to take the opportunity to comment on animal welfare relevant aspects of these two recent nanotechnology related documents from the EU Commission.

The 2nd Implementation Report refers to the promotion of alternatives to animal testing as a “*particular requirement in EU policy*” (page 6, regarding: “Integrating the social dimension: addressing expectations and concerns”). Resulting activities are spelled out to be research activities at the Joint Research Centre and funding activities: “*The Commission funds research into alternative testing methods and strategies in partnership with industry and cooperates within OECD on this issue. The Commission’s JRC is also active in the development and assessment of alternative methods.*” The conclusions regarding future action drawn in the 2nd Implementation Report, however, do not address the promotion of alternative methods to animal testing.

The Commission Staff Working Document makes a number of references to promoting non-animal test methods. Regarding “short-term needs to determine human health effects”, it spells out the goal (page 91): “*To develop further, compare and validate in vitro, in vivo and in silico test methods and strategies, in order to speed up the adjustment of current test guidelines for nanomaterials and to enable a gradual shift towards alternatives to animal testing. This is required for existing as well as for new test methods and strategies.*”

Regarding “medium to long-term needs to determine human health effects”, the Staff Working Document recommends (page 91) “*to further develop, harmonise and validate alternatives to animal testing methods, including high throughput testing systems.*” These same goals are also spelled out as short-term, medium and long-term needs to determine ecotoxicological effects.

We welcome the fact that the Staff Working Document spells out the goal to develop alternatives to animal testing. However, it is not evident that this goal it is being pursued in a target-oriented manner and has indeed been fully integrated into all relevant aspects of the nanotechnology action plan. The mere *development* of alternative methods is not sufficient to ensure that non-animal test methods and testing strategies will be available and implemented for nanomaterial regulatory testing – more so, since in vivo methods obviously are to be promoted alongside in vitro and in silico methods. Instead of aiming for a “gradual shift towards alternatives to animal testing”, **for legal, ethical and scientific reasons, a new European Action Plan on Nanotechnologies should explicitly set the goal to implement a fully non-animal testing strategy for nanomaterial testing and set a target date for meeting this goal.**

Legal reasons to develop, validate and implement non-animal testing methods for nanomaterial testing

As laid down in Article 7(2) of Directive 86/609/EC on the protection of laboratory animals, animal experiments should not be conducted if alternative methods are available. Furthermore, the Commission is called to promote and fund the development, acceptance and application of further non-animal test methods. Art 23 (1) of Directive 86/609/EC, states: “*The Commission and Member States should encourage research into the development and validation of alternative techniques which could provide the same level of information as that obtained in experiments using animals but which involve fewer animals or which entail less painful procedures, and shall take such other steps as they consider appropriate to encourage research in this field.*”

Whereas Directive 86/609/EC is currently under revision, it is expected that the revised Directive will contain similar provisions requesting the development and application of alternative methods in accordance to the 3Rs principle.

Scientific reasons to develop, validate and implement non-animal testing methods for nanomaterial testing

So far, validated test methods for nanomaterial testing do not exist – neither in vivo, nor in vitro test methods. In consequence, the safety testing of nanotechnological products requires the development, validation and acceptance of new test methods and new test batteries. It would not be state-of-the-art to found such new testing strategies on animal tests. The National Academy of Sciences (2007) points to the scientific deficiencies of animal test methods: “*Using the results of animal tests to predict human health effects involves a number of assumptions and extrapolations that remain controversial.*”

Test animals are often exposed to higher doses than would be expected for typical human exposures, requiring assumptions about effects at lower doses or exposures. Test animals are typically observed for overt signs of adverse health effects which provide little information about biological changes leading to such changes leading to such health effects. Often controversial uncertainty factors must be applied to account for differences between test animals and humans. Finally, use of animals in testing is expensive and time consuming, and it sometimes raises ethical issues.”

Accordingly, the US National Research Council has spelled out a paradigm change from *in vivo* to *in vitro* testing strategies as a vision for the 21st century (CTTAEA and NRC, 2007): “*The committee envisions a new toxicity-testing system that evaluates biologically significant perturbations in key toxicity pathways by using new methods in computational biology and a comprehensive array of in vitro tests based on human biology.*”

As a consequence of this vision, international efforts are striving to accomplish this paradigm change for the safety testing of bulk chemicals. As regards the safety testing of nanomaterials, where validated test methods or testing strategies so far do not exist, scientific and political efforts should set out to develop a non-animal testing strategy from the beginning, basing these upon the latest scientific technologies. At a time, when global incentives strive for a paradigm change in toxicology, it is no longer ethically acceptable to start out by devising testing strategies, which are based on outdated and unreliable *in vivo* test methods.

Promotion of non-animal test methods in fundamental nanotechnological research

In the 2nd Implementation Report and the Commission Staff Working Document, the promotion of alternatives to animal testing, so far, is only mentioned in the context of regulatory safety testing. However, in nanotechnological research animal experiments are also being performed in the fundamental research area of nanomedicine. Also in this area, the EU Commission should provide political and financial incentives to promote the development (if applicable, validation) and acceptance of non-animal test methods and testing strategies.

The Foundation Animalfree Research would like to see nanotechnological research being conducted without causing sentient animals pain, suffering or distress altogether. If proper consensus for a total ban on animal experiments cannot be achieved at this point in time, at least moderately and severely distressful animal experiments should be banned; and the questions pursued should be addressed by using alternative methods or by altering the research strategy accordingly. As a further minimum requirement, *in vivo* experiments should not be permissible and thus should not be conducted in research fields where the ethical implications of the results (the products aimed for) are questionable and/or have not yet been discussed and agreed upon publicly. It is totally unacceptable if animal experiments are performed in research fields that are later abandoned for ethical reasons. Appropriate regulations should be implemented clarifying under which circumstances animal experimentation must not take place. To enforce these requests, an authorisation procedure should be implemented in the field of nanotechnology research, in which an independent committee weighs the necessity of the respective animal experiment against the expected benefit of the respective project and its overall research goal. This committee should have the expertise and the remit to determine the availability of alternative methods, to evaluate the expected overall severity of the respective animal experiment and **the scientific and ethical validity of the project itself as well as of the products and techniques that are expected to evolve in the long-term.**

The field of nanotechnology includes a change of paradigm in more than one respect. Technologies are being developed that also serve to improve the scientific application spectrum of non-animal biomedical research and safety testing.

The further development of such technologies should be promoted with highest priority. In consequence, animal experiments and animal tests should no longer be considered the gold standard methods for biomedical research or safety testing. In addition to the novelty of characteristics, chances, applications and risks of new nanotechnological materials and products, the innovative nature of the emerging field of nanotechnology provides the chance to change paradigms and eliminate prejudices in traditional research. Thus, the creative and flexible nature of nanotechnological research should be used to achieve a paradigm change in biomedical research and regulatory testing to turn from in vivo to in vitro and other non-animal test methods.

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ANEC/BEUC

BEUC: Laura Degallaix – safety@beuc.eu - X/009/2010 - 12/02/10

ANEC: Chiara Giovanni - ChiaraGiovannini@anec.eu - ANEC-PT-2010-Nano-001final

Summary

Consumer organisations acknowledge that nanotechnology may bring important benefits but are concerned that they may also pose new risks which have never been evaluated. In spite of a drastic lack of knowledge about the safety of nanomaterials and nanotechnologies and early warnings, consumer products containing nanomaterials and nanotechnologies continue to come on to the EU market as illustrated by the ANEC/BEUC inventory of November 2009¹.

The EU 2004-2009 Action Plan on nanosciences and nanotechnologies had unfortunately not been shaped with a view to put environment, safety and health at the center of the technology development. In view of its upcoming revision, we strongly call for the 2010-2015 EU Action Plan to take account of consumer-relevant concerns. In this paper, we make concrete proposals for actions to be included in the future Action Plan. In particular, we urge for the future Action Plan to:

- Carefully and objectively **assess the risks and true benefits** posed by the use of nanotechnologies and nanomaterials to human health, safety and the environment;
- Urgently **address** the main consumers' concerns such as the **lack of** knowledge and transparency about products on the market containing nanomaterials and the lack of proper consumer product information;
- Put in place a pro-active governance approach at EU level by **developing specific nano-regulations** and better implementing existing ones to provide a high level of safety for consumers;
- Increase the pace of **revision of existing regulations** in order to meet the specific characteristics of nanotechnologies and nanomaterials
- Develop new policy actions aimed at establishing a **mandatory reporting scheme** for the notification of the use of nanomaterials and a **public inventory of nanomaterials** which are used in consumer products;
- Increase and support funding for research regarding health, safety and **environmental aspects** of nanotechnologies and nanomaterials;
- Set up a **long-term societal dialogue** in order to increase consumer awareness and knowledge about nanotechnologies and nanomaterials.

Introduction

The EU 2005-2009 Action Plan for Nanosciences and Nanotechnologies² came to an end in December 2009 and the European Commission is planning to develop a new action plan for the time period 2010-2015. In this context, the Commission has recently launched a public consultation³ that takes the form of an online questionnaire in order to gather stakeholders' opinions and ideas for the new action plan and the consultation will end on 19th February 2010. ANEC and BEUC have contributed to the consultation by filling in the Commission's questionnaire online⁴ but felt frustrated about the nature of the consultation that did not allow us to develop our views and recommendations further to the Commission.

¹ ANEC/BEUC inventory of products claiming to contain nanoparticles, Nov 09, available on ANEC and BEUC websites at www.anec.eu and www.beuc.eu

² COM(2005) 243.

³ Towards a Strategic Nanotechnology Action Plan (SNAP) 2010-2015.

⁴ Contribution available on the ANEC and BEUC websites. The Commission may also decide to publish individual contributions on its website after the consultation's closing date (19 Feb. 2010).

This paper is therefore a complementary contribution of our online contribution aiming at better explaining the views we put forward in our answers and developing on our recommendations for an ambitious and efficient future action plan on nanomaterials and nanotechnologies. In preparation for it, ANEC and BEUC considered not only the questions raised by the Commission in the public consultation's document but more importantly the recent Commission Communication on the second implementation report⁵ of the 2005-2009 Action Plan.

1. Overall comments

We have long deplored the fact that the 2004-2009 Action Plan had not been shaped (and implemented) with a view to put environment, safety and health at the center of the technology development. Although we acknowledge that some actions have been undertaken (e.g. adoption of the recommendation for a Code of Conduct for responsible nanosciences and nanotechnologies research⁶), the previous action plan consisted mainly of developing research aimed at fostering innovation and promoting the interest of industry thereby making the EU competitive in the nanotechnology area. However, not sufficiently ambitious has been done in view to ensure the sustainable and safe development of this technology for our society.

The new action plan is THE opportunity for the Commission to get things right from a consumer point of view. In light of the concerns raised by nanotechnologies and nanomaterials, in particular regarding their safety, environmental and health aspects, much more needs to be done to reassure citizens and consumers that in the future action plan, a right and fair balance is aimed for between economic benefits on the one hand and with societal, social and environmental benefits on the other hand. In particular, efforts with respect to societal dialogue, adaptation of regulations, market transparency and monitoring, and safety assessment must be stepped up as a matter of urgency. Ambitious and forward looking actions in these areas must constitute the core of the next Action Plan and the Commission must ensure that the necessary resources and efforts are foreseen. In this paper, we make recommendations for specific actions that would help deliver tangible results and progress under these four headlines. We also make proposals for other actions to be foreseen in order to ensure the sustainability of the technology. We appeal to the Commission to include these actions in the next Action Plan and to take our concerns into account.

2. Reviewing and adapting legislation

Given the rapid development and use of nanotechnologies and nanomaterials, it is crucial and particularly urgent to adapt nano relevant regulatory measures in order to safeguard consumer health and safety, as well as the environment. As already raised in our policy position of June 2009⁷, we are convinced that regulatory measures ought to be urgently taken without further delay to protect health, safety and the environment.

Although we consider it a late decision, we welcome that in the second implementation report of the 2004-2009 nano action plan, the Commission stresses the need to review the adequacy of regulation, adapt implementation instruments and make regulatory change when necessary, and engage where possible with international developments⁸.

To this aim, the Commission announced its commitment to present an updated regulatory review in 2011⁹, where particular attention to the points raised by the European Parliament¹⁰ and the European Economic and Social Committee¹¹ will be given. Depending on needs, the Commission commits to propose regulatory changes.

We call on the Commission to:

⁵ Commission Communication COM(2009) 607.

⁶ C(2008) 424.

⁷ Joint ANEC/BEUC position "Nanotechnology: Small is beautiful but is it safe?", June 2009.

⁸ COM(2009) 607, p.10.

⁹ COM(2009) 607, p.7.

¹⁰ European Parliament's Resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials (2008/2208(INI)).

¹¹ Opinion of 25 February 2009 on the Communication on Regulatory Aspects of Nanomaterials, INT/456.

- a) **Undertake a thorough review of all EU legislation that is relevant to nanomaterials and nanotechnologies by 2011** (and not simply evaluate the need to review legislation)
The review should address consumer protection policies and product safety legislation. It should also encompass chemical legislation such as REACH, and environmental¹² and workers' protection legislation. In particular, the review should address the adequacy of specific legal safety requirements such as limit values for certain chemicals in products. It is important to foresee the adaptation of such specific requirements in legislation while fostering standardisation developments for technical specifications only such as nomenclatures and test methodologies.
Further to the review, the Commission should publish an extensive report highlighting data gaps and needs for adapting existing relevant legislation (e.g. specific legal requirements) and identifying follow up actions that ought to be undertaken to fill in those gaps. The report should include a clear timeline for the adaptation of legislation or the establishment of new ones if deemed necessary.
- b) **Close the regulatory gaps in the field of nanotechnologies and nanomaterials as soon as possible.** This should be done either through adapting existing legislation or developing new legislation.
In its 2008 Communication on nanomaterials¹³, the Commission had concluded that current regulations are suitable with regard to the use of nanotechnologies and the management of related risks. ANEC and BEUC expressed a strong disagreement with this conclusion on several occasions: concerns about regulatory deficits have been raised repeatedly and ought to be addressed as a matter of urgency in order to ensure comprehensive and consistent product life cycle analysis and risk identification and upfront management.
The Commission should close regulatory gaps that have already been clearly identified and demonstrated¹⁴ without waiting for the legislative review to be finished. With regard to specific provision that should be included in European product safety legislation, please refer to section 4.
- c) **Improve the implementation of legislation¹⁵** through e.g. increased market surveillance and control activities, empowered related authorities and improved cooperation between Members States and non-EU countries.

3. Concrete recommendations to adapt legislation related to consumer products that contain nanomaterials

In order to ensure that European legislation is adapted to nanomaterials, we call for the Commission to undertake the following actions:

- a) **Make clear reference to nanomaterials in all legislative texts governing sectors concerned by nanosciences and nanotechnology applications**
This should be done by e.g. introducing a legal definition for nanomaterials and adopting nano specific provisions in existing legislation.
- b) **Adopt legal definitions to support defined regulatory requirements**
The lack of specific definitions in legislative texts leads to legal uncertainties and hampers the development of regulatory requirements. These definitions should be consistent with those developed by independent scientific bodies, such as the EU Scientific Committees. The EU should work towards the development of legal definitions of nanomaterials and nanotechnologies for all EU legislation. Although these definitions may not necessarily be the same than those used in the fundamental research area, they should be coherent with the

¹² E.g. WEEE Directive, RoHS Directive.

¹³ Commission Communication "Regulatory aspects of nanomaterials", COM(2008) 366.

¹⁴ Such as the inadequacy of volume thresholds that are set for chemicals' registration and safety assessment in the REACH Regulation.

¹⁵ This action is identified in the consultation document "Towards a Strategic Nanotechnology Action Plan (SNAP) 2010-2015", section 8 "Improve the implementation of existing legislation".

latter. They should however remain clear and easily applicable to ensure proper enforcement of the legislation.

c) Ensure the application of the precautionary principle

It is important to ensure that the precautionary principle is applied in the field of nanotechnologies and in particular in product safety and consumer policies that are relevant to nanomaterials. There are major knowledge gaps in all phases of the risk assessment of nanomaterials hence scientific bodies call for the precautionary principle to be applied. This principle should be explicitly identified as a driving principle for all actions foreseen in the action plan and ought to be introduced as a basis for all nano-relevant legislation.

d) Require a pre-market safety assessment of nanomaterials before they are allowed to be used in products

It is crucial that nanomaterials and products that contain nanomaterials are fully risk-assessed by independent Scientific Committees before they are allowed on the market. This is particularly important for nanomaterials that are intended to be used in consumer products with which consumers come in direct, close or regular contact (e.g. food products) or in products leading to important impacts on the environment. The risk assessment should be performed taking into account all steps of the life-cycle of the products.

The "no data - no market" principle should apply. Industry should be required to provide data about the identification and specification of the substance, the quantity in which the substance is used, the toxicological profile of the substance and relevant safety data, information about the test methodologies used and finally, reasonably foreseeable exposure conditions.

e) Introduce labelling requirements

In the case of products that must indicate a list of ingredients (e.g. food), the name of the ingredient in nano form should be followed by the word 'nano' in brackets. This labelling provision would not constitute a warning as such; it would rather present factual information about the ingredients used herewith allowing consumers to make informed choices and judgements about any potential risks or benefits involved. This approach would also help traceability of products and surveillance of potential effects. We are also convinced that this will also help evaluate the level of consumer and environmental exposure to nanomaterials.

For products that do not contain a list of ingredients, the need for labelling should be evaluated on a case-by-case basis, taking into account the level of exposure and related potential risks.

f) Ensure specific safety requirements are adapted to the characteristics of nanomaterials (e.g. content limit value for certain chemicals in products)

4. Market transparency and monitoring

Today, identifying consumer products that contain nanomaterials is barely possible. Data about what is currently on the market or in the pipeline, and information about use and exposure is urgently needed. The establishment of robust mechanisms for market transparency and monitoring is urgently needed in order to:

- ensure that the public receive the information they need to make informed judgements and decisions about the use of nanomaterials and nanotechnologies in relation to consumer products;
- allow effective regulation as regulators cannot make decisions based on speculations. In particular, given the significant gaps in knowledge, market data are particularly crucial to provide information on exposure and exposure pathways that are needed for identifying risk management measures.

In this context, we welcome as a first step the Commission's announced intention to present information on types and uses of nanomaterials, including safety aspects in 2011¹⁶.

¹⁶ COM(2009) 607, p9

We urge the Commission to be proactive and ambitious and to set up mechanisms to comprehensively monitor the market and beyond, adopt measures to create adequate conditions for market transparency.

ANEC and BEUC call on the Commission to:

- a) **Establish a mandatory reporting scheme** through which industry would have to notify the use of nanomaterials, the quantity they produce and the products in which nanomaterials are contained.

Considering the UK and US experiences with voluntary reporting schemes that failed to live up to expectations, it is crucial that the EU reporting scheme is made mandatory. Such an approach has already been taken up by Canada and France who are going to institute national mandatory reporting schemes. The Commission may need to consider how best to link this scheme with existing reporting systems of chemicals such as those foreseen under REACH and the new Cosmetics Regulation.

- b) **Set up an authoritative / official inventory of all nanomaterials that are used in consumer products**

This inventory should be made publicly available in order to ensure transparency and contribute to building consumers' confidence. It should contain information as to the types, quantities, uses and safety aspects of nanomaterials and must be based on the mandatory reporting scheme mentioned above.

- c) **Require clear and truthful information on consumer products**

In particular, the Commission should propose measures with regard to the labelling of consumer products (see section 3) but also the substantiation of 'nano' claims¹⁷.

- d) **Develop traceability mechanisms and ensure information provision** all along the value chain, from producers to consumers and recyclers, following the entire life-cycle of products ('cradle to cradle')

5. Need for allowing risk assessment and risk management throughout the product life cycle

Significant gaps in knowledge must be addressed for regulators to adequately assess the risk of nanomaterials.

ANEC and BEUC call on the Commission to:

- a) **Support the development of specific test methods for nanomaterials**

Traditional risk assessment methodologies have been shown to be inadequate for taking account of all characteristics of nanomaterials. Safety and risk assessment methodologies taking account of all characteristics of nanomaterials ought to be developed and harmonised. Standardisation could be used to establish such methods and other technical specifications. Research allowing classifying nanomaterials would also be complementary.

- b) **Commission and support research regarding health, safety and environmental (HSE) aspects** of nanotechnologies and nanomaterials

The Commission should ensure that priority is given to research on HSE issues. This includes for instance research to allow identification of nanomaterials and understanding of their behaviours, but also toxicology and ecotoxicology research. Public funding to research on HSE implications ought to be increased drastically. So far, the majority of research resources in particular under the previous action plan have been allocated to innovation and commercial developments. In the early stages of development, we urge the Commission to restore the balance and significantly increase the proportion of resources devoted to HSE research. Prioritisation of areas for research funding would be an important field with which the public could be engaged.

¹⁷ This action is identified in the consultation document "Towards a strategic nanotechnology action plan (SNAP) 2010-2015", section 9 "Require adequate information on consumer products (e.g. claims verification, labelling of consumer products)".

- c) **Support the generation of data regarding exposure of workers, consumers and the environment¹⁸** on the basis of adequate measuring tools
So far, research on exposure has focused on workplace exposure¹⁹; although these efforts must be pursued, more attention to consumers and environment exposure assessments is urgently needed.
- d) **Assess the relevance and effectiveness of the EC voluntary Code of Conduct for responsible nanosciences and nanotechnologies research²⁰**
A revision of the Code of Conduct is planned for 2010 and a public consultation has already been carried out by the Commission²¹. In case the code of Conduct would be shown to be ineffective or insufficient, as ANEC and BEUC expect, we urge the Commission to take action in order to ensure that research in this area will be made in the best responsible and sustainable manner possible in the future.
- e) **Give mandate to the EU Agencies to review and adapt safety and risk assessment procedures and guidelines**
For instance a mandate could be given to EFSA regarding the guidelines that exist for food additives, supplements, packaging and novel foods. Such mandates to the EU Agencies would ensure that:
i. Nanomaterials are explicitly identified and adequately characterised in the evaluation dossiers; ii. Risk assessment approaches take account of the specific risks associated with the particular characteristics of nanomaterials.
- f) **Develop research on ethical, legal and social implications (ELSI) of nanotechnologies and nanomaterials**
- g) **Promote scientists' capacity building to communicate independent and balanced information** on the benefits and risks associated with the use of nanotechnology, in a transparent manner
- h) **Pursue and reinforce support to collaboration, networking and knowledge sharing among researchers**, in particular in the area of toxicology, ecotoxicology and risk assessment research²²

6. Ensuring responsible industrial innovation and technology development

As highlighted by the Commission, there is a need to strengthen the mechanisms available for industrial innovation, stressing the concept of open innovation and to facilitate technology transfer. ANEC and BEUC call on the Commission to:

- a) **Apply the “no data – no market” principle to drive safe and responsible product developments and technological innovation**
The Commission should establish the adequate regulatory conditions to ensure that product developments and technological innovation are inseparable from the evaluation of health, safety and environmental impacts. The “no data - no market” principle ought to be considered as a basic principle in the area of nanotechnologies and nanomaterials (see section 4).

¹⁸ The accompanying document (SEC(2009)1468) to the second implementation report itself indicates that the activity “Promote safe and cost-effective measures to minimize exposure of workers, consumers and the environment (...)” has shown “(...) relatively little progress”.

¹⁹ SEC(2009)1468, p28.

²⁰ EC Recommendation C(2008) 424.

²¹ http://ec.europa.eu/research/consultations/nano-code/consultation_en.htm

²² In document SEC(2009)1468, this action area is said to be “partially fulfilled”. We do not fully agree with this statement and consider that more efforts must urgently be undertaken.

- b) **Foster innovation that is driven by public expectations and societal demands** (e.g. in the areas of environmental protection and medical treatments)

7. Societal dialogue and access to information

We welcome the Commission's conclusion in its second implementation report on the existing action plan that a societal dialogue should be implemented. The Commission also states that public opinion and issues related to consumer, environmental and worker protection ought to be monitored. We agree with this statement and consider that specific actions ought to be foreseen in order to improve the present EU governance related to nanotechnologies, guarantee full transparency and ensure public engagement and effective dialogue with citizens.

Under the future Action Plan, we call on the Commission to undertake the following actions:

- a) **Support communication about nanomaterials and nanotechnologies, related benefits and risks as well as uncertainties** through media designed to give the public easy access to balanced and reliable sources of information
Past experience²³ has shown that citizens including consumers are willing to know about nanotechnology and should be given the power and means to make their mind about it and react in case of a damage.
- b) **Develop, encourage and support public engagement activities** with a view to steering the development of nanotechnologies in directions which are socially desirable and publicly negotiated
*Public engagement activities, such as effective participatory processes and public dialogues, allow the public to fully engage into decisions which will have an impact on their everyday life. Citizens should not only be given the opportunity to express their views and concerns but should also be reassured that their opinions are fully integrated in the development of such a technology and its applications, research programmes and regulatory advances.
Public engagement is a prerequisite to true communication and citizens' empowerment, and a condition for building public trust. This is also a way to prevent a full rejection of the technology and ensure the sustainable development and use of nanotechnologies and nanomaterials.
We strongly support all public engagement activities (including dialogues, citizens' juries and public debates) that have already been undertaken at various levels including at European level and national level²⁴. However these actions are still very limited in number and geographically (only a few Member States have taken initiatives) and should be improved and multiplied in the future.*
- c) **Pursue and reinforce dialogue with stakeholders** and ensure that dialogue leads to identifiable outcomes and follow up actions
Unlike the Commission²⁵, we consider that dialogues that are being held between institutional bodies including the Commission and stakeholders in relation to nanotechnology are neither sufficient nor effective. At European level, our organisations have been taking part in DG SANCO's dialogue on nanotechnologies and nanomaterials. Although we appreciate that this dialogue has already been run for several years, we remain sceptical as to what concrete actions or decisions, such as the introduction of regulatory developments from the side of the Commission, they have lead to. For instance, in the past years, it has mainly been the European Parliament (and stakeholders) proposing the introduction of nano-specific provisions rather than the European Commission (cf. Cosmetics Regulation, Novel Foods Regulation).

²³ E.g. Which? Consumer panel in the UK, VZBV Consumer survey in Germany, Publifocus undertaken in Switzerland.

²⁴ http://ec.europa.eu/nanotechnology/dialogues_en.html

²⁵ The accompanying document of the Action Plan 2005-2010 implementation report identifies the action area "Create the conditions for and pursue a true dialogue with the stakeholders concerning N&N (...)" as "partially fulfilled" (SEC(2009) 1468).

In addition, we are disappointed by the absence of a dialogue that would involve all the Commission's DGs concerned by nanotechnology. The future Action Plan should consider the establishment of dialogues involving a wide range of DGs and stakeholders. However, it is crucial that any dialogue ought to be set with a view to identifying key actions and policy instruments that ensure the sustainability of technology development.

In the third Nano Safety for Success Dialogue conference²⁶ that was held in Brussels in November 2009, DG SANCO announced that four focused dialogues would be organised to ensure progress on some of the key issues that emerged during the conference and called on stakeholders to highlight the issues they considered as priorities. Although ANEC and BEUC already made concrete proposals for issues to be subject to dialogues, we would like to reiterate our call for these dialogues to lead to concrete actions and recommendations²⁷.

d) **Develop measures that guarantee public access to information** including safety data and list of nano-products available on the market (see section 4)

e) **Develop research about public perception and understanding of nanotechnologies and nanomaterials**

The Eurobarometer special survey on science and technology²⁸ carried out between January and February 2005 is a good example of the types of actions that could contribute to increasing policy-makers' knowledge about citizens' opinions, needs, wills and concerns in relation to nanotechnologies and nanomaterials. We encourage the Commission to consider, among other actions, the launch of a European-wide citizens' survey on nanotechnologies, nanomaterials and related applications in the future Action Plan.

8. Enhancing coordination and exchange of information

ANEC and BEUC call on the Commission to pursue development of collaboration between European institutions, Member States, non-European countries, and with international organisations and stakeholders.

²⁶ http://ec.europa.eu/health/ph_risk/ev_20091103_en.htm

²⁷ LDE/2009277/cma – ANEC Ref.: ANEC-PT-2009-Nano-023, 03/12/2009.

²⁸ Special Eurobarometer "Social values, Science and Technology", published in June 2005 and available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs_225_report_en.pdf

CEA (Commissariat à l'Energie Atomique et aux Energies Alternatives)

This document summarizes the points that CEA considers as particularly important for the future European Nanoscience and Nanotechnology Action plan 2010-2015.

First of all, we would like to stress that nanoscience and nanotechnologies remain today emerging scientific, technological and engineering activities of vital importance for Europe competitiveness and its capability to address the energy, environment preservation, health and aging population challenges it is facing.

The first European nano-action plan 2005-2009 was a strong and significant action recognizing the importance of nanoscience and nanotechnology for Europe and stressing their enabling sciences and technologies nature. In our opinion, the principles it set forth are still fully valid, including the sizeable effort it recommended to develop a responsible approach of nanotechnologies.

Consequently, the CEA believes that a global European 2010-2015 action plan for nanoscience and nanotechnology, encompassing their different aspects, is needed, fully justified and should be quite ambitious. Complementing the principles of the first action plan, the CEA considers that the following points are of particular importance and should be appropriately taken into account in the 2010-2015 action plan.

1. Focusing on technological research at the heart of the innovation process by developing a network of technology integration centers

Overall basic sciences research is excellent in Europe as demonstrated by different studies (EU report, OECD report) but Europe is less efficient at converting research into innovation. Our analysis (cf nanoInnov on the MESR website) is that technological research, which is pivotal in the innovation process to transform basic research advances to products is not enough developed.

This prevents advancing towards products development on a quick pace. We consider that development of specific technology integration research centers are needed to fill the existing gap between basic research and industry. Examples of such centers are (of course a non exhaustive list) LETI-MINATEC(F), IMEC(B), VTT(Fi), KIT or FhG-Dresden(D), ICMAB(ES), CSEM (CH),...

Such centers are integrating basic research concepts and technologies of different natures (materials, ICT, bio and life sciences) and proved capable to bring the concepts towards Technology Readiness Level 4-7, where industry can take the relay. Those centers are definitely needed to cope with the complexity issues that unavoidably arise when dealing in the same system with nanometric and metric (user) scales.

Most importantly those centers must work as nodes of a network, to which i) local, smaller scale, nanocenters and ii) academic community are connected. Needless to say, the technology integration centers are key players in the realization of the strategic agenda of the European Technology Platforms, Joint Technology Initiatives and Knowledge Integration Communities.

2. Sustaining the development of a strong basis of simulation and characterization as enabling tools:

Nanoscience and nanotechnologies are defined by a scale at which matter is examined, mastered and used. They are enabling sciences and technologies where the borders between disciplines are ill-defined. Quite a large part of the innovation is generated at the frontiers where the disciplines converge. Further developing the, fundamental and applied, knowledge at those frontiers remains a very important need. Besides and most importantly, the enabling tools of nanocharacterization and nanosimulation need a dedicated and sustained effort. Both have shown remarkable progresses in the last years, face tremendous but attainable challenges and will prove vitally important. Moreover in both cases, Europe is well positioned and can be the world leader.

Nanocharacterization is one of the, if not the, domains where relationships between industry and research is easy and fruitful. It faces the challenge of developing in situ and in operando characterization of working systems in the various application domains (energy, environment, nanoelectronics, materials under constraints, etc). The associated leading – edge instrumentation and the related sensor development domains have in addition a large innovation potential. With the progresses of multi-scale and multi-physics simulation, from ab-initio description of matter to system level, a revolution in the way devices, systems and products are designed is on the way.

Beside the fact that mastering simulation will prove vital for products design in the future, Europe has the potential (excellence in ab-initio and basic science, High performance computing plan, leaders in design among others) opportunity to lead this revolution.

3. Placing a specific emphasis on educating a skilled workforce

A European scale, coordinated effort is needed to educate the necessary workforce. Indeed, the very nature of nanoscience and nanotechnologies, at the frontiers of different disciplines require dedicated effort to educate the workers, engineers and researchers. Moreover entrepreneurship and ethics should be included in part of the curricula. Education to nanoscience and nanotechnology should be part of the necessary early education to sciences and technologies that should be given to children. A strong effort is needed to develop educational resources available to teachers or museums and more generally to sustain support for educational programs at all levels.

4. Reinforcing the societal dialogue around nanoscience and nanotechnologies.

Nanoscience and nanotechnologies are questioning the relationship between the society and science. The societal dialogue must be pursued. Conclusions must be extracted from a thorough analysis of the various experiences that where launched so that the best solutions for a constructive and sustained dialogue are identified. This dialogue is necessary taking many different forms, has to be based on a minimum knowledge of nanoscience and nanotechnologies by the public (see above point) and in our opinion should avoid globalizing nanoscience and nanotechnologies but consider them on case by case basis (safety risks are different from enhanced(sic) human issues).

5. Coordinating the European effort on nanosafety, and human and environmental nanotoxicology

The very complex issues of nanosafety on the one hand, nanotoxicology on the other hand are definitely issues of European dimension both because of their complexity and because a European standardization and inter-comparison of measurements is absolutely mandatory. In those domains a European coordination is very much needed so that European's position is listened to for what concerns standards. This is vital to European economy! The development of toxicology and ecotoxicology and of nanosafety, taking properly into account the life-cycle management of nanobased products, must be accelerated with a dedicated effort on metrology.

Finally, we would like to stress the importance of:

- including a specific strategy on nanoscience and nanotechnologies for low carbon energy, as well as on nanomedicine, in the nano-action plan;
- strongly supporting nanoelectronics. Indeed nanoelectronics devices are the physical basis of the information and communication infrastructure we do need for a future European knowledge society as well as for an efficient energy management. The leading position of the Europe in advanced SoC (System on Chips) and embedded systems is highly depending on the level of European research on scientific and technological issues where a revolution is expected in the next 5 to 10 years: disruption in the ultimate lithography methods (EUV, multi-ebeam), disruption in the advanced substrates for the future technology nodes 22nm and below (ultrathin FdSOI), rise of 3D assembled nanosystems.

CIEL (Center for International Environmental Law)

The Center for International Environmental Law (CIEL) appreciates the possibility of giving input to the Commission's Nanotechnology Action Plan for 2010-2015. However, we are highly concerned that the form chosen for this consultation (a rigid multiple choice questionnaire based on undefined assumptions and vague concepts, with very limited space provided for additional comments) is inadequate to accurately reflect public's expressions and views and to allow meaningful input from the public.

The comments below are meant to complement and relativise the answers given to the clear-cut questionnaire and outline some crucial aspects of the debate which are missing from the online consultation and which we believe the Commission ought to consider when drawing its new action plan.

Benefits Vs risks: vague concepts for a failed analysis framework:

Questions 2, 3 and 4 of the Questionnaire are based on vague concepts that do not seem appropriate to capture the complexity of the issues nor particularly helpful in confronting the challenges brought up by the "nano-revolution".

In effect, Question 2, 3 and 4 are based on "expected benefits and risks" which are rather ill defined concepts. Is the questionnaire referring to economical or financial benefits for the industries involved in the production of nanomaterials or incorporation in nano-enabled applications? Is the questionnaire rather referring to life-style benefits to be expected by "the man in the street" from nano-enabled applications? Or, is the questionnaire referring to societal benefits increasing social justice and sustainability of our society? Or maybe to all these various potential benefits together, although surely the level of expected benefits would be different depending on which types of benefits are considered.

Conversely, when asked to evaluate "expected level of risks", is the questionnaire referring to Human health risks caused by a prolonged exposition to nanomaterials that could enter in the making of products or that would be present in finished products from the various sectors listed? Is the questionnaire referring to environmental risks that may arise from unregulated release of nanomaterials in the environment, as is currently the case? What consideration should be given to other broader societal and ethical risks such as e.g. aggravation of a north south divide or privacy violation risks etc.?

As far as human health and environmental risks are concerned, it should be stressed that the level of risks associated with the use of nanomaterials is currently unknown although nanotoxicologists are starting to agree that risks of severe impacts to health and the environment are real. There is, however, a continuing lack of knowledge about the risks generated by each particular nanomaterial and how to avoid those.

In consequence, the very framework chosen of expected risks Vs expected benefits, in particular where it appears to ignore the potential for broadly transformative and disruptive impacts, (although these clearly challenge existing governance systems), does not seem appropriate to frame the future EU strategy in relation to nanotechnology, especially in the context of undefined concepts such as expected risks and expected benefits.

Depending on which types of benefits and risks you consider, they are most likely to be borne by different stakeholders and sectors of society. Opposing risks and benefits in such a framework to define a strategic action plan can thus only lead to opposing different sectors of society, impeding consensus building and potentially creating social unrest.

In preparing a strategic nanotechnology action plan (whose ultimate goal should be to ensure that the use and developments of nanotechnology based innovations benefit the society as a whole in a sustainable way in agreement with the EU's core objectives) the Commission should therefore:

- Come up with a strategy to involve the public at national and European level in order to identify what are the core societal values that should guide the development of nanotechnology as well as any future new technology, and;
- Devise strategies (including an action plan) to ensure that these values are used to guide and inform innovation and problem solving strategies.

This includes launching a true EU-wide open public debate on nanotechnologies and on their regulatory aspect as requested by the European Parliament in April 2009.

Furthermore, while implementing this strategy, and in view of the current level of ignorance that characterises our understanding of nanotechnologies, the Commission's should:

- Prioritise eliminating knowledge gaps regarding the levels of risks and potential harm to human health and environment;
- Strictly apply the precautionary principle in all areas mentioned in the questionnaire, given that the design of reliable nano-specific risk assessment methodologies might take up more than a decade.

Main concerns in relation to the present EU governance of nanotechnology (comment on question 6)

CIEL is very much concerned by:

- The increasing number of products containing nanomaterials available on the market resulting in increasing potential for risks exposure of people and the environment associated with the lack of EU and national regulations preventing these risks from happening (failure to apply the precautionary principle).
- The failure to support meaningful public participation in decision making about nanotechnology, including in relation to the establishment of research priorities, the development of EU strategy and related governance and regulation.
- The marginalization of all non-science based dimensions of nanotechnology from the debate about its governance. Experiences from other technologies such as GMOs or nuclear power have shown that social and ethical aspects are key to public opinion and its willingness to support technological development. The same is likely to be true for nanotechnology. Issue such as corporate control, intellectual property, ethics, privacy and civil liberties, arms development and military escalation, impacts for Southern countries, market and labour force disruption are vital to a discussion about the responsible development of nanotechnology. Yet these issues are largely ignored, or effectively marginalised from EU discussion.
- The current failure to put the public interest first in management of nanotechnology, and a failure to implement the precautionary principle.
- Research priorities (comment on question 10)

Despite the growth of research funding in the field of nanotechnologies, all recent studies show that knowledge gaps (such as the lack of data on environmental toxicity) remain high, which does not allow for an accurate assessment of potential health and environmental impacts from nanomaterials to be carried out. Yet only 5% of EU research budget is currently dedicated to these aspects, while the vast majority of research funding focuses on technological development aimed at enhancing competitiveness and growth.

In its Action Plan for 2010-2015, the Commission ought to prioritize research projects aiming at closing fundamental knowledge gaps over increasing funding in technological developments. According to most experts, closing this knowledge gap cannot however reasonably be expected to be achieved before several years. In the meantime, the work on the closing of this knowledge gap should not hinder the setting up of governance mechanisms and precautionary measures, e.g. by ensuring that all new projects receiving EU funding include sustainability assessment, public participation and participatory decisions making mechanisms.

Commission's priorities for 2010-2015 (comment on questions 8 and 9)

In view of the comments above, CIEL invites the EU Commission to:

- Urgently adopt a wide definition of nanomaterials, covering all nanomaterials with specific new or enhanced nano-properties, regardless of their sizes, as well as aggregates and agglomerates as this is the critical first step in implementing any regulatory initiatives in relation to nanomaterials;
- Review and amend all relevant EU legislation to ensure safety to human health and the environment of all applications of nanomaterials as well as ensuring the strict and timely implementation of these;
- Further integrate Sustainability criteria (i.e. social, ethical and environmental aspects) in the assessment of nanotechnology in all EU governance mechanisms;
- Strictly apply the REACH "no data, no market" principle to nanomaterials i.e. making sure that no market introduction is allowed for products containing manufactured nanomaterials which have not been properly assessed through validated nano-specific sustainability and risk assessment framework;
- Involve the public in a broad sense by developing more democratic decision-making instruments in close cooperation with Member States;
- Prioritize research funding in favour of eliminating the knowledge gaps on environmental and health impacts and based on to true societal needs;

DIGITALEUROPE

The IT/semiconductor industry understands the importance of proactive engagement on social, ethical, and environmental, health, and safety (EHS) issues as we develop sustainable and responsible policies to realize the promised benefits of nanotechnologies, and fully supports collaborative efforts for open and public discussions to address the potential risks of this emerging technology.

Although significant government funding support to encourage the development of nanoscience and nanotechnologies is a recent phenomenon, in fact, nanoscience and nanotechnologies have contributed for many years to unparalleled advances in miniaturization, performance, and functionality in the field of semiconductor and information technology (IT) from microprocessors to data centers. The semiconductor/IT industry has an outstanding safety record on the use and application of nanoscience and nanotechnologies, and the UK Royal Society & Royal Academy of Engineering concluded in 2004 that the IT industry use of nanotechnologies "does not present any unique hazards". Members of the semiconductor/IT industry were among the first companies to create safe work practices and health and safety training for their employees in nanoscience and nanotechnologies. The industry also has partnered with governmental agencies and other organizations to engage in and support the development of the necessary EHS information that leads to greater human health and environmental protection, and responsible and sustainable nanotechnology development. We believe our unmatched experience in the use and application of nanoscience and nanotechnologies can contribute in a most substantial way to efforts to accurately understand and effectively manage the potential human health and environmental risks. We fully support thoughtful chemical management policies and regulations that are based on sound science. At the same time, it is important to highlight that well-meaning but poorly structured nanoscience and nanotechnologies policies and regulations can have a devastating effect on innovation, blocking advances that can help solve the world's most pressing problems, from poverty to climate change.

We have two additional suggestions/comments that we hope you will find useful in achieving the goals of the SNAP questionnaire.

- On question 5, we draw your attention to several recent studies that indicate that China, and perhaps other national and regional ventures in the developing world, have committed resources to leapfrog the EU in nanoscience and nanotechnologies, which may result in economic benefits at the expense of the EU.
- Also on question 5 and Question 6, it may be important to refine the question regarding public dialogue and stakeholder consultation. A 2010 report notes that the current outreach efforts on nanotechnology are leaving behind key stakeholders; there is a widening nanotechnology knowledge gap between the highly educated citizens and the least educated citizens. Therefore, one of the focus of SNAP may to develop innovative user friendly approaches to close the nanotechnology knowledge gap.

A last remark is that our answer regarding "Household/consumer products" concerns only the electrical and electronic "Household/consumer products" according to the scope of products our association covers.

We sincerely appreciate this opportunity to share our views and experience on nanoscience and nanotechnologies. We are committed to the sustainable and responsible development of this transforming technology. Thank you

EEB (European Environmental Bureau)

FEBRUARY 2010

The European Environmental Bureau, Europe's largest federation of environmental organisations, welcomes the consultation on the Commission's Strategic Nanotechnology Action Plan for 2010-2015. However, we are disappointed by the inappropriate use of a multiple choice questionnaire which allows too limited responses to a too simplified set of questions. The comments below give the refined details not possible in the set-up of the simplistic questionnaire, and outline some crucial aspects of the debate which we believe the Commission ought to consider when drafting the new Action Plan.

Questions 3 and 4: Concerns about the wording of the questions

EEB is disappointed with the groupings of examples of benefits and risks expected from nanotechnologies in questions 3 and 4. An example is the grouping of weight reduction and self cleaning coatings for aerospace, automotive and transport applications, when especially the need and benefits (but also the risks) for both of these are very different. Weight reduction is far more important than self-cleaning coatings, yet the questions do not allow distinguishing between them in the tick box design. This is neither welcomed nor acceptable in a consultation on new technologies that are still in development, some of which are very controversial. The Commission should learn to anticipate such controversy and adapt its consultation document structures with more sensitivity if it wishes to use such consultation tools effectively in future.

EEB is also concerned by the wording of the questionnaire which seems to consider a trade-off between risks and benefits, while leaving out wider societal costs or impacts. Technological innovation is assumed to have benefits (which remain largely unexamined) that are used to counter-balance unintended side-effects or risks. This very narrow framework ignores likely social, economic or environmental costs associated with technology development that go beyond technical risk. It also ignores the potential for broadly transformative and disruptive impacts, although these clearly challenge governance systems. We believe this is an inappropriate framework for the new Commission's Action Plan.

Question 3: Defining the needs for true societal benefits

We believe that the debate on the strategic management of nanotechnologies at this point must include a discussion on the needs for some developments, particularly regarding societal benefits. This would have also been appropriate in questions 2, 5, 6, 8, and 9.

In a number of applications mentioned in the questionnaire, the need for societal benefits is questionable (e.g. textiles, food, household and other consumer products, tracking of objects or of persons). The Commission must differentiate areas where nanotechnologies have a potential of bringing about societal benefits (which need to be defined and proven) and areas where the use of nanotechnologies merely serves short-term economic purposes. In other terms, it should ensure that the use and development of nanotechnology benefit the society as a whole and in a sustainable way.

The benefits generated by a technology cannot be defined without consulting its potential beneficiaries, i.e. the public in a broad sense. There is currently a failure to "democratise scientific and technological developments"²⁹ and allow citizens to actively shape the future and not simply be victims or consumers of developments³⁰. We therefore urge the Commission to come up with a strategy to involve the public at national and European level in order to identify what are needs to

²⁹ The necessity to "democratise scientific and technological developments" has been outlined by the Royal Commission on Environmental Pollution in "Novel Materials in the Environment: The case of nanotechnology", November 2008, Chapter 4, notably pp 57-58, paragraphs 4.10-4.12.

³⁰ An example of this failure are the three stakeholder dialogues held by DG SANCO which have so far lacked clear objectives, timetable and relationship with the events and official decision-making process.

be fulfilled by the development of nanotechnologies, and to evaluate whether or not these needs could be met by investing in less expensive and less risky technologies, or non-technological options. This should include launching an EU-wide public debate on nanotechnologies and on their regulatory aspects as requested by the European Parliament in April 2009³¹.

Question 4: Unknown levels of risks

Although we have endeavoured to answer best the question about the levels of risks expected from nanotechnologies, we stress that these levels are currently unknown. Whereas nanotoxicologists have started to agree that risks of severe impacts on health and the environment are real, there is a continuing lack of knowledge as to the levels of these risks and how to avoid them³².

In view of the current level of ignorance that characterises our understanding of nanotechnologies, the Commission's should:

- Prioritise eliminating knowledge gaps regarding the levels of risks and potential harm to human health and the environment.
- Strictly apply the precautionary principle in all areas mentioned in the questionnaire, given that the design of reliable nano-specific risk assessment methodologies might take up more than a decade³³.

Question 6: Main concerns about the present EU governance of nanotechnology

EEB is very pleased to see such a question in the consultation, particularly as the governance of nanotechnologies is still in very initial stages, and as the issue is regularly raised in discussions. We are very much concerned by:

- The lack of EU and national regulations preventing existing risks from happening, i.e. a serious lack of understanding and willingness to engage with application of the precautionary principle, as this appears to be seen as a barrier to innovation and competitiveness.
- The failure to support meaningful public participation in decision-making, including in relation to acceptable or not areas of future development, research priorities, the development of EU strategy and related governance.
- The marginalisation of all non-science based dimensions of nanotechnology from the debate about its governance. Experiences from other technologies such as GMOs or nuclear power have shown that social and ethical aspects are key to public opinion and its willingness to support technological development³⁴. The same is likely to be true for nanotechnology, as has been seen from some national dialogue processes³⁵.
- The lack of critical evaluation of industry claims for future public or environmental benefits which are used to justify extensive investment in nanotechnologies and delay regulation.

³¹ EP non legislative resolution on Regulatory aspects of nanomaterials, 2008/2208(INI).

³² Nanocap issue 2, "Nanotechnologies in the 21st century: Nanomaterials – Health and environmental concerns", 2009, p. 7. Available at <http://www.eeb.org/?LinkServID=540E4DA2-D449-3BEB-90855B4AE64E8CE6&showMeta=0>.

³³ See for instance: Andrew D. Maynard, Robert J. Aitken, Tilman Butz, Vicki Colvin, Ken Donaldson, Günter Oberdörster, Martin A. Philbert, John Ryan, Anthony Seaton, Vicki Stone, Sally S. Tinkle, Lang Tran, Nigel J. Walker and David B. Warheit, "Safe handling of nanotechnology", NATURE, Vol. 444, 16 November 2006.

³⁴ Issues such as corporate control, intellectual property, ethics, privacy and civil liberties, arms development and military escalation, impacts for Southern countries are vital to a discussion about the responsible development of nanotechnologies. Yet these issues are largely ignored or effectively marginalised from EU discussion.

³⁵ See current French controversy around national debate on nanotechnologies, http://mobile.lemonde.fr/opinions/article/2010/02/18/nanotechnologies-oser-mettre-en-debat-les-finalitespar-bernadette-bensaude_1308062_3232.html

Questions 8 and 9: Commission priorities for 2010-2015

In view of our more detailed comments³⁶, and echoing the European Parliament (in its resolution on the Regulatory aspects of nanomaterials), Commission Scientific Committees, relevant FP7 projects and other respected bodies such as the UK's Royal Commission on Environmental Pollution and the International Risk Governance Council, we call for:

- A more informed, transparent, prospective and adaptive approach to nanotechnologies to ensure effective and trustworthy governance arrangements³⁷. Further to our comments on question 3, we stress the need to introduce effective public engagement (seeking public views that are then acted upon by private and public bodies and not seeking public acceptance) into governance of current and future nanotechnologies. Such democratic decision-making instruments need to be delivered and designed in close cooperation with Member States and stakeholders, notably public interest organisations.
- Further integrating social, ethical and environmental aspects related to the assessment of nanotechnology in EU governance.
- The strict application of the REACH “no data, no market” approach to nanomaterials, i.e. making sure that no market introduction is allowed for products containing manufactured nanomaterials which could lead to exposure of consumers or uncontrolled release into the environment.
- Reviewing and amending all relevant EU legislation to ensure safety to human health and the environment of all applications of nanomaterials as well as ensuring the strict and timely implementation of these.
- Providing a clear and coherent definition of nanomaterials with a focus on size (being defined from 0.3nm to 300nm) and specific nano-properties (regardless of the size), and covering all nanomaterials (not just those that are insoluble or bioaccumulative) as well as aggregates and agglomerates.
- The implementation of mandatory reporting on products containing nanomaterials made available in a public register.
- The creation of a multi-disciplinary observatory on nanotechnologies made up of a deliberative panel and a decision-making panel, as per recommendations from the FramingNano project, and incorporating recommendations from the DEEPEN project³⁸.

³⁶ See EEB's series of papers on Nanotechnologies, <http://www.eeb.org/index.cfm/activities/industryhealth/nanotechnology/>.

³⁷ Royal Commission on Environmental Pollution, “Novel Materials in the Environment: The case of nanotechnology”, November 2008, Chapter 4, but notably pp 57-58, paragraphs 4.10-4.12. Similar messages can be found in the Woodrow Wilson PEN 18 report, “Oversight of Next Generation Nanotechnology”, April 2009.

³⁸ See the website of the respective projects for extensive coverage: DEEPEN: <http://www.geography.dur.ac.uk/projects/deepen/Home>; FRAMINGNANO: <http://www.framingnano.eu>.

Question 10: Research priorities

Despite the growth of research funding in the field of nanotechnologies, recent studies show that knowledge gaps (such as the lack of data on environmental toxicity³⁹) remain high, which does not allow an accurate assessment of potential health and environmental impacts from nanomaterials. Yet only 5% of EU research budget is currently dedicated to these aspects, while the vast majority of research funding focuses on technological development aimed at enhancing competitiveness and growth⁴⁰. In its Action Plan for 2010-2015, the Commission ought to prioritise research projects aiming at closing fundamental knowledge gaps over increasing funding in technological developments. A sliding scale starting at 80% and reducing over time to around 15% should be reserved for the environmental, human health and social, economic and ethical implications of nanotechnology⁴¹.

The Commission must also ensure that all new projects receiving EU funding are required to include sustainability assessment, public participation and decision making mechanisms.

Finally, research priorities must include identification and monitoring of areas of uncertainty as described in an EEA report on the application of the precautionary principle⁴². We believe it is essential that the Commission allows the necessary funding of research and monitoring in order to pick up "early warnings"⁴³.

For more information, please contact

Louise Duprez
European Environmental Bureau
Boulevard de Waterloo 34 1000-Bruxelles Belgium
louise.duprez@eeb.org

³⁹Gottschalk, F. Sonderer, T., Scholz, R.W. and Nowack, B., "Modeled Environmental Concentrations of Engineering Nanoparticles (TiO₂, ZnO, Ag, CNT, Fullerenes) for Different Regions", *Environmental Science & Technology*, 2009, 43: 9216-9222.

⁴⁰EEB position paper on nanotechnologies and nanomaterials, "Small scale, big promises, divisive messages", February 2009.

⁴¹Ibid.

⁴² "Awareness of uncertainty and ignorance helps the posing of appropriate research questions for scientific evaluation"; European Environment Agency; "Late lessons from early warnings: the precautionary principle 1896-2000", 2001; pp171-172.

⁴³ 15 Ibid., pp171-172.

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The potential of human exposure to nanomaterials has become a priority; workers need to be fully involved on the risk management measures that should apply to nanomaterials and for this purpose, a cooperative risk management approach in required.

**European
Trade Union Institute**

Bd du Roi Albert II, 5
1210 Brussels
Belgium

Tel: +32 (0)2 224 04 70
Fax: +32 (0)2 224 05 02
etui@etui.org
www.etui.org
aisbl 0418 812 841

It is a priority to address safety issues concerned specifically to the workplace including mandatory health surveillance. Involve workers and their representatives in the assessment and reduction of nanomaterials-related risks, and to apply a precautionary approach to the risk management throughout the life cycle of manufactured nanomaterials.

This involvement requires improving workers information about nanomaterials that may be present in products to which they are exposed. Currently there is a lack of eco-toxicological data and workers need to understand and comprehend what they are handling with and the possible hazardous properties.

It would be also necessary to develop an inventory of workers exposed to nanomaterials either in the production of the product and all along its life cycle and waste management.

Focus on the implement the *Dakar Statement on Manufactured Nanomaterials*, adopted by the Sixth Session of the Intergovernmental Forum on Chemical Safety (Forum VI), in order to minimise risks of manufactured nanomaterials.

It is necessary to modify the Chemicals Agents Directive 98/24/EC, to establish nano-specific exposure controls, to involve workers in the design and monitoring of those controls and measures, and provide them with training and health surveillance to minimize exposure.

Safety data sheets must state whether nanomaterials are present. This improves workers' information about the nanomaterials in the products. The goal of an effective communication is to assure safety at the work place.

With respect to research and development of nanotechnologies, there is a gross imbalance between investments for development of commercial applications and budgets for occupational safety and health research. All projects must contain OSH aspects. In consequence at least 15% of public nano research budgets to be earmarked for health and environmental matters.

Another aspect to remark is the standardisation of terminology for nanomaterials. It is necessary to adopt a definition of nanomaterials which is not restricted to objects below 100 nanometers in one or more dimensions.

Concerning the labeling, workers and consumers have the right to know what does the product contains. Products with manufactured nanoparticles or nano that might be delivered out of the product should be named on the label. ETUC calls on Member states authorities to set up a national register on the production, import and use of nanomaterials and nano-based products. With this measure will be easier to monitor any human on environmental contamination.

The precautionary principle has to be applied to nanotechnologies, it is a priority principle in the European regulation and is an essential prerequisite for the responsible development of nanotechnologies and for helping ensure society's acceptance of nanomaterials. And develop a better communication and information strategy with all members of society, assuring their participation.

Products should not be manufactured without their potential effects on human health and the environment being known, unless a precautionary approach has been applied and made transparent to the workers.

Hence, is imperative to apply the REACHs' principle "No data, no market" which states that nanometre forms of chemicals should not be allowed on the market unless, sufficient data are supplied to show no harmful effect for human health and the environment. No nanomaterials products should be in the market without their potential human health and environment effects being known.

Consequently a chemical safety assessment must be done for all REACH-registered substances for which a nanometre scale use has been identified.

Foster and reinforce the allocation of funding to health and safety. A full implementation of the regulatory European instruments, namely REACH and the workers protection legislation- should be done in order to achieve a responsible and sustainable development of nanotechnologies.

References/further reading:

ETUC (2008) Resolution on nanotechnologies and nanomaterials <http://www.etuc.org/a/5163>

FRIENDS OF THE EARTH – Australia

Prepared by the
Friends of the Earth Australia Nanotechnology Project
For more information or for queries:
e | rye.senjen@foe.org.au
e | georgia.miller@foe.org.au
w | <http://nano.foe.org.au>

Question 3: Level of benefits expected from nanotechnology in each of the areas mentioned.

Question 4: Level of risk expected from nanotechnology in each of the areas mentioned.

'Benefits versus risk' framing is problematic: the EU must broaden its inquiry

The framing of nanotechnology in terms of 'benefits versus risks' is too narrow and problematic on a number of levels. This framing assumes that technological development necessarily offers benefits with no potential downsides beyond narrowly defined toxicological risk. Widely claimed social, economic and environmental benefits remain largely unexamined, but are used to justify funding for 'innovation'. Worse, although claims of benefits are rarely subject to careful assessment or scrutiny, they are used to 'counter balance' or 'offset' risks. 'Risks' generally remain very narrowly defined as toxicological risks to human health or the environment. This framing thereby ignores likely social, economic or environmental costs associated with technology development that go beyond technical risk. It also ignores the potential for broadly transformative and disruptive impacts, although these clearly challenge governance systems.

The inconsistencies inherent in benefits versus risks framing have implications for nanotechnology governance, further underscoring the inappropriate nature of this framework for the European Commission to adopt in its SNAP. We are concerned that unscrutinised claims of social or economic benefit may be used in a regulatory impact statement to 'counterbalance' potential risks associated with nanomaterials' commercial use. This would be inappropriate, without also evaluating the social or economic costs that may follow nanomaterials' use, and without assessment of other, less risky options to achieve claimed public benefits.

Discordant evidentiary standards are already apparent in the EU's approach to managing nanotechnology development. Innovation policy, including generous government support for nanotechnology research, and industry development and promotion, is underpinned by widely claimed, but poorly scrutinised predictions of economic, social and broader benefits. The perceived value of these benefits underpins practical and financial government support for rapid nanotechnology commercialisation, and forestalls precautionary scientific risk management. Yet claimed benefits remain largely unexamined and outside the scope of any systematic assessment; the inevitability of these benefits is assumed. Conversely, regulation is considered legitimate only to address proven examples of toxicological risk. Contrary to the lax evidentiary standards applied to claims of benefits, risks must be definitely proven and quantified before regulation will be enacted to protect public health and safety, and even before nano-specific safety assessment of new products will be required. Broader costs, challenges and social dimensions are generally ignored by both innovation and regulatory policy.

The key issue for Friends of the Earth Australia is not whether nanotechnology used for textiles may be more 'beneficial' than it is for renewables, or if one sector is likely to be more 'risky' for the environment and human health than another, but to point out to the Commission that the focus of the questions is entirely wrong. FOEA suggest that rather than rely on this problematic 'benefits versus risks' framing, the Commission could contemplate widening the discussion to one in which the role of technology in helping address our most pressing environment and social needs is questioned critically. This would involve an evaluation of whether or not nanotechnology offers better or poorer opportunities to meet these needs than other technology or non-technology options, including related advantages and drawbacks.

The evaluation and debate would necessarily involve broad public participation. That is, we suggest that the discussion be based on the idea that real progress and innovation involves informed choice about technology futures.

Finally, we wish to recognise that many claimed applications of social or environmental benefit are either slow to materialise, or come with unexpected costs. Despite the many promises that nanotechnology proponents have been making about the ability of nanotechnological solutions to solve our pressing environmental problems and provide for a more sustainable production of goods, few solutions have been delivered to-date. For instance, many potentially beneficial solutions in the areas of water treatment and environmental remediation/ waste treatment are either in the pilot stage or are being tested in the field. Commercialisation of these applications may be 5-10 years in the future. Further, many of these products or techniques are being developed without due concern for environmental, health and safety issues. As the field of nanotoxicology is slowly catching up with technological innovation, more worrying signs are emerging that applications developed precisely for their environmental benefits (eg carbon nanotube strengthened aeroplane or car parts to reduce weight and improve fuel efficiency) may introduce their own serious new risks.

Social or economic benefits may be doubtful at best

An additional issue we wish to raise is, that benefits of a technology cannot be defined without consulting the potential beneficiaries, i.e. the public in a broad sense (rather than industry who benefit in a narrow, monetary sense). Therefore the Commission urgently needs to come up with a strategy to involve the public at national and European level in order to identify true needs and hence benefits that can be expected from nanotechnologies, and to evaluate whether or not these needs could be met by investment in less expensive, less costly and less risky technologies, or nontechnological options. This includes launching an EU-wide public debate on nanotechnologies and on their regulatory aspect as requested by the European Parliament in April 2009⁴⁴.

It is also essential to question and identify if nanotechnology's claimed benefits satisfy actual public needs – rather than simply offering new commercial opportunities. In some areas mentioned in the questionnaire, the benefits generated by nanotechnologies are questionable (textiles, food, household and other consumer products) if not seriously worrying (tracking of objects or of persons). Many applications that are touted to offer consumer benefits (eg cosmetics, textiles, antibacterial children's toys) offer negligible advantage to the user, while posing broader social costs and health and environment risks. Despite claims of consumer benefit, the application of nanotechnologies in these products is primarily motivated by commercial opportunities for the manufacturers.

FOEA suggests that it is not appropriate for nano-products that offer negligible public benefits, for example light-diffracting cosmetics, fullerene-containing anti-ageing creams or odour-eating socks, to pose new health and environment risks. Even if the risks are low, they are unacceptable because there is no public health benefit to be derived from the product's use. Furthermore, the potential for such products to pose broader social costs must be investigated.

The use of nanosilver in clothing is a useful example. Its capacity to reduce odour has resulted in the growing use of silver nanoparticles in socks, high end wool-wear, sporting clothing and work wear. Yet Benn and Westerhoff (2008)⁴⁵ have demonstrated that nanosilver treated socks can release up to 1300 µg/L silver following washing, with at least some of that released as nanoparticles of silver. Asharini et al. (2008, p7)⁴⁶ caution that given their findings of nano-silver's adverse impacts on aquatic organisms: "all applications involving silver nanoparticles should be given special attention and promoted only after detailed studies.

⁴⁴ EP non legislative resolution on Regulatory aspects of nanomaterials, INI/2008/2208

⁴⁵ Benn T and Westerhoff B. 2008. Nanoparticle Silver Released into Water from Commercially Available Sock Fabrics. *Environ. Sci. Technol.* 42:4133–4139.

⁴⁶ Asharini P, Lian Wu Y, Gong Z, Valiyaveetil S. 2008. Toxicity of silver nanoparticles in zebrafish models. *Nanotechnol* 19: 255102

The release of untreated nanoparticle waste to the environment should be restricted for the well being of human and aquatic species." Furthermore, beyond its potential acute toxicity, the growing use of antibacterial nanomaterials may have a broader social cost. The president of the Australian Society for Microbiology, Professor Hatch Stokes, and microbiologist Professor Peter Collignon of Canberra Hospital, have publicly agreed with FoEA that widespread use of antibacterial nano-silver could result in dangerous bacterial resistance that would compromise the use of nano-silver in a medical setting where it is of most use (ABC Online 2009, AM 2009).⁴⁷

Professor Peter Collignon agrees nano-silver should be used sparingly to avoid resistance developing. "If you overuse [silver biocides] you do run the risk of getting cross-resistant bacteria developing that are not only resistant to silver, but to other compounds including antibiotics," says Professor Collignon. "The more you use, and the more widespread its use, the bigger that risk." Toxicologist, Dr Paul Wright of Royal Melbourne Institute of Technology also told ABC Online (2009) that he agrees nanosilver shouldn't be used "needlessly". "We don't need nano-silver in every product," says Wright, who is researching nano-silver with CSIRO, which he says hopes to use nano-silver in biosensors. He says different products shed different amounts of nanosilver, with some brands of socks losing it all after just four washes"

It is FOEA's view that given that odour reduction offer small benefits to the individual wearing the clothing, but poses social costs to the wider public, including threatening the efficacy of life-saving use of antibacterial nanoparticles or antibiotics in a medical setting, the social costs outweigh the social benefits. Further, less-risky and socially costly options exist. Odour in clothing can be reduced regular washing, or employ of non-toxic antibacterials such as tea tree or eucalyptus. We therefore strongly back the calls for restriction of nano-silver's use in frivolous applications, as made by medical experts cited above. The use of nano-silver in clothing should not be permitted until such time as further research may demonstrate that it does not pose unacceptably high risks to human health and the environment, and will not compromise public health more broadly. We emphasise that the reasons for this are not only the toxicological risks for human health and the environment, but also the social costs of nano-silver's use in products which deliver negligible public health benefit.

Can nanotechnologies be sustainable?

Sustainability has been defined by the Brundtland Commission as "that [which] meets the needs of the present without compromising the ability of future generations to meet their own needs"⁴⁸.

This definition needs to be enacted. The key to providing good lives for everyone in the world, without further undermining ecological systems, requires that we address the underlying problems in how we have structured our societies and economies. It requires that we undertake a fundamental re-think of production, consumption and our economic system as a whole. Living within limits must include creating the systems that lead to sustainable behavior, by amongst other things addressing the public as citizens in society, not simply as consumers and making both production and consumption sustainable.

As part of a plan for a future that is based on innovation, production and consumption sustainability, we particularly need to start looking at options and strategies for evaluating new technologies to ensure that technological innovation and development will deliver greater positives than negatives for our global society.

47 ABC Online. 2009. Call for control of nano-silver use (ABC Online). 12 June 2009. Available at: <http://www.abc.net.au/science/articles/2009/06/12/2594441.htm?topic=latest> (last accessed 4 February 2010)

⁴⁸ Brundtland Commission, Our Common Future, Chapter 2: Towards Sustainable Development. . UN Documents , available from <http://www.undocuments.net/ocf-02.htm> accessed 20th of August 2009, 1987.

More concretely:

- Sustainable technology assessment embodying above policy objectives should shape the direction of innovation
- Cost-benefit analysis will investigate and take into account alternative technology/ non-technology options – based on measurement goals that include life cycle assessment, social impact assessment and/or fourth hurdle assessment (public benefit tests)
- The allocation of public research funding should be tied to sustainable technology innovations that fulfil above policy aims.
- Subject technology benefit claims to critical review in terms of social benefits
- Create not only coordinated state-based nanotechnology oversight, but also binding intergovernmental oversight.

Uncertainties about nanotechnology are a serious impediment to effective oversight

Currently the knowledge gaps around the characteristics of nanotechnologies are so large, that the application of the precautionary principle is a minimum requirement in the research, development and use of nanotechnologies. Clearly there is a need to rapidly reduce knowledge gaps regarding the levels of risks and potential harm to human health and environment posed by nanomaterials. However the extent of uncertainty is such that strict application of the precautionary principle is required in all areas mentioned in the questionnaire.

Swiss Re, one of the world's largest reinsurance agents, has also called explicitly for application of the precautionary principle in management of nanotechnology risks. In its detailed report into nanotechnology Swiss Re (2004, p 47)⁴⁹ warns: "In view of the dangers to society that could arise out of the development of nanotechnology, and given the uncertainty currently prevailing in scientific circles, the precautionary principles should be applied whatever the difficulties".

Even if we filled some of the knowledge gaps regarding nanomaterials behaviour, we have still not dealt with the fundamental problems of uncertainty that surround many applications in this field. Dupuy and Grinbaum have convincingly argued that we are entering deep uncertainty with regards to how many of these nanotechnologies will behave and that when we find out it will be too late⁵⁰. The extent of the uncertainty is such that even design of reliable risk assessment systems for nanomaterials and validated nano-specific risk assessment methodologies may take up to 15 years to develop (Maynard et al. 2006)⁵¹.

So again we would like to alert the Commission to the issue that the solution is not necessarily only in creating more knowledge, but also critically reviewing the constraints on risk assessment in a field like nanotechnology. A different stance vis-a-vis innovation and technology governance is required, something not really mentioned in the questionnaire.

⁴⁹ Swiss Re. 2004. Nanotechnology: Small Matter, Many Unknowns. Zurich: Swiss Re. Available at: http://www.swissre.com/resources/31598080455c7a3fb154bb80a45d76a0-Publ04_Nano_en.pdf (last accessed 4 February 2010).

⁵⁰ Dupuy, J.-P. and A. Grinbaum, Living with Uncertainty: Toward the Ongoing Normative Assessment of Nanotechnology. *Techné* 8:2 2004. 8(2): p. 4-26.

⁵¹ Maynard A, Aitken R, Butz T, Colvin V, Donaldson K, Oberdörster G, Philbert M, Ryan J, Seaton A, Stone V, Tinkle S, Tran L, Walker N, Warheit D. 2006. Safe Handling of Nanotechnology. *Nat* 444: 267-269.

Question 5: Main concerns about the present situation of nanotechnology

Meaningful public participation is urgently needed

There has been a prominent (rhetorical) commitment by European governments and industry internationally to 'engage' with broader societal issues at an early stage of nanotechnology's development (Joly and Kaufmann, 2008)⁵². However there appear to be little willingness on the part of decision makers to open up their assumptions, institutions, nanotechnology practice, funding or governance to critical public or NGO questioning. The EC has supported an extensive series of well-publicised public 'engagement' forums. However, these do not appear to have been designed with any intention of incorporating community views into government or industry nanotechnology research or governance strategies, or of involving the broader community in the process of imagining and constructing their technological futures. Disappointingly, the stated objective of many European countries' public engagement programs on nanotechnology is to build public acceptance of the emerging industry (CIPAST, 2008)⁵³.

The failure to support meaningful public participation in decision making about nanotechnology, including in relation to the establishment of research priorities, the development of EU strategy and related governance and regulation, is in our opinion one of the most serious failures in the present handling of nanotechnology. There is a lot of 'window dressing', but public engagement activities remain largely tokenistic. It will only move away from this tokenistic stance when public participation moves from engagement and education (a narrowly one way form of communication) to allowing the public to actually participate in decision making about research, use (or not use) of nanotechnologies.

Non-science based concerns must be given full consideration

A further and very serious concern is the attempt to marginalise all non-science based concerns and dimensions of nanotechnology from debate about its oversight and governance. We know that in relation to other technologies such as GMOs, nuclear power and others that social, ethical and other aspects are key to public opinion and willingness or not to support their development.

The same is likely to be true of nanotechnology. Issues such as corporate control, intellectual property, ethics of 'playing God', privacy and civil liberties, arms development and military escalation, impacts for Southern countries, market and labour force disruption etc are vital to a discussion about what 'responsible' development of nanotechnology could look like. Yet these issues are largely ignored, or effectively marginalised from EU discussion. Further, nowhere is there a critical assessment of public interest in relation to nanotechnology, eg an evaluation of industry claims for public or environmental benefit. There is a lot of uncritical acceptance of 'blue sky' claims for future benefits that is used to justify extensive investment in nano sand to delay regulation. Finally, there has been a failure to put the public interest first in management of nanotechnology, and a failure to implement the precautionary principle.

Successful regulation will be very challenging

Unfortunately, successful regulation of nanomaterials faces considerable challenges and it is not clear how these can be overcome – which is why FOEA continues to call for a moratorium on the commercial use of nanomaterials until the safety science, metrology and measurement work can catch up. Challenges include

- A lack of knowledge regarding nanomaterials' behaviour, biokinetics, biopersistence and risk, how to design reliable risk assessment systems, and how to reliably characterise, measure and detect nanomaterials in products, workplaces and the environment;

⁵² Joly, P.B. and A. Kaufmann (2008), 'Lost in translation? The need for 'upstream engagement' with nanotechnology on trial", *Science as Culture*, 17(3), 225-247

⁵³ Citizens Participation in Science and Technology (2008), 'Nanotechnology and Society: Where do we stand in the ladder of citizen participation?', CIPAST Newsletter Nanotechnology March 08. Available at: www.cipast.org/download/CIPAST%20Newsletter%20Nano.pdf (last accessed 27 May 2009).

- The fact that nanomaterial form, function, bioavailability and risk profile changes significantly throughout the production, handling and manufacture process, through to consumer use and environmental disposal or recycling;
- A lack of regulatory authority, political will and resources to effectively educate manufacturers, importers, handlers, workers and the public to assist them to accurately identify and understand their own use of nanomaterials, to make informed choices and management decisions, and to enforce compliance with new regulations.

EFSA has stressed that current uncertainties about nanomaterial behaviour compromise our capacity to design a risk assessment process in which we can have confidence, and that is capable of guaranteeing safety:

"Although, case-by-case evaluation of specific ENMs may be currently possible, the Scientific Committee wishes to emphasise that the risk assessment processes are still under development with respect to characterisation and analysis of ENMs in food and feed, optimisation of toxicity testing methods for ENMs and interpretation of the resulting data. Under these circumstances, any individual risk assessment is likely to be subject to a high degree of uncertainty. This situation will remain so until more data on and experience with testing of ENMs become available" (EFSA 2009, p2-39)⁵⁴.

For these reasons, FOEA wishes to emphasise, as we have previously, that it is not yet appropriate to allow nanomaterials' commercial use, and that governments should institute a moratorium on the commercial use of manufactured nanomaterials, until the safety science catches up and until it becomes possible to design risk assessment and regulatory regimes in which both technical experts and the wider public can have confidence. Nonetheless, we recognise that irrespective of early signs of the potential for serious harm, and the extent of persisting uncertainty, there is considerable economic and political pressure to increase the pace of commercialisation of manufactured nanomaterials. We therefore make this submission in the hope of helping strengthen the fledgling regulatory systems established to oversee them.

Question 6: Perception of the present governance at EU level related to nanotechnologies

The present attempts at governance are at best piecemeal.

We are concerned that regulation is ad hoc, that many commercial applications of nanomaterials remain effectively unregulated, that it will be years before the first nanoproducts are regulated and that we do not yet know enough to design risk assessment regimes in which we can have any confidence. Further, we are concerned that there has been almost no effort to integrate social and ethical assessments in governance attempts.

The new cosmetics regulation is a useful first step but the definition of nanoparticles as insoluble and biopersistent is problematic, while the size range stated is too narrow. There is significant evidence (see FOEA submission to NICNAS) that soluble nanoparticles pose serious toxicity risks. Further, so little is known about biopersistence that it is an inappropriate criterion for definitional purposes. Based on evidence that many particles up to a few hundred nanometres in size exhibit novel, nano-specific behaviours and toxicity, we recommend that the size range used to define nanoparticles be extended to this.

Question 8: How should the EU policy actions related to nanotechnologies be continued in the new Action Plan?

⁵⁴ EFSA. 2009. Scientific Opinion: The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety; EFSA-Q-2007-124a, Brussels. EFSA. Available at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm (last accessed 3 February 2010).

Question 9: Which new policy actions related to nanotechnologies should be pursued?

The Action Plan 2010-2015 must focus on an active implementation of the precautionary principle

We recommend that the SNAP:

- Strictly apply the REACH “no data, no market” approach to nanomaterials i.e. make sure that no market introduction is allowed for products containing manufactured nanomaterials which could lead to exposure of consumers or uncontrolled release in the environment.
- Review and amend all relevant EU legislation to ensure safety to human health and the environment of all applications of nanomaterials. Regulations must be mandatory and nano-specific.
- Prioritise research funding on the functioning of natural and human systems with respect to possible impacts of nanomaterials on these.
- All areas of nanotechnology should be regulated, especially those where the use of nanotechnology can potentially harm fundamental liberties (e.g. tracking of objects and of persons)
- Require the Commission to make all communication, data and other relevant information transparent and available for public scrutiny
- Supports public participation in nanotechnology decision making.
- Takes the broader impacts (social, economic, cultural) of nanotechnologies into account when assessing these technologies.

Making the precautionary principle real

Conventionally, the precautionary principle has been applied in cases of uncertainty where there is the potential for serious harm, with the potential for serious harm determined by experts (who in theory are open for critical input by non-experts and communicate transparently). In this traditional view, the decision whether or not to act and the appropriate response remains a political decision to be enacted by government.

However we propose a wider view of precaution, and one implicitly demanded by many NGOs. In this operationalisation of precaution it becomes a means to guide decision making about uncertainty and is essentially a collective and citizen driven process. This view will require a shift of perspective. Rather than viewing, for instance the governance of nanotechnologies as a principally technological or bureaucratic problem (determination of toxicity levels, public engagement to inform the public and sell the technology, enactment of legislation, monitoring compliance), it becomes an opportunity to encourage and enact new forms of technology governance, based on precaution and foresight.

Social, not technological innovation is required. The social innovation that can turn the precautionary principle into precautionary and sustainable governance of nanotechnologies needs to encompass:

- New democratic decision making processes in the form of direct involvement of citizens in upstream decision making in for instance how and to whom public funding of innovation is allocated,
- Representation of inter/inter generational justice in the assessment of future scenarios and decision making processes, and
- Invention of new non-technological ways of assessing the social benefit of proposed innovations (social impact statements requirements, fourth hurdle assessment etc).

Question 10: Which EU research actions related to nanotechnologies should be reinforced or reduced?

Despite the growth of research funding in the field of nanotechnologies, recent studies show that knowledge gaps (such as the lack of data on environmental toxicity⁵⁵) remain, which does not allow an accurate assessment of potential health and environmental impacts from nanomaterials. Yet only 5% of EU research budget is currently dedicated to these aspects.

In its Action Plan for 2010-2015, the Commission must prioritise research projects aiming at closing fundamental knowledge gaps over increasing funding in technological developments. A sliding scale starting at 80% and reducing over time to around 15% should be reserved for the environmental, human health and social, economic and ethical implications of nanotechnology. All new projects receiving EU funding should be required to include sustainability assessment, public participation and decisions making mechanisms.

⁵⁵ Gottschalk, F. Sonderer, T., Scholz, R.W. and Nowack, B. (2009). Modeled Environmental Concentrations of Engineering Nanoparticles (TiO₂, ZnO, Ag, CNT, Fullerenes) for Different Regions. *Environmental Science & Technology*. 43: 9216-9222.

German Advisory Council on the Environment

Luisenstr. 46 - 10117 Berlin

Telefon: +49-30-26 36 96-0

Internet: www.umweltrat.de E-Mail: info@umweltrat.de

Nanomaterials have a high potential for innovative technologies and diverse areas of application. From the perspective of the protection of environment and human health, particular attention has to be given to free nanoparticles, nanotubes and nanofibres. The small size of structures may change patterns of absorption and distribution in the organism and promote disperse distribution in the environment. The risks and opportunities of nanomaterials vary considerably between different materials and areas of application and have to be analysed in a differentiated way. Although considerable efforts are undertaken to assess safe use, the risks have not yet been fully understood. Given remaining uncertainty and the possibility that knowledge about hazards may emerge in the future, it is essential to have an overview of applications of nanomaterials. For this reason, the European Union's approach for dealing with nanomaterials should be based on the precautionary principle.

The German Advisory Council on the Environment sees a particular need to act in relation to nanomaterials which are being diffusely distributed and which can be assumed to be biologically active given their physico-chemical properties. Here, the precautionary principle – as understood in the Commission Communication (COM(2000) 1 final) – implies that the European Commission (in cooperation with Member States) should ensure the basis of an adequate and comprehensive knowledge about the risks of nanomaterials. Further precautionary measures are necessary to regulate the use of those nanomaterials for which the preliminary risk assessment provides an abstract concern that possible hazards for human health and the environment are unacceptable or not in line with the high level of protection of the European Union. A range of measures can be considered to ensure a responsible use of nanomaterials. The measures selected should be proportionate with the chosen level of protection and coherent with similar measures already taken. As a first measure a register of products containing nanomaterials should be introduced. Furthermore, the main instrument of the European chemicals law for the procurement of information on substances – the registration obligation of the REACH Regulation – should be further developed to ensure that nanomaterials are registered as separate substances and that required information is systematically requested.

Moreover, the relevant areas of product law should be reviewed. The European Commission should evaluate in the light of the precautionary principle whether further authorisation requirements could be an appropriate measure for the regulation of especially critical nanomaterials, specifically in product areas characterised by weak regulation. A possible requirement of prior approval could either take the form of a general authorisation by including a nanomaterial in a “positive list” of authorised substances or through an individual authorisation for a nanomaterial or a product which contains the material. Generally, all authorisation procedures should ensure that it is possible to require an authorisation on the basis of a science based abstract concern (rather than a confirmed hazard) and that the specific features of nanomaterials are appropriately considered. Furthermore, an authorisation procedure could be linked with a precautionary shift of the burden of proof.

The European Commission should also consider the instrument of mandatory labelling for selected products containing nanomaterials. This could be applied where nanomaterials are used in consumer goods and where there is a possibility that they are released during use in relevant amounts and human exposure is likely. In addition to protecting human health, the European Commission should increase its efforts to ensure the protection of the environment. Here, measures should in particular be taken to address the issue of nanomaterials in waste and waste water. *The German Advisory Council on the Environment (SRU) is an independent scientific advisory body established by the German Federal Government. It will further develop its recommendations for a precautionary approach to the use of nanomaterials in a Special Report which is due to be published in early 2011.*

German Animal Welfare Federation

Baumschulallee 15 - 53115 Bonn
Tel: 0228/60496-0
Fax: 0228/60496-40
E-Mail: bg@tierschutzbund.de
Internet: www.tierschutzbund.de

The German Animal Welfare Federation appreciates the opportunity given by the European Commission (EC) and its DG Research to comment on the needs in nanotechnology in the next five years. We hope that the EC will consider animal welfare and aim at the avoidance of animal experimentation for the risk assessment of nanomaterials as their highest priority when formulating the Strategic Nanotechnology Action Plan (SNAP) 2010-2015. Manufactured nanomaterials (MN) are becoming more and more important and there are an increasing number of products available on the market and consumers may be directly exposed to them in their everyday life.

We agree with the former European Commissioner for Science & Research, Janez Potočnik, that Nanotechnology is an area which has highly promising prospects for turning fundamental research into successful innovations. Nevertheless, the protection of consumers, animals and of our environment should always be paramount.

Due to their special properties the health risks posed by nanomaterials are likely to depend on many more factors than those normally considered in safety assessments for the bulk scale materials. This has to be taken into account when assessing possible adverse effects of nanomaterials. Furthermore, nanoparticles of the same substance but produced by different manufacturers show substantially different properties. The storage and manufacturing conditions can heavily influence the behaviour of the particles as well as factors like the level of chemical impurities, likelihood of agglomeration, stability, biodegradability and solubility of the particles and can therefore impact on health risks. Risk assessment of nanomaterials thus not only should be planned as a case-by-case approach for each substance, but also with respect to differing manufacturing conditions.

All of these difficulties have to be overcome when designing a new strategy for research on the safety of nanomaterials. The current methods employed to observe the toxicity of nanoparticles mostly focus on the use of animals. Results do point to serious adverse effects on the health of the species tested in some of these studies (for representative examples please see^{56,57,58}) but animal tests have limited value to predict effects on humans because of their inherent uncertainties. Differences in anatomy, physiology, biochemistry, metabolism and pharmacology make the extrapolation of test data between species, genders and breeds of animals (including humans) very difficult. In addition, there are numerous basic nanomaterial-specific scientific problems related to in vivo experimentation. Practical problems that affect each experiment performed in animals include challenges related to tracking nanoparticles in vivo and delivering a relevant dose to animals. Due to these problems current OECD in vivo test guidelines are inappropriate for risk assessment of nanomaterials and the same is true for the current in vivo test guidelines for the EU chemicals Regulation, REACH.

For these reasons it would be a grave mistake to rely on adapting common in vivo methods for risk assessment to be used on nanomaterials as many existing animal tests have not been validated for assessing the adverse effects of the corresponding bulk scale materials and these same tests do not represent viable methods for the nano-sized equivalent.

⁵⁶ Poland C A et al (2008) Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study. *Nat Nanotechnol* 3(7): 423-8

⁵⁷ Shimizu M et al (2009) Maternal exposure to nanoparticulate titanium dioxide during the prenatal period alters gene expression related to brain development in the mouse. *Part Fibre Toxicol* 6:20

⁵⁸ Ji JH et al (2007) Twenty-eight-day inhalation toxicity study of silver nanoparticles in Sprague-Dawley rats. *Inhal Toxicol* (10): 857-71

Argumentation principally used states that the extensive experience already gained in the testing of chemicals with in vivo assays indicates that they can be used for the detection of some potential hazards of nanomaterials. The German Animal Welfare Federation would like to clarify that experience in conducting a method does not prevent it from being of low quality or producing misleading results. Hence, in vivo studies should not be used as the gold standard based on which new in vitro and other animal-free methods are developed. This would not only hinder the process of validation of alternative methods but also misconceive from the wrong standard. To gain human-relevant results and avoid arising difficulties with in vivo testing, non-animal tests offer several advantages: they represent the most recent advances in biotechnology compared to outdated in vivo methods. They avoid species differences by using human cells or sub-cellular components, and high-throughput systems allow the rapid and cost-effective testing of multiple nanomaterials at the same time. By this approach, it is also possible to assess differences in mode of action and toxicity of nanomaterials of the same substance but produced by different manufacturers. In vitro methods are already developed in related modern fields such as particulate matter toxicology, and they appear to be applicable to nanotechnology with some adjustment. Experts in the area of alternative methods should be actively involved in the task to develop non-animal testing strategies for nanomaterial safety testing, e. g. scientists from ECVAM and national authorities dedicated to the replacement of animal experiments such as ZEBET in Germany.

There already are a fair number of current in vitro OECD test guidelines that will be applicable for nanoparticles, namely in vitro test guidelines to assay skin corrosion, mammalian chromosome aberration test and mammalian cell gene mutation tests. The OECD phototoxicity test is relevant for testing with relation to sunscreens and cosmetics. The use of human skin samples as a component of the skin absorption testing strategy is already being applied to nanomaterials and represents the most scientifically robust method for observing nanoparticle penetration. With some adjustments this method could also be employed to look at abnormal skin types as well. Additionally, there is a vast range of available in vitro techniques that can be developed further for use with nanomaterials (e.g.: human cell culture techniques; in vitro skin penetration techniques; lab-on-chip technology; computer modeling and simulation techniques).

The German Animal Welfare Federation and its 800.000 members expect the European Commission to focus their research and innovation efforts on the promotion, development and validation of non-animal test methods and the development of non-animal testing strategies for the safety testing of nanomaterials. In consistency with related European legislation like REACH, the Replacement and Reduction of animal experimentation should be the main objective. As long as there is not enough information available about possible risks for human health and the environment the use of nanotechnology and of manufactured nanomaterials in consumer products should be restricted and in the long-term regulatory measures are needed. It is crucial that testing on vertebrate animals for the purpose of a future legislation for nanomaterials should be avoided at all costs.

League of European Research Universities (LERU)

E-mail address: laura.keustermans@leru.org

The League of European Research Universities has consulted its members for feedback on a LERU vision on the consultation 'Towards a strategic nanotechnology action plan (SNAP) 2010-2015'. As a limited number of member universities replied, and their responses varied quite often, it is not possible for LERU to give a correct univocal response on the questions of the consultation. Therefore the answers given are a weighed representation of the responses LERU received. Nevertheless we want to share with you the responses we received and hope you are able to use them despite their different format.

6. Which of the following reflects your opinion about nanotechnologies best?

The LERU member universities have high expectations from nanotechnologies or are at least reasonably optimistic.

7. Please indicate for each area what level of benefits you expect from nanotechnologies:

The LERU institutions expect a very high level of benefit from nanotechnologies in 'Health care' and 'ICT'. 'Environment', 'Energy' and 'Nano-bio-cogno technology applications' are also areas to which they think nanotechnologies can contribute a lot.

On the other areas their expectations on the benefit from nanotechnologies are very diverse and therefore difficult to align, but it clear that they have quite high expectations on the level of benefit for 'Aerospace, automotive and transport', 'Sustainable chemistry' and 'Security'.

When it comes to 'Agriculture', 'Construction', 'Food and feed', 'Protective equipment' and 'Textiles and clothing' their expectations are modest to high.

They agree that level of benefit from nanotechnologies on 'Household products' is rather modest.

8. Please indicate for each area what level of risk you expect from nanotechnologies:

It is fair to say that the LERU member institutions do not expect many risks from nanotechnologies. Their overall expectation is, for almost all areas, modest. For Aerospace, automotive and transport, Energy and ICT, their expectations on the risk from nanotechnologies is modest to none at all. The level of risk for Agriculture, Construction, Environment, Health care, Nano-bio-cogno-technology applications, Protective equipment, Security, Sustainable chemistry is considered to be more or less modest.

The level of risk in the fields of Food and feed, Household products and Textiles is considered to be higher but still not very high.

9. What are your main concerns about the present situation of nanotechnologies?

From the responses received it is clear that the members agree that all these concerns are important. All issues are considered to be major by at least one member institution and none of the issues are considered to be 'not an issue' by more than one member. There is however some degree of distinction:

'Europe lagging behind its competitors in exploiting the benefits of nanotechnologies' and 'Obstacles to innovation' are considered to be major issues by all universities that participated.

'The lack of knowledge and transparency regarding products on the market containing nanomaterials', 'The possible toxicity of poorly understood nanomaterials', 'The possible effects of nanomaterials on workers' health' 'The possible risks from accidents when manufacturing nanomaterials', 'The possible effects of nanomaterials on the environment' and 'The lack of adequately skilled personnel' are also considered to be very important issues.

'The lack of adequate information to the public on benefits and potential risks', 'The lack of proper consumer product information' and 'The ethical issues' are important but smaller issues.

On 'The lack of tools to implement and enforce existing regulation on environment, health and safety', 'The lack of uniform technology', 'The lack of public dialogue/debate', 'The lack of new specific regulations' and the 'Security and privacy issues' the views are quite diverse. Some members consider it to be major issues while others think these are smaller issues or not issues at all.

10. How do you perceive the present governance at EU level related to nanotechnologies?

The responses received are very diverse. None of the points is considered to be very good. On the other points the answers vary between good and poor. Only the last two points 'Addressing especially nano-bio-cogno applications by additional targeted regulation' and 'Implementation of regulation' were not considered to be poor by any university.

11. Are you aware of the following EU documents/activities related to nanotechnologies?

From the responses received it is very clear that 'Research and research funding (FP7)' is best known by the LERU member institutions.

'The European strategy and action plan on nanosciences and nanotechnologies', 'The 1st and 2nd implementation reports on the action plan' and 'The code of conduct for responsible research' are known by all and read or used by most members.

'The EGE Opinion on ethics of nanomedicine' and the 'Opinions of the European Parliament of the European Parliament on nanotechnologies' are not used by any of the members and not known by some of them.

12. How should the following EU policy actions related to nanotechnologies be continued in the new Action Plan?

From the responses it was clear that EU policy should do more or at least keep the current actions, but for none of the issues a majority thinks Europe should do less.

All or most LERU members think EU policy actions on 'International dialogue', 'Develop education and training in Nanosciences and nanotechnologies', 'Incentives and tools facilitating innovation in nanotechnologies', 'Development of infrastructure for nanotechnology application studies including assessment' and 'Develop better tools for assessment of risk and benefits for nanotechnologies' need to be increased.

On 'Active communication and dissemination of information', 'Public dialogue with stakeholders including targeted feedback', 'International cooperation', 'Support to the EU foresight studies' and 'Address safety concerns linked to nanotechnologies' some members think the current EU policy actions suffice while others think the EU should do more on these points.

When it comes to 'Remove barriers to innovation in nanotechnologies', 'Promote cost-effective measures to minimise exposures', 'Adapt existing legislation for nanomaterials' and 'Improve the implementation of existing legislation' the views are scattered, but a majority still thinks the EU policy actions on these points need to be increased.

13. Which new EU policy actions related to nanotechnologies should be envisaged?

A majority thinks the first and the second action, 'Establish an inventory of types and uses of nanomaterials, including safety aspects' and 'Require adequate information on consumer products', should be realised while none are opposed to this.

On the third action point, 'Develop new specifically targeted regulation for nanotechnologies - especially related to nano-bio-cogno-applications (e.g. enhancement)', the views are scattered, but the majority is not convinced this should be taken forward.

14. Which EU research actions related to nanotechnologies should be reinforced or reduced?

All members agreed the following EU research actions should be reinforced: 'Support enabling research'; 'Support the development of research infrastructures'; 'Support centres of excellence including their networking' and 'World-wide international cooperation'.

A majority thinks that more should be done for 'EU – wide cooperation of national/regional R&D', 'Support research into applications that can contribute to EU policy objectives', 'Support research into industrial applications leading to more eco-efficient production', 'Support research into other industrial applications of nanotechnologies with a high potential for innovation, new employment and new markets', 'Support research on ethical, legal and social aspects of nanotechnology' and 'Foster the industrial exploitation of nano R&D results'. None of the respondents thinks less should be done on these action points.

When it comes to 'Support research needed for implementing regulation', views are divided. Some think more should be done and others think the current actions are sufficient. None think the EU research actions on these points should be reduced.

On two points 'Promote industrial involvement in EU R&D projects' and 'Ensure ethical review of EU nano R&D projects' the respondents do not agree. Some think less should be done on these points while others think more should be done or the current research actions suffice.

REPRÉSENTATION PERMANENTE DE LA FRANCE AUPRÈS DE L'UNION EUROPÉENNE

NOTE DES AUTORITÉS FRANÇAISES

OBJET : Réponse des autorités françaises à la consultation publique « Towards a strategic nanotechnology action plan (SNAP) 2010-2015 »

Les nanotechnologies sont un ensemble de technologies émergentes liées à l'échelle nanométrique et présentant un potentiel de développement industriel sans précédent. Les multiples potentialités de ces technologies, identifiées par la Commission parmi les technologies clés génériques, justifient une politique ambitieuse permettant à ce secteur de tenir ses promesses pour la compétitivité européenne. Les impacts des nanotechnologies (et de ses productions) et de la convergence avec les biotechnologies, l'infotechnologie, et les sciences cognitives (dite convergence NB1C) sont multiples. Il convient d'en tenir compte dans les politiques de mises en œuvre.

Le développement, la production (à l'aide de nanotechnologies ou non) et l'utilisation des nanoparticules comportent pour leur part de nombreuses incertitudes sur le plan de l'existence ou de la caractérisation des risques pour la santé et l'environnement, et ceci tout au long de leur cycle de vie : fabrication, transformation, stockage, transport, utilisation, traitement en fin de vie.

Conformément à un engagement du Grenelle Environnement, le gouvernement français met en place une série de dispositions visant à mieux connaître les nanomatériaux présents sur le marché et leurs impacts éventuels. La loi de programmation relative à la mise en œuvre du Grenelle Environnement du 3 août 2009 énonce, dans son article 42, l'objectif pour l'Etat, dans les deux ans suivant sa promulgation, que " la fabrication, l'importation ou la mise sur le marché de substances à l'état nanoparticulaire ou des matériaux destinés à rejeter de telles substances, dans des conditions normales ou raisonnablement prévisibles d'utilisation, fassent l'objet d'une déclaration obligatoire, relative notamment aux quantités et aux usages, à l'autorité administrative ainsi que d'une information du public et des consommateurs"

Cet objectif est confirmé par les dispositions du projet de loi portant engagement national pour l'environnement (Grenelle 2), rendant obligatoire la déclaration de l'identité, des volumes et des usages des matériaux mis sur le marché contenant des substances à l'état nanométrique et en fixant les conditions. Elles permettront plus particulièrement la constitution d'une base de données nationale sur les nanomatériaux présents sur le marché.

Ce projet de loi est actuellement en discussion au Parlement et le projet de décret d'application de cette disposition sera prochainement soumis à la Commission européenne au titre de la directive 98/34/CE.

Les autorités françaises appellent de leurs vœux une mesure d'harmonisation européenne sur ce sujet, qui permettrait de disposer d'une base de données européenne, nécessaire à une meilleure connaissance de la problématique par les autorités communautaires et nationales.

Par ailleurs, les autorités françaises souhaitent que la mise en œuvre des règlements REACH et CLP prennent mieux en compte la problématique des substances à l'état nanoparticulaire. Dans l'attente d'une révision du règlement REACH, notamment pour abaisser le seuil de tonnage au-delà duquel une substance doit être enregistrée dans sa forme nanométrique, les autorités françaises participent actuellement aux travaux menés par la Commission pour adapter les outils permettant l'évaluation des risques des nanomatériaux manufacturés.

Enfin, un débat public national sur le sujet des nanotechnologies a été mené en France afin d'informer la population et de recueillir ses questions et propositions. Ce débat s'est achevé le 24 février 2010. Les autorités françaises apporteront des compléments aux réponses communiquées ci-dessous, une fois les résultats du débat public exploités.

L'ensemble des documents relatifs à ce débat, et notamment les cahiers produits par les acteurs intéressés, en France, par ce sujet, sont disponibles sur le site dédié au débat :

<http://www.debatpublic-nano.org>.

Dans ce contexte, les autorités françaises remercient vivement la Commission pour cette consultation publique visant à préparer une stratégie européenne en matière de nanotechnologies. Elles souhaitent pleinement y contribuer, si la Commission l'estime nécessaire, notamment en partageant leurs propres réflexions et les résultats du débat public français. Elles interrogent à cette fin la Commission sur le calendrier qu'elle envisage pour faire aboutir la stratégie européenne en matière de nanotechnologies.

La Commission trouvera ci-dessous les réponses des autorités françaises à sa consultation.

1. Risques et bénéfices des nanotechnologies - questions 3 et 4

Afin d'évaluer au mieux les bénéfices et risques potentiels des nanotechnologies pour notre société, il est nécessaire de mettre en place une méthodologie d'analyse scientifique partagée par les acteurs, appropriée et spécifique aux domaines d'emploi. En effet, les méthodes classiques ne sont pas adaptées aux nanomatériaux, qui ont des caractéristiques particulières différentes de celles rencontrées aux échelles non-nanométriques. Par conséquent, les autorités françaises estiment indispensable d'élaborer un référentiel commun au niveau européen pour évaluer les risques réels des nanomatériaux et les véritables intérêts de leurs applications.

Par ailleurs, comme toute technologie nouvelle, les nanotechnologies sont susceptibles de générer des attentes et des préoccupations quant aux bénéfices accessibles et risques réels. Les domaines alimentaire ou environnemental en sont des exemples.

L'information et la formation du public et des travailleurs) éventuellement par voie d'étiquetage, sont essentiels pour limiter les craintes générées par l'usage des nanomatériaux. Au vu de craintes parfois non proportionnées aux bénéfices et risques dont font l'objet les nanotechnologies convergentes (nano-bio-cognitif) et exprimées dans le cadre du débat public, ce domaine doit faire l'objet de mesures d'informations spécifiques.

Question 3: Pour chaque secteur d'activité (aérospatiale, construction, énergie, environnement, TIC.) quels sont les bénéfices des nanotechnologies ?

Domaines	Exemples de bénéfices attendus
Transports	Matériaux avec de meilleures performances, électronique embarquée, économie d'énergie, voiture verte (voiture hybride ou électrique), sécurité, systèmes embarqués innovants, multimédia, véhicules plus compétitifs.
Agriculture	Pesticides mieux ciblés, et donc réduction des pollutions. Cela est valable pour les engrais.
Instructions	Economies d'énergie et de matière. Maison à énergie positive.
Energies	Economies d'énergie, énergies renouvelables, meilleures performances en production et en stockage, meilleurs rendements, miniaturisation.
Environnement	Purification de l'eau et de l'air, nouvelles techniques de dépollution, réduction des émissions, stockage de gaz
Alimentation	Nouveaux emballages, adjuvants, conservateurs.
Santé	Nano-raédecine, nouveaux traitements contre le cancer, etc. Nouveaux systèmes de diagnostics, nouvelles méthodes d'imagerie, systèmes de surveillance médicale personnel, matériaux et prothèses biocompatibles, hygiène.
Nano-bio-cogno	Correction des handicaps (surdit�, c�cit�, paralysie, etc.).
Domotique	Gestion de l'�nergie, maison interactive et plus confortable.
TIC	Meilleurs ordinateurs, stockage des donn�es, multim�dia, internet, e-learning, culture, aménagement du territoire, communications mobiles.
Equipements de protection	V�tements innovants, durcis aux environnements hostiles, protection personnelle.

Sécurité	Sécurité civile, terrorisme (détection NRBC, portiques, imagerie THz...), détection de catastrophes naturelles.
Chimie durable	Meilleur rendement, économie de matière, amélioration du cycle de vie.
Textiles	Vêtements innovants.

Question 4: Pour chaque secteur d'activité (aérospatiale, construction, énergie, environnement, TIC.) quels sont les risques des nanotechnologies ?

A ce stade, les risques des nanomatériaux restent difficiles à évaluer en raison notamment du déficit de données pertinentes en matière d'identification et de caractérisation des dangers intrinsèques, de l'absence d'outils de traçabilité (détection de la présence de nanomatériaux), de lacunes en matière d'information de la part des industriels et de l'inadaptation des moyens traditionnels de tests et de mesures, ainsi que de l'absence de définition des différents termes liés à ces technologies. Ces difficultés ne sont pas exhaustives et les autorités françaises pourraient en identifier d'autres suite au débat public.

Outre les questions méthodologiques essentielles pour déterminer les risques et les bénéfices, il paraît important de souligner l'importance de la prise en compte des incertitudes : l'analyse des risques et des bénéfices doit se faire dans le respect du principe de précaution.

D'une manière plus générale, l'inadaptation des moyens traditionnels de tests et de mesures, ainsi que le manque de données, de recensement, d'information des industriels et des administrations qui en découlent, sont des obstacles au développement de ces technologies.

2. Principales préoccupations qui ressortent de la situation actuelle (manque d'outils, manque de cohérence, manque d'une réglementation adaptée etc.) - question 5

A ce stade, les autorités françaises ont identifié quatre préoccupations majeures :

- la valorisation des travaux européens et internationaux (ISO, OCDE, etc.) en matière de nanotechnologies : l'Union européenne dispose de nombreux résultats académiques qui ont du mal à être valorisés ; cette valorisation devrait donc être renforcée (notamment dans le cadre du futur plan européen pour l'innovation), en particulier en ce qui concerne l'amélioration des connaissances en matière de dangers, la métrologie des nanomatériaux et les moyens de protection;
- les incertitudes sur les effets et les lacunes réglementaires : la prise en compte des spécificités des substances de taille nanométrique, notamment dans le cadre des règlements REACH et CLP afin d'améliorer la connaissance et la diffusion de l'information notamment dans les fiches de données de sécurité et l'étiquetage, serait souhaitable. Une convergence internationale serait requise sur le sujet, le cas échéant sur propositions européennes ;
- en milieu professionnel comme pour les usagers, au même titre que pour les autres agents chimiques susceptibles de présenter un danger pour la santé ou la sécurité des travailleurs, les nanoparticules relèvent de l'ensemble de la réglementation du code du travail relative à la prévention du risque chimique notamment les dispositions relatives à la prévention des risques liés aux agents chimiques dangereux (ACD) et, le cas échéant, celles applicables aux agents chimiques dangereux cancérigènes, mutagènes ou toxiques pour la reproduction (CMR) de catégorie 1 ou 2. Néanmoins, les efforts doivent être poursuivis pour :
 - améliorer la connaissance et permettre, en particulier, d'affiner l'évaluation des effets et des risques ;
 - créer des instruments de régulation de portée européenne, voire internationale.

- l'information du public et l'information sur les produits devrait être renforcée, notamment par la mise en œuvre d'outils de traçabilité des nanomatériaux. A titre d'information, les autorités françaises soulignent que l'article 42 de la loi Grenelle 1 (3 août 2009) fixe déjà, pour les produits fabriqués et mis sur le marché, les objectifs de déclaration à l'autorité administrative et d'information du public et des consommateurs.

3. Perception au niveau européen de la gouvernance actuelle en matière de nanotechnologies et connaissance des documents⁵⁹ - questions 6 et 7

Il convient tout d'abord de considérer la gouvernance au sens large, c'est-à-dire comme l'ensemble des dispositions qui permettent un développement acceptable et accepté d'une nouvelle technologie. Dans ce contexte, il est indispensable que la gouvernance européenne passe du stade des interrogations à celui de la fixation de priorités d'action accompagnées de calendriers de travail précis. C'est la raison pour laquelle les autorités françaises sont favorables à l'élaboration d'un Plan d'action stratégique sur les nanotechnologies. Il serait également utile que la Commission implique mieux les Etats membres dans la réflexion en amont de ses décisions.

Dans cette perspective, les autorités françaises estiment que le développement de la recherche ainsi que l'amélioration des connaissances et leur diffusion constituent un enjeu essentiel. A cet égard, elles indiquent, qu'à leur sens, une meilleure coordination des recherches conduites dans les Etats membres et au niveau communautaire serait nécessaire. L'adaptation des règlements REACH et CLP et des outils pour leur mise en oeuvre serait de nature à y contribuer,

Les questions du respect de la vie privée, de la protection des données personnelles et des droits fondamentaux, en lien avec les nanotechnologies, mériteraient également une attention plus importante de la part de la Commission.

Enfin, la coopération entre les programmes de soutien à l'innovation régionaux, nationaux et européens devrait être renforcée notamment par un lien cohérent entre programmes de recherche et projets territoriaux (en France, Nano-Innov et les pôles de compétitivité), en mutualisant les compétences et en partageant les bonnes pratiques (« benchmarking »). Cette coopération pourrait aussi être renforcée en mettant en évidence des complémentarités entre Etats après avoir dressé un tableau clair de l'existant.

⁵⁹ Documents: The European Strategy and Action Plan on nanosciences and nanotechnologies, The 1st and 2nd implementation reports on the Action Plan. The Code of Conduct for responsible research. The EGE Opinion on ethics of nanomedicine, Opinions of the European Parliament on nanotechnologies. Research and research funding (FP7)

4. Inclusion des actions européennes existantes dans le cadre d'un Plan d'action ad hoc, nouvelles actions à envisager au niveau européen et domaines de recherche renforcer ou réduire - questions 8, 9 et 10

Les autorités françaises souhaiteraient que le plan d'action se concentre sur les priorités suivantes :

a) Les règles de gouvernance

Les autorités françaises soulignent le caractère divers des applications et des implications. Une gouvernance interdisciplinaire, coordonnée par la Commission européenne, notamment par le biais de réunions régulières des parties prenantes et une implication dans les enceintes internationales, semble nécessaire.

b) Le champ d'application des nanotechnologies et définitions compatibles avec les définitions mondiales

Un travail de normalisation dans chacun des secteurs concernés des définitions est indispensable pour mieux appréhender les bénéfices et les risques potentiels des nanomatériaux. Il convient par ailleurs de bien segmenter les problématiques entre nanoparticules (naturelles ou pas), nanotechnologies et nano-objets.

Cette clarification des définitions doit permettre de parvenir à un inventaire des nanomatériaux, des opérateurs et des usages. Une cartographie européenne devrait constituer le socle d'une stratégie européenne cohérente.

c) Les aspects santé-sécurité-environnement (HSE)

Des méthodes de caractérisation, de détection et de mesure de la toxicité et de l'écotoxicité des nanomatériaux est un préalable à la prise de mesures normatives en faveur de la protection de la santé, de la sécurité des travailleurs et des consommateurs et de l'environnement.

Une attention particulière doit être portée sur l'analyse du cycle de vie et la gestion des nanomatériaux en fin de vie.

d) La promotion d'outils pour une innovation responsable

Des mesures européennes peuvent contribuer à l'optimisation des investissements en termes de recherche, de développement, d'innovation et de production. Ces mesures doivent s'inscrire dans le cadre d'une innovation intégrant la gestion des incertitudes, c'est-à-dire évaluant correctement les bénéfices et risques et actualisant en permanence les conclusions avec les nouveaux résultats issus de la recherche, dans le respect du principe de précaution.

En France, le programme Nano-Innov, les pôles de compétitivité et le grand emprunt témoignent du soutien à la recherche fondamentale et appliquée. Les autorités françaises sont favorables à un soutien équivalent au niveau européen.

e) L'information du public

L'information de tous les publics concernés, éventuellement par le biais d'affichage ou d'étiquetage des risques pour la santé ou l'environnement, est indispensable pour permettre une bonne appropriation et une diffusion de ces technologies.

Des actions d'information sur le domaine technologique (intérêts attendus, développement scientifique et industriel, maîtrise des impacts sociétaux, sanitaires et environnementaux, évaluation des risques résiduels) et de formations à destination des consommateurs et des travailleurs seront nécessaires.

f) La veille et la surveillance épidémiologique, en particulier pour les travailleurs

g) Les sujets de recherche listés en annexe

5. Commentaires et suggestions - question 11

Ce questionnaire ne peut en totalité s'adresser comme tel aux trois profils types identifiés et mériterait peut être de s'accompagner d'un recensement de l'état des lieux et des initiatives prises par les différents Etats membres.

Les autorités françaises tiennent à nouveau à souligner le caractère pluridisciplinaire d'une stratégie en faveur des nanomatériaux. Ainsi, l'ensemble des acteurs concernés doivent être impliqués- Par ailleurs, les aspects sécurité et défense pourraient être développés au niveau communautaire et soutenus par exemple au niveau d'une agence comme l'AED, pour ces applications particulières des résultats obtenus dans le secteur général.

Annexe - Programmes de recherche que la France souhaite voir soutenir au niveau européen au titre des nanosciences et nanotechnologies

Thématique	Déclinaisons
Médecine	<ul style="list-style-type: none"> • Nanomédicaments, vectorisation • Interface neuronale • Imagerie • Surveillance médicale personnelle • Matériaux anti-bactériens • Laboratoire sur puce, bio-puce • Nanoinstrumentation, nanofluidique • Nanochirurgie
Energie	<ul style="list-style-type: none"> • Meilleure gestion de l'énergie • Photovoltaïque • Eclairage • Sources de lumière • Conversion d'énergie • Génération d'énergie portable • Pile à combustible • Stockage
Matériaux	<ul style="list-style-type: none"> • Matériaux auto-réparants • Matériaux bio-inspirés • Isolation thermique et phonique • Ecrans et éclairages souples • Matériaux hautes températures • Matériaux auto-organisés • Matériaux intelligents • Matériaux multi-fonctionnels • Matériaux à hautes performances
ICT	<ul style="list-style-type: none"> • Stockage de données (mémoire, enregistrements,...) • Nanoélectronique moléculaire, à spin, ADN, • supraconductrice, organique, grande taille, souple,.. • Nanophotonique • Cryptographie et informatique quantique • Nouveaux processeurs de calcul • Sources THz, optiques, composants hybrides • Informatique pour la santé et bio-informatique
Textiles	<ul style="list-style-type: none"> • Vêtements du futur (communicants, santé, etc...) • Récupération d'énergie • Vêtements pour la sécurité
Environnement	<ul style="list-style-type: none"> • Technologies pour la dépollution et la purification de l'eau, de l'air et des sols. • Matériaux pour remplacement de matériaux rares et substances toxiques • Catalyse • Toxicologie et écotoxicologie
Transport	<ul style="list-style-type: none"> • Batteries • Gestion de l'énergie

Thématique	Déclinaisons
	<ul style="list-style-type: none"> • Revêtements auto-cicatrisants • Voitures et infrastructures communicantes • Matériaux ultra-légers • Usine du futur
Sécurité	<ul style="list-style-type: none"> • Détection • Protection • Identification • Authentification • RFID • Capteurs, senseurs, réseaux,... • Surveillance de santé personnelle, auto-diagnostic. • toxicologie
Société	<ul style="list-style-type: none"> • Protection des travailleurs • Protection du consommateur • Information du public • Formation et diffusion de la connaissance auprès du public et des gouvernants • Participation de la société civile à la gouvernance • Sociologie des nanotechnologies • Gestion de l'incertitude et des risques.

WECF (Women in Europe for a Common Future)

There is a broad view that nanotechnology is fueling a new industrial revolution and that many benign applications are yet to come. However, what is really available and visible for the EU consumers are rather commonplace uses like the biocidal use of nanosilver. These applications have a questionable added value for the consumer (they are at least not to call "revolutionary") while they may pose risk that we don't yet fully understand. The hype surrounding the technological expectations is not accompanied with a broad communication of toxicity data and exposure evaluations while regulators seem not to have the right instruments to deal with the environmental and health issues. WECF is concerned with the fact that nanotechnologies are being presented as THE solution to for all our current global challenges: loss of biodiversity, climate change, water contamination global chemical contamination, land shortages and soil degradation and finally the economic crisis. This bears the risk to distract the international community, researchers and vital investments from addressing these issues with available and existing low-technology solutions, which are based on renewable resources and not dependent on limited resources like fossil fuels. Within this context, WECF likes to point to the fact that many substances currently used to make nanomaterials are of concern and synthesis processes are often quite inefficient, leading to substantial waste generation, energy consumption, and water use. Our recommendation to the Commission for the Plan of Action: Before entering into a broad and general use of nanotechnologies, their social benefits should be assessed on a case by case basis, considering the opposed risk. Decisions for investment in one or the other nanotechnology should be taken based on a measurable risk/benefit assessment.

Require toxicity data disclosure for all nanoparticles manufactured or purchased before entering the EU market including a thorough estimation of the expected exposure - independent of their volume

WECF does not see a need for additional investment in this domain (EU research actions), as the current level of financial public support is already very high. WECF warns that there is a risk to distract EU policymakers from investing into available and proven solution to achieve EU policies. Nanotechnology is not the solution to solve every problem.

Nanotechnology is very often discussed in terms of benefits and risks. WECF is not a priori objecting that nanotechnology (or any new technology) can bring long term profits and overall societal benefits. However, in order for us to make an overall judgment, we need to have data regarding the hazards, exposure and risks for humans, the environment and our society as a whole. Ethical and social issues and possible risks are of even higher importance but the immediate risks we have to deal with relate to the environmental and health impacts of rather "prosaic" nano-consumer products with no obvious or revolutionary added value for the consumer. The management of their risks requires a timely settlement. Please note that when answering the questionnaire we assumed that the area of application indicated as "Household products and other consumer products" also refers to "Cosmetics". We would have preferred to see "Cosmetics" as a separate area of application as we believe that it entails specific risks that do not necessarily apply to other household consumer products.

We regret that the questionnaire didn't differentiate between "nanotechnologies" and "nanomaterials/-particles", "nanoproducts" and the different risks involved.

The risks of ecotoxicity and human health. are of entire other nature than the ethical, legal and governance issues involved in NBIC and security applications and the subsequent outreaching consequences for our societies including questions about fundamental rights and individual freedom, about the increasing "sophistication" of our lives and the increasing dependence on technologies and related experts. These issues need to be specifically addressed in a public debate.

WECF highlights also the risks related to the divergence in spread of technology between poor and wealthy countries, which directly impacts the gap between rich and poor.

WECF advises that clear terminology is applied when informing the public or organizing public consultations.

Finally, after 15 years of very high investments in nanotechnologies, we should be able to make a first assessment of the results achieved. Therefore WECF advises the European Commission to adopt as a main objective of the Action plan a general review/assessment of measurable results achieved, with nanotechnologies in comparison to the expectations that had been set when investing in different fields, such as healthcare, employment, environment.