NANO CODE

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

MasterPlan

Issues and Options on the Path Forward With the European Commission Code of Conduct on Responsible N&N Research

November 2011

Project Consortium:

NANOCODE MASTERPLAN: ISSUES AND OPTIONS ON THE PATH FORWARD WITH THE EUROPEAN COMMISSION CODE OF CONDUCT ON RESPONSIBLE N&N RESEARCH

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The content of this documents is based on the activity undertaken by the project during its two years of activity and condensed in the Workpackage 1 and Workpackage 2 reports and the other reports prepared by all the partners with reference to the stakeholders' consultation they made in their countries.

St. Gallen / Rome in November 2011

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

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

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1 Executive Summary

NanoCode is a European project funded under the Programme Capacities, in the area Science in Society, within the 7th Framework Program (FP7). The aim of NanoCode is to develop a strategic framework (called MasterPlan) guiding the further development and implementation of the Code of Conduct for Responsible Nanosciences and Nanotechnologies (N&N) Research (EU-CoC). The development of a practical tool (the CodeMeter) to help stakeholders assess their performance in complying with the CoC's principles form a key element of the framework.

This MasterPlan builds on the insights gained from encompassing stakeholder consultations in eight European countries as well as at international level, in particular in the associated project countries Argentina, South Korea and South Africa. The consultations, made by an electronic survey, structured interviews and focus groups, involved more than 400 stakeholders worldwide, to assess attitudes, expectations, needs and objections regarding the EU-CoC. The findings are summarised in separate reports[1]. The results of the survey, the first draft of this MasterPlan and the CodeMeter prototype were deliberated during the National Workshops with national stakeholders in all partner countries.

In this report, selected ideas, options and recommendations concerning revision and implementation of the EU-CoC will be presented and discussed with a focus on stakeholder preference, practicability, need for structural and substantial changes of the EU-CoC, and compatibility with the governance context of the existing EU-CoC.

The NanoCode stakeholder consultation unveiled that awareness and implementation of the EU-CoC remain very limited to date due to:

- **Lack of Legitimacy**. It was questioned whether N&N (still) deserve their own code of conduct.
- **Difficult Practicability**. Deriving concrete and verifiable actions in practice is hampered by the all-embracing and unspecific character of the principles and guidelines of the EU-CoC.
- **Stumbling Blocks.** Specific contents, formulations and requirements in the EU-CoC have led to a rejection of parts or the entire EU-CoC among some of its target groups.
- **Lack of Pressure.** Many deemed it necessary to associate the EU-CoC with incentives, disincentives or penalties (in case of non-compliance) to encourage stakeholders to adopt and comply.
- **Poor Communication.** Communication and dissemination by the European Commission and Member States do not make the impression that the EU-CoC is of high priority.
- **Inadequate Commitment.** Commitment, coordination and lead have been lacking in the light of the very different structural preconditions applying for the implementation of the EU-CoC in different national contexts.

In the light of the identified flaws, stakeholders expressed the need for a fundamental revision of the current EU-CoC and the development of an implementation strategy. This can build up on some unambiguous positive aspects of the EU-CoC identified during the consultation:

[1] NanoCode WorkPackage 2 Country and Synthesis Reports, available at www.nanocode.eu

- **The EU-CoC principles**: stakeholders largely agree they are essential aspects to be taken into consideration in the development of nanotechnologies (as well as in emerging technologies in general).
- **The voluntary character:** the EU-CoC, though acknowledging some weaknesses associated to its voluntary character, is seen as appropriate tool to implement these principles, favouring trust building and confidence amongst stakeholders.
- **The broad scope:** the EU-CoC encourages dialogue amongst stakeholders and acts as an early warning system for relevant safety and societal issues.

The universal character of the principles is expected to offer necessary flexibility for adaptation to particular scope and target groups.

In order to solve the **legitimacy** issue of the EU-CoC, it was suggested to extend the scope of the EU-CoC in two dimensions. It was agreed that the principles and most of the guidelines of the EU-CoC are valid universally, beyond N&N research. It is therefore recommended to *extend the scope of the EU-CoC* (e.g. emerging technologies, or science in general), encompassing perspectives along a product's elaboration and life cycle stages (e.g. an "Innovation CoC") in alignment with the *Innovation Union* flagship initiative[2].

Although the present EU-CoC is considered suitable in principle to provide a foundation for a reflection process on responsible research, it is also considered to be of difficult **practicability,** for the EU-CoC does not offer practical *criteria* to determine what is good enough and how compliance can be achieved. This renders statements of compliance subject to ambiguity and they remain difficult to be verified.

The recommendation is to revise the EU-CoC with the intention to shift its functionality from being a *general framework of behaviours* to a *voluntary, verifiable standard*. Agreeing on concrete criteria thus represents a prerequisite to allow any meaningful form of adoption, verification and monitoring of compliance. Those criteria should be developed in close cooperation with stakeholders and experts and be integrated into the revised EU-CoC. The CodeMeter prototype as well as benchmarking of other standards provides a starting point for the development of such criteria.

With the development and testing of the *CodeMeter prototype*, feasibility and acceptance of an implementation assistance tool have been evaluated. The CodeMeter helps stakeholders to self-assess their compliance with the EU-CoC's principles and guidelines on the basis of a set of concrete criteria. The CodeMeter also provides context information about important aspects of the guidelines, presents hints at how to improve compliance and allows monitoring and documentation of compliance over time. Since the CodeMeter prototype has been overall well accepted, this approach is strongly recommended to be further developed, adapted and implemented with the revised EU-CoC.

A number of content-related, formal and structural issues seem to **be stumbling blocks** preventing broader stakeholder acceptance and more widespread adoption of the EU-CoC. In particular, the French and the German translations of the "accountability" principle as "responsibility" earned mistrust as they were interpreted with a connotation of *implying legal liabilities* as well as suggesting that scientists are held responsible for what is done with their work by decision outside their control or by other actors in the future.

[2] The Innovation Union is one of seven flagship initiatives within Europe's 2020 strategy for growth and jobs. With over thirty action points, the Innovation Union aims to improve conditions and access to finance for research and innovation in Europe, to ensure that innovative ideas can be turned into products and services that create growth and jobs. http://ec.europa.eu/research/innovation-union/index_en.cfm

This was considered inappropriate in the context of the voluntary EU-CoC. In addition, large parts of the EU-CoC are written in a distinct *Commission language* which may create problems of understanding. The order of the content elements of the EU-CoC booklet puts a lot of emphasis on the political process rather than on the principles and guidelines themselves. These points represent barriers to an intuitive approach to the EU-CoC which could be improved quite easily

Another fundamental decision must be taken regarding the future role of the EU-CoC in the broader context of governance. The current EU-CoC has been *designed as a voluntary measure*, thereby with no means to be verified, monitored or enforced, that cause a **lack of pressure**. It is recommended to keep the EU-CoC voluntary. But by increasing its specificity and practicability with the aforementioned criteria, it could be aligned to play a role as a *voluntary standard*. Linking, for example, compliance with the EU-CoC to a priority in the allocation of public funding (e.g. in the framework programme) seems to represent a possible, though controversial option for the European Commission to set up a strong incentive to comply with the (revised) EU-CoC. Again, criteria and tools are required to reliably and reproducibly assess compliance with the EU-CoC.

On the level of the European Commission and Member State governments almost complete **poor and uncoordinated communication, dissemination and awareness-raising** about the EU-CoC was observed. Strengthening dissemination of the current EU-CoC in order to foster its implementation seems pointless in the light of the proposed fundamental revision of the EU-CoC, nevertheless transparency and information should immediately be improved. It is recommended to immediately launch an *official EU-CoC information platform*, independent from strategic and content-related changes which the EU-CoC might undergo. This platform is to inform about past, on-going and upcoming activities and transparently document the consultation and revision process. It could later serve to host the CodeMeter. Other means of communication (e.g. development of “marketing” and educational materials) should be envisaged later, depending on the outcomes of the on-going revision, and be closely coordinated with the (to-be-renewed) dissemination activities.

Due to the interdisciplinary character of the EU-CoC, now and even more after a revision, multi-agency collaborations are needed to coordinate and lead the dissemination. **A clear and unambiguous commitment** at EU level, accompanied by a series of (policy) actions to foster Member States and stakeholders to adopt the EU-CoC is necessary to push countries which lack particular coordination actions and clear responsibilities at national level on nanotechnology-related issues. Activities should be clearly assigned to the European Commission, Member States governments and agencies.

In conclusion, the analysis carried out has highlighted specific issues related to the **role and scope**, the **format and contents** and the **implementation** of the EU-CoC that are at the base of the MasterPlan and CodeMeter. They are summarized below together with a number (25) of recommendations/options discussed in more detail in the report.

1.1 Overview and Recommendations

Stakeholder Awareness of the EU-CoC

Situation

- Awareness of the existence of the EU-CoC among N&N research stakeholders and N&N experts is rather low. Only about half of the relevant stakeholders from research, industry and public authorities had heard about the EU-CoC previously. This can (partly) be attributed to the low effectiveness of the communication and dissemination activities by the European Commission along the dissemination pathways originally envisaged in the EU-CoC.

Recommendations

1. Intensifying the dissemination of the EU-CoC with the aim to foster its implementation is not considered useful until the revision process has resolved the identified issues (see sections 3.2, 3.3 and 3.4). In the meantime, it is recommended to develop and implement information and awareness - raising activities to ensure proper and effective stakeholder engagement and transparency in the revision process as well as in the (further) implementation of the EU-CoC (see section 3.4.3).

2. The large pool of experts collected and involved in the NanoCode project should be used in the revision process, in particular those who are more sensitive to the issues of applying the EU-CoC.

Support for the Basic Idea of the EU-CoC and Status of Implementation

Situation

- A high level of agreement with the European Commission's approach of a voluntary code of conduct and with the underlying general principles was observed. However, the good agreement with the idea of the EU-CoC does not currently translate into high rates of adoption.

- Many N&N stakeholders indicated that the EU-CoC's principles are "implicitly adopted" in their organisations by other means than the EU-CoC guidelines, and many declared their intention to adopt the EU-CoC in the future. In addition, respondents were over-optimistic about the degree of implementation of the EU-CoC among Member States and governments.

Recommendations

3. The positive attitude towards the principles of the EU-CoC and its voluntary character should be taken as a solid basis to build on during the envisaged revision of the EU-CoC while some aspects of the EU-CoC need to be revised and adapted (see section 3.3).

4. The tendency of stakeholders to consider the EU-CoC implemented "implicitly" (through other standards and guidelines) must be addressed in the light of the future role and scope of the EU-CoC after revision (section 3.2.2).

From N&N Research to an "Innovation" Code

Situation

- It has been contested whether a dedicated CoC for N&N research is (still) needed. On the other hand, it is agreed that the principles and guidelines of the EU-CoC are universally valid and do not only apply to N&N research. It seems therefore possible to derive general principles for "emerging technologies" or, more generally, "responsible innovation" from the existing ones and extend the scope of the EU-CoC to other disciplines and along the entire chain of a product's elaboration and life cycle stages.
- There are a set of strategic options in terms of scope of the EU-CoC, which seem all viable in their corresponding governance context, defined by the combination of the two possible lines of actions. **Action Line 1:** Extend the scope of the EU-CoC to include other disciplines (e.g. all emerging technologies or science in general); **Action Line 2:** Include a more encompassing life cycle perspective (e.g. an "innovation CoC"). The situation is summarised in figure 2 From the NanoCode consultation, a preference towards extending the scope of the EU-CoC beyond N&N (Action Line 1) was identified, while the opinion about an "innovation CoC" (Action Line 2) seems to be less viable.
- The extension of the scope of the EU-CoC has to satisfy the unambiguous demand for increasing its specificity and practicability. In all of the above cases (N&N research, science or innovation code), fundamental revision of the current EU-CoC is required to align it to its future role.

Recommendations

5. Whether to extend the scope of the EU-CoC beyond N&N research to emerging technologies, science or innovation remains a strategic decision which must be brought in line with the future role of the EU-CoC in its governance context (e.g. the Innovation Union flagship initiative[2]). This decision should be taken before any further steps with the current EU-CoC contents are initiated.
6. Revision of the EU-CoC is recommended to be directed towards an extension of the scope beyond N&N (action line 1). The extension along the entire chain of a product's elaboration and life cycle stages (action line 2) remains a controversial issue.
7. It seems reasonable to retain the general principles of the current EU-CoC (see section 3.1.2) and combine and integrate them with the type of extension chosen. The extension of the scope of the EU-CoC has to satisfy the unambiguous demand for increasing its specificity and practicability and a better focus of the target groups of the EU-CoC should be aspired.

From a Framework of Behaviours to a Standard

Situation

- As long as the EU-CoC does not offer practical criteria and guidance about how to put its principles into practice and how to measure compliance, both implicit and explicit adoption of the EU-CoC remain a lip service. The development and integration of concrete criteria into the EU-CoC represents a prerequisite to allow any meaningful form of adoption of the EU-CoC.
- Instead of detailing the EU-CoC itself with concrete criteria, another viable option seems to complement it with implementation assistance tools. These assistance tools may be tailored to different target groups, technologies or application sectors, in order to provide the appropriate level of

specificity and practical guidance.

- Amending the EU-CoC with criteria could effectively convert it to a verifiable standard[3]. Compliance with the criteria of the standard has to be explicitly demonstrated. Whether the "standard" approach can be realised critically depends on the level of specificity that will be aspired with the revision of the EU-CoC's guidelines.

Recommendations

8. The EU-CoC should be revised with the intention to shift its functionality from the current general framework of behaviour to a voluntary standard. The need for explicit adoption should be part of the scope of the EU-CoC and should be taken into account in defining tools for its implementation.

9. Concrete criteria should be developed in close cooperation with stakeholders and experts taking into consideration existing initiatives and the experiences made with the CodeMeter prototype (section 3.4.2).

10. Accompanying the EU-CoC with implementation assistance tools (CodeMeter) could help providing the adequate level of specificity and practical guidance to the EU-CoC. The CodeMeter should be developed and evaluated in parallel to the revision of the EU-CoC.

Structure and Language of the EU-CoC

Situation

- Large parts of the EU-CoC are written in a distinct "Commission language" which is sometimes difficult to fully understand. The order of the content elements of the EU-CoC booklet puts a lot of emphasis on the political process which led to the EU-CoC rather than on the principles and guidelines which are only found in the Annex. There is no introduction, outlining who should be addressed and what the benefits of using the EU-CoC are. These points present a barrier to an intuitive approach to the EU-CoC for most of its target groups.
- There is a lack of correlation between the principles and the guidelines in the EU-CoC. The guidelines are not ordered according to the seven principles, but arranged under different subtitles. This complicates a structured top-down approach from the general perspective (principles) to the applied measures (guidelines).

[3] Not necessarily containing stringent requirements (e.g. for a certification process), but rather concrete guidance, see e.g. the voluntary International Standard ISO 26000:2010 "Guidance for Social Responsibility". http://www.iso.org/iso/iso_catalogue/management_and_leadership_standards/social_responsibility/sr_discovering_iso26000.htm

Recommendations

11. Both the choice of the wording used and the particular structure of the content elements in the EU-CoC booklet[4] should be addressed in the revision of the EU-CoC and be better adapted to the primary target audiences of the EU-CoC in an easy, simple and short manner. An introduction, outlining who is addressed and what the benefits of using the EU-CoC are, should be added. A proposal for the structure is presented in Annex 4.1.

12. The lack of correlation between the principles and the guidelines is inherent to the entire EU-CoC and could only be removed through fundamental revision of all guidelines. If such deep revision is envisaged, ordering the guidelines according to the topics of the principles is recommended.

The "Accountability" Principle

Situation

- Many stakeholders involved in the NanoCode consultation have indicated reluctance to hold researchers accountable for negative impacts that their research may impose on future generations. This is perceived to be beyond the influence and accountability of individual researchers.
- The French and the German translations of the "Accountability" principle earned particular mistrust among non-English speaking stakeholders. Many interpreted it with a connotation of implying legal liabilities which was considered inappropriate in the context of the voluntary EU-CoC. It was therefore suggested to replace the term "accountability" by "responsibility".
- Some stakeholder communities made a fundamental revision of the "Accountability" principle a precondition to reconsider implementation of the EU-CoC as a whole.

Recommendations

13. The explicit attribution of accountability to N&N researchers for potential impacts of their research on future generations seems unacceptable. The EU-CoC should be more specific so that it is clear *who needs to do what* to be "accountable". Scientists remain accountable for adopting good scientific practice, but not for what is done with their work by others in the future.

14. It is crucial to recognize that criticism about the understanding of the "Accountability" principle has contributed to an overall rejection of the EU-CoC among a considerable number of N&N stakeholders. Fundamental revision and/or clarification of this principle is therefore pivotal to the success of the revision and further implementation of the EU-CoC. The objecting stakeholders should be included in the revision and reformulation of this principle. Particular care is needed in the translation of the term in the various languages.

[4] http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf (text version) or http://ec.europa.eu/research/science-society/document_library/pdf_06/nanocode-apr09_en.pdf (booklet)

The "Innovation" Principle

Situation

- The role of the "Innovation" principle in the EU-CoC remains unclear. It is considered too general and not addressed to specific stakeholder groups. Moreover, the EU-CoC does not seem to present specific guidelines to mention concrete actions to be taken to fulfil the "Innovation" principle.
- Since "responsible innovation" is discussed as a possible extension of the scope of the EU-CoC beyond N&N research, this aspect deserves particular attention (section 3.3.3).

Recommendations

15. A clarification of the roles of the different target groups of the EU-CoC and further specification of suggested actions in relation to the "Innovation" principle should be provided.
16. It is recommended to establish unambiguous links between the "Innovation" principle and the guidelines section. Some of the keywords mentioned in the "Innovation" principle ("novelty", "creativity", "flexibility", "planning ability", etc.) could therefore be taken up again in the guidelines section.

Embedding the EU-CoC in the Governance Context: Incentives and Disincentives

Situation

- Although the instrument of a voluntary code of conduct and its principles were regarded adequate, some external motivation or pressure is considered necessary to support widespread implementation of the voluntary EU-CoC.
- Linking the EU-CoC to incentives or enforcing mechanisms requires monitoring and evaluation procedures to be in place which stands in contrast to the concept and design of the current EU-CoC. The general and unspecific guidelines of the EU-CoC are not appropriate to derive unambiguous, verifiable requirements.

Recommendations

17. The EU-CoC should be kept voluntary and it should not become a surrogate for enforceable (legal) regulations.
18. A number of implementation options have been identified, from weak forms of incentives to strong enforcing and monitoring mechanisms. These include: Introducing a label on EU-CoC compliance; giving priority to research complying with the EU-CoC in the public research funding process; developing a white list / black list of EU-CoC applicants; making compliance with the EU-CoC a precondition to receive public funding for research; or turning the EU-CoC into a standard for quality control.
19. Objective monitoring and verification need to be enabled by revising its guidelines in order to become more specific, practical and verifiable, or by providing implementation assistance tools.

Prototype of an Implementation Assistance Tool: The CodeMeter

Situation

- A prototype of the CodeMeter has been developed. It breaks down the general principles and guidelines of the EU-CoC into more concrete criteria and indicators. As a voluntary tool for self-assessment and implementation assistance, the CodeMeter would support researchers in reflecting ethical, legal and societal consequences of their research.
- The CodeMeter has been In general, well received. Its practicability, explanatory notes on key aspects of the EU-CoC (e.g. definitions, further information, and examples) and hints how to improve, are regarded helpful.
- The need for a simple and well-structured implementation assistance tool is expected to persist beyond the revision of the EU-CoC, and the CodeMeter prototype offers the necessary flexibility to be adapted to the revised EU-CoC.

Recommendations

20. Due to the appreciation of the CodeMeter approach, it is recommended to follow up on this concept. The CodeMeter should be adapted to the results of the on-going revision of the EU-CoC, to the feedbacks from the prototype testing and be developed in parallel to the revised EU-CoC.

Organising the Dissemination Process of the EU-CoC

Situation

- To date, awareness amongst the EU-CoC target groups is moderate and there are only few sources of information on the EU-CoC. There is no (official) EU-CoC platform or webpage. Awareness of the EU-CoC is a precondition and the first step on the path to implementation.
- Dissemination did not effectively reach the target groups of the EU-CoC. There is a limited awareness of dissemination activity concerning the EU-CoC, which refers to the entire dissemination chain (European Commission, Member States, governmental bodies, organisations and individual N&N stakeholders). Key reasons have been poor commitment and lack of clear responsibilities for dissemination as well as controversial content elements of the EU-CoC.
- Recent and ongoing consultations regarding the EU-CoC lack transparency in terms of the impacts they have on the further development of the EU-CoC.

Recommendations

21. As a primary communication measure, an official EU-CoC platform should be launched, independent from strategic and content-related changes to the EU-CoC (see sections 3.2 and 3.3). This platform should inform about past, ongoing and upcoming activities and transparently document the consultation and revision process. It could later host the CodeMeter (section 3.4.2).
22. Other means of communication should also be developed, depending on the outcomes of the on-going revision, and be closely coordinated with the (renewed) dissemination activities. A number of options, related to different target groups, could be used: Development of marketing materials; Dissemination through European Technology Platforms; Initiatives on education and professional

formation.

23. Dissemination activities should be supported by a reference point for the dissemination of the EU-CoC at the level of the European Commission as well as in each of the Member States.

24. A clear and unambiguous commitment at EU level, accompanied by a series of (policy) actions to foster Member States and stakeholders to commit to and adopt the EU-CoC is necessary, in particular to push countries which lack particular coordination actions and clear responsibilities at national level on nanotechnology-related issues. These are key barriers for the implementation of a tool such as the EU-CoC. Former dissemination structures (duties, responsibilities, coordination and monitoring) should thus be reviewed to identify the reasons for the lack of success at EU and Member State level.

25. Explicit responsibilities and goals for a targeted communication about the EU-CoC should be identified. Due to the interdisciplinary character of the EU-CoC, multi-agency collaborations are needed. Activities should be coordinated between European Commission and Member States government agencies.

A mapping exercise presenting a selection of the key issues ("hot topics") and the options identified to promote the adoption and the implementation of the CoC is reported in Figure 1. They refer to the entire "value chain" of the CoC and a number of possible path forward are shown, implying a different degree of complexity as well as a different level of commitment (EU, national and individual stakeholders level).

The directions chosen have to be closely related to what is the overarching role (vision) set for the EC-CoC (e.g. a reference document, a voluntary standard, *the* international Code on responsible innovation) and some of them rely, ultimately, on a political decision.

As the experience with the EC-CoC provided by some of the non EU countries (such as South Africa and Argentina) has shown, the EU-CoC could represent a tool to accompany and support emerging technologies since the beginning of their development. From a political point of view, the challenge is to define a widely accepted and acknowledged tool, aiming to foster (not hinder) innovation.

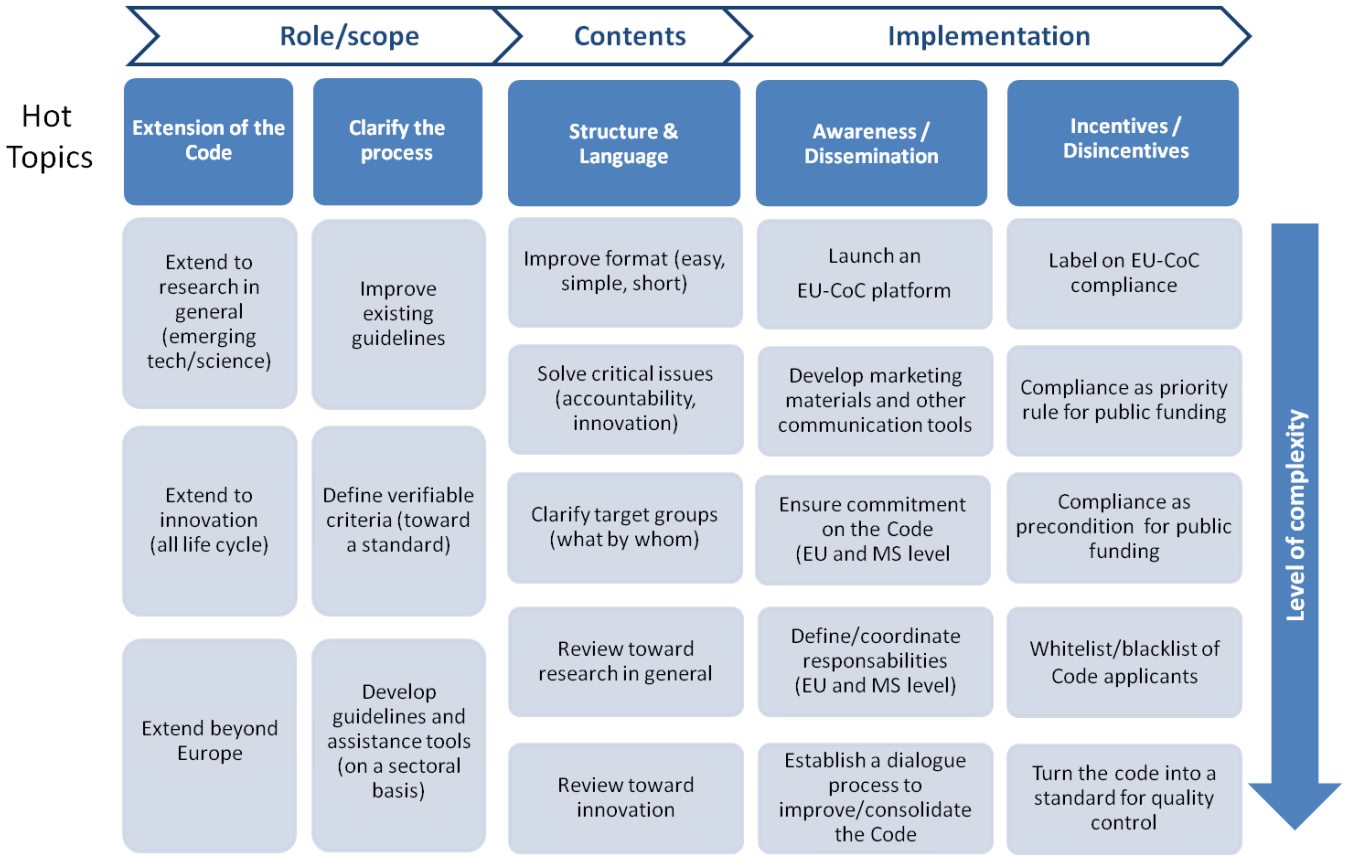

Figure 1: "Hot topics" and options (19 out of 25) identified by the NanoCode project to promote the adoption/implementation of the EU CoC

2 About

2.1 What is NanoCode?

NanoCode is a European project funded under the Programme Capacities, in the area Science in Society, within the 7th Framework Program (FP7). The objective of NanoCode is to define and develop a framework (MasterPlan) aimed at improving and strengthening awareness and supporting the successful integration and wider implementation of the European Commission Code of Conduct (EU-CoC) for responsible nanosciences and nanotechnologies (N&N) research at European level and beyond, integrated with an implementation assistance tool (CodeMeter).

The project rests on four pillars[5]:

- **Analysis** of existing/proposed codes of conduct, voluntary measures and practices for a responsible R&D in N&N and identification of the relevant stakeholders (work package 1 (WP1)).
- **Consultation** of stakeholders to assess attitudes, expectations, needs and objections regarding the EU-CoC through a survey (electronic questionnaire and structured interviews) to more than 400 stakeholders worldwide (WP2).
- **Design** of a MasterPlan and a performance assessment tool (CodeMeter) enabling the implementation and articulation of the EU-CoC, based on the WP2 consultation phase, a series of National Workshops in partners' countries and a final international conference (WP3).
- **Communication** in a suitable form and to the widest possible audience of project objectives, findings and outcomes (WP4).

The project brings together 10 partners representing 8 European countries, plus Argentina, South Africa and South Korea (associated member).

The EU-CoC can be downloaded in German, English and French from the European Commission Nanotechnology webpage: http://ec.europa.eu/nanotechnology/index_en.html.

2.2 What is the MasterPlan?

The MasterPlan provides a portfolio of options, ideas and recommendations for the further development and implementation, at European level and beyond, of the EU-CoC. The MasterPlan is intended to:

- Point out the level of awareness as well as criteria and indicators of the level of implementation and application of the EU-CoC.
- Indicate the need for future changes to the EU-CoC.
- Identify best practices, incentives and disincentives to foster widespread adoption of the EU-CoC.

[5] Outcomes of the different phases of the project are illustrated in a series of national and synthesis reports available on the project website (www.nanocode.eu). References to these reports are provided in the text, whenever relevant.

The MasterPlan puts together all the feedback, comments, suggestions and conclusions from the different, extensive review and consultation phases of the NanoCode project. During the WP2 of the NanoCode , as well as the findings that have been gained in each Partner's individual national contexts to provide an aggregated, wider set of options and recommendations concerning the EU-CoC.

Issues, ideas and recommendations have been reflected in view of practicability, political feasibility, and compatibility with the existing EU-CoC and the context it is embedded in.

The CodeMeter, developed in the process, will help the implementation of the CoC allowing the self assessment of the compliance with it, but it will be also a learning toll for raising awareness on RRI and engaging with the Code.

3 Lessons from the NanoCode Consultation Process

More than three years have passed since the European Commission released its "Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research" in February 2008[6]. Dissemination and implementation of the EU-CoC among Member States and the targeted N&N research stakeholders was expected, as the EU-CoC was intended to be used as an instrument to encourage dialogue at all governance levels among policy makers, researchers, industry, ethics committees, civil society organisations and society at large with a view to increasing understanding and involvement by the general public in the development of new technologies[7].

However, both the European Commission's first review[8] of the EU-CoC implementation and the NanoCode consultation[9] have shown that awareness and impact remain limited to date and that many N&N research stakeholders see a considerable need to review certain elements of the EU-CoC's principles and guidelines. According to the findings of an empirical study by Kjølberg and Strand among N&N researchers[10], the current EU-CoC is failing to be appreciated as an invitation to dialogue between N&N researchers and decision-makers in politics, but it is rather seen as an imposition "from above" with the purpose of controlling the researchers' work. The NanoCode stakeholder consultation has indeed confirmed this position, but it has also revealed aspects where the concept of the EU-CoC received strong support.

The following section of the MasterPlan builds upon the findings from the NanoCode analysis and consultation phase (WP1 analysis, WP2 survey and WP3 national workshops). They gave insights about existing situation at national level in different countries, stakeholder's patterns of awareness, their expectations, attitudes and appraisals[11].

3.1 Current Situation and Recommendations

3.1.1 Stakeholder Awareness of the EU-CoC

Awareness of the existence of the EU-CoC is poor among N&N experts and N&N researchers in particular. Only about half of the total of 304 NanoCode survey participants indicated that they have been aware of the EU-CoC prior to the survey, although all of them had been selected according to their expertise, involvement and experience in the N&N area. The percentage of awareness was independent from whether

6 Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, 1st Revision: Analysis of results from the Public Consultation of the Public Consultation. Available at http://ec.europa.eu/research/consultations/nano-code/consultation_en.htm

7 Commission recommendation on A code of conduct for responsible nanosciences and nanotechnologies research, C(2008) 424. Brussels, 7 February 2008 (Recommendation No 8).

8 Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, 1st Revision: Analysis of results from the Public Consultation of the Public Consultation. Available at http://ec.europa.eu/research/consultations/nano-code/consultation_en.htm

9 NanoCode WP2 Synthesis Report (Deliverable D2.3 for Work Package 2), March 2011. Available on www.nanocode.eu

10 Kamilla Lein Kjølberg & Roger Strand: Conversations about Responsible Nanoresearch. Nanoethics (2011) 5:99–113.

11 If percentages and numbers are mentioned in this MasterPlan, detailed references to these values can be found in the WP2 Synthesis Report.

N&N experts from EU countries or non-EU countries were asked, and independent from the N&N activity group their country was attributed to[12].

The low level of awareness could explain the low level of implementation of the EU-CoC (see section 3.1.2). However, several content-related and strategic aspects of the current EU-CoC are considered unclear or they are under criticism (see sections 3.2 and 3.3), and a revision of the EU-CoC is pending. Therefore, taking into account that changes to the EU-CoC are likely to result from the revision, fostering the implementation of the current EU-CoC through increased dissemination activities seems of little use at this stage.

In the meantime, however, increasing awareness-raising and communication activities with the intention to inform N&N stakeholders about the progress of the ongoing revision and to provide publicly available information about the EU-CoC seem necessary to prepare the path to a revised EU-CoC. These measures should be initiated immediately. Communication and dissemination needs and means are further discussed in section 3.4.3 and 3.4.3.2.

Recommendations

- Intensifying the dissemination of the EU-CoC with the intention to foster its implementation is not recommended until the revision process has resolved the identified issues (see sections 3.2, 3.3 and 3.4). In the meantime, it is recommended to develop and implement information and awareness raising activities to ensure proper and effective stakeholder engagement and transparency in the revision process as well as in the (further) implementation of the EU-CoC (see section 3.4.3).
- The large pool of experts collected and involved in the NanoCode project should be used and those included in the revision process who are sensitive to the issues of applying the EU-CoC.

3.1.2 Support for the Basic Idea of the EU-CoC and Status of Implementation

A broad support for the basic idea and some of the main elements of the EU-CoC has been observed. In the NanoCode survey, all seven principles of the EU-CoC[13] received remarkable levels of agreement[14], with more than of 75% of respondents in favour of them (N=297[15]). In addition, two thirds of the participants appraised the EU-CoC as an appropriate instrument to complement regulation and encourage dialogue about health, safety, environmental, ethical, social and legal issues of N&N. Only 15% indicated that they regarded the EU-CoC "not useful at all". Furthermore, 75% (N=237) agreed with the method of engaging the matter of responsible N&N research with a voluntary code of conduct.

Despite these encouraging indications, the EU-CoC is implemented only to a limited extent. In fact, only 21% of the respondents indicated that their organisations had already adopted the EU-CoC[16]. Moreover,

[12] WP2 Synthesis Report, chapter 2.1. Countries were distinguished according to their level of activities in N&N R&D. Higher level (Type A-countries): France, Switzerland, United Kingdom, The Netherlands, Germany etc.; Lower level (Type B-countries): Italy, Spain, Czech Republic, Argentina, South Africa etc.

[13] Meaning, Sustainability, Precaution, Inclusiveness, Excellence, Innovation and Accountability

[14] In the following and throughout the entire document, the term "agreement" comprises all responses that were in the form of "rather agree" and "strongly agree". On the contrary, "disagreement" comprises those responses where "rather disagree" or "strongly disagree" was returned.

[15] The numbers in brackets (N=...) indicate how many valid responses were received from the overall 304 participants on a specific question in the quantitative survey. The survey participants were allowed to proceed to the next question without providing an answer to each of the questions.

[16] However, fewer valid answers were received for this question in comparison to the previous questions about the level of agreement with the EU-CoC. Many participants seemed uncertain or uneasy to answer this question.

only very few participants (10%, N=175) indicated that their organisation explicitly mentioned the EU-CoC in its internal directives, mission statements, policy guidelines, or in its communication on the Internet.

On the other hand, more than half of the survey participants (62%, N=146) stated that their organisations apply other codes of conduct, principles or guidelines[17] in order to ensure compliance with the EU-CoC's principles. This suggests that in many cases there is some sort of "implicit adoption" of the EU-CoC, meaning that the principles of the EU-CoC are fulfilled by other means than the EU-CoC's guidelines themselves. This is a key point for the implementation of the EU-CoC and will be discussed in detail in section 3.2.2 and 3.4.1.

Respondents were optimistic about future implementation of the EU-CoC among organisations and governmental bodies. About half of them stated that their organisations intend to adopt the EU-CoC in the future, and they expected their governmental bodies to do so too. Even so, half of the NanoCode survey participants thought that their countries' governmental bodies had already adopted the EU-CoC, although only The Netherlands have so far announced to introduce mandatory contractual obligations to comply with the EU-CoC in their national funding scheme for N&N R&D[18].

Recommendations

- The positive attitude towards the principles of the EU-CoC and its voluntary character should be taken as a solid basis to build on during the envisaged revision of the EU-CoC while some aspects of the EU-CoC need to be revised and adapted (see section 3.3).
- The tendency of stakeholders to consider the EU-CoC implemented "implicitly" (through other standards and guidelines) must be addressed in the light of the future role and scope of the EU-CoC after revision (section 3.2.2).

3.2 Role and Scope of the EC-CoC: A Standard for Responsible Innovation?

The current EU-CoC focuses on N&N research. "N&N research" is defined in the EU-CoC as encompassing all research activities dealing with matter between 1 and 100 nanometers[19]. This includes fundamental research, applied research, technology development and pre - and co -normative research underpinning scientific advice, standards and regulations. The other elements of the entire chain of a product's development process and its life cycle remain out of the scope of the EU-CoC. Consequently, although the EU-CoC states to include "all individuals and civil society organisations engaged, involved or interested in N&N research", the N&N stakeholders addressed by the EU-CoC's guidelines are Member States, employers, research funders and (public and private) researchers.

Critical discussions have been led in the context of the NanoCode stakeholder consultation about whether it is justifiable to employ the EU-CoC's principles and guidelines on N&N research only. As a consequence,

[17] In the free text comments corresponding to this question, a broad variety of different voluntary approaches were mentioned, including ISO standards (ISO 9000/14000/16000), the precautionary principle, internal HSE operating instructions, and many other private and public guidelines or standards. For a complete list of these "alternatives", please refer to the NanoCode Synthesis Report, section 2.3.

[18] WP 2 Country Report: The Netherlands, Abstract. Available on www.nanocode.eu

[19] However, only man-made (deliberately engineered and involuntarily generated) nano-objects are within the scope of the EU-CoC. Naturally occurring nano-objects are excluded.

extending the scope of the EU-CoC beyond N&N to all emerging technologies and from the research stage to innovation was intensely discussed.

3.2.1 From N&N Research to an "Innovation" Code?

When the first version of the Code has been drafted, N&N could doubtlessly be considered as a specific entity. Today, however, participants of the NanoCode consultation agreed that N&N should not be considered as isolated from other technologies, and it was not evident why N&N deserves "its own code of conduct".

The principles and guidelines in the EU-CoC are of very limited explicit specificity for N&N. Rather than opposing to the meaning of the principles of the EU-CoC[20], it was thus criticised to link these and the corresponding guidelines *uniquely* to N&N. However, since the principles are regarded valid beyond N&N, it seems possible to extend the scope of the EU-CoC to other disciplines. It was also argued that an effective code for responsible behaviour should encompass the entire chain of a product's development process and its life cycle, and not only its research stage.

Many thus claimed that a widening of the scope of the EU-CoC from research to "science" or "innovation" would be welcome. The different possible directions of such widening are summarised in figure 2. On the basis of these observations, there seem to be several options in terms of scope of the EU-CoC:

- Keeping the EU-CoC with its current focus on N&N research.
- Extending the EU-CoC to other disciplines (e.g. all emerging technologies or science in general, vertical axis in figure 2)
- Add a more encompassing life cycle perspective (e.g. to "innovation", horizontal axis in figure 2). Such "innovation CoC" would address responsibilities along a products elaboration process and its life cycle.

From the NanoCode consultation, a preference towards extending the scope of the EU-CoC beyond N&N was identified. In terms of covering the entire innovation process, no clear preference was apparent. There is rather a range of different expectations towards the role and scope of the EU-CoC, and a number of different "visions" emerged during the consultation, ranging from having a useful reference document (the EU-CoC as one of many initiatives), a voluntary standard, or the EU-CoC as the only international "Code". Another vision that has emerged during the German national workshop saw the future EU-CoC in analogy to the "Hippocratic Oath" of medical doctors.

[20] Some aspects and guidelines were however subject to criticism (see section 3.3).

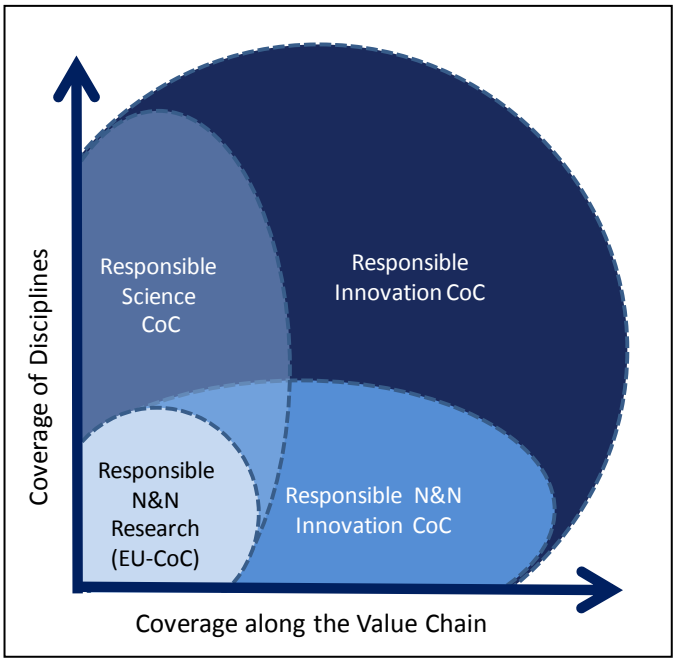

Figure 2: Options for the extension of scope of the EU-CoC beyond N&N research.

In contrast to the endorsement of extending the EU-CoC's scope, many stakeholders reported that the EU-CoC was too general even with its scope limited to N&N research only. The principles of the EU-CoC, in their current form, cover a broad range of topics and issues. They are not well-defined and specific enough so as to lead to *unambiguous requirements and actions* in the daily practice of N&N research. Practical metrics to determine the level of what is "good enough" are largely missing, thus making it difficult to monitor and assess compliance with the EU-CoC. Owing to the diverse target groups of the EU-CoC, the principles and guidelines are subject to varying interpretations, and where the EU-CoC is more specific, many stakeholders seemed to struggle with the fact that not all aspects of the EU-CoC are equally appropriate for all stakeholder groups[21]. It was therefore requested almost across-the-board to make the EU-CoC more readily applicable, more explicit and more specific.

As a general framework for responsible N&N research, the EU-CoC should not be expected to offer detailed and unambiguous *instructions* that are valid throughout all included target groups and research areas. The perspective of extending the scope of the EU-CoC is thus competing with the need to achieving a higher level of specificity and applicability. If the scope of the EU-CoC is extended, more stakeholders will need to be addressed and more subject areas to be covered. Clearly, a code with a broader focus on responsible science and innovation would need to take into account the several initiatives undertaken at international level related to good scientific practices and research integrity[22]. An in-depth benchmarking process of their

[21] See experiences made with the prototype of the CodeMeter tool, section 3.4.2.

[2] Among them can be cited the European Code of Conduct on Research Integrity (March 2011) of European Science Foundation (EFS) and the federation of All European Academies (ALLEA), the Singapore Statement on Research Integrity (September 2010), resulting from a large stakeholders' debate in 3 international conference), the Practical Guide for Investigating Research Misconduct Allegations International Collaborative Research Projects (2009), from the OECD , as well as other institutional and industry Code developed on the matter.

respective aims, elements, criteria and the wording of the principles, followed by a stakeholder engagement process is envisaged to develop an acknowledged tool.

In conclusion, the need for a dedicated CoC for N&N research has been contested, but on the other hand, it is agreed that the principles and guidelines of the EU-CoC are universally valid and do not only apply to N&N research.

It seems therefore possible to derive general principles for "emerging technologies" or "responsible innovation" from the existing ones and extend the scope of the EU-CoC to other disciplines and along the entire chain of a product's elaboration and life cycle stages.

Two possible lines of actions can be envisaged**. Action Line 1:** Extend the scope of the EU-CoC to include other disciplines (e.g. all emerging technologies or science in general); **Action Line 2:** Include a more encompassing life cycle perspective (e.g. an "innovation CoC"). The situation is summarised in figure 2.

From the NanoCode consultation, a preference towards extending the scope of the EU-CoC beyond N&N (Action Line 1) was identified, while the opinion about an "innovation CoC" (Action Line 2) seems less shared. The extension of the scope of the EU-CoC has, in any case, to satisfy the unambiguous demand for increasing its specificity and practicability. In all of the above cases (N&N research, science or innovation code), fundamental revision of the current EU-CoC is required to align it to its future role.

Recommendations

- Whether to extend the scope of the EU-CoC beyond N&N research to emerging technologies, science or innovation remains a strategic decision which must be brought in line with the future role of the EU-CoC in its governance context (e.g. the Innovation Union flagship initiative[2]). This decision should be taken before any further steps with the current EU-CoC contents are initiated.
- Revision of the EU-CoC is recommended to be directed towards an extension of the scope beyond N&N (action line 1). The extension along the entire chain of a product's elaboration and life cycle stages (action line 2) remains a controversial issue.
- It seems reasonable to retain the general principles of the current EU-CoC (see section 3.1.2) and combine and integrate them with the type of extension chosen. The extension of the scope of the EU-CoC has to satisfy the unambiguous demand for increasing its specificity and practicability and a better focus of the target groups of the EU-CoC should be aspired.

3.2.2 From a Framework of Behaviours to a Standard

Only few indicated that the EU-CoC's guidelines have been directly implemented anywhere in their organisation. On the contrary, more than 60% of the survey participants stated that their organisations apply other standards, guidelines or (voluntary) measures to ensure compliance with the EU-CoC's principles. In contrast to explicit adoption, implicit adoption of the EU-CoC thus means ensuring that the principles of the EU-CoC are fulfilled by other means than through the EU-CoC guidelines themselves.

Implicit and explicit adoption of the EU-CoC would ideally both lead to the same result: The principles of the EU-CoC are adhered to. In practice, however, as long as the EU-CoC does not offer practical criteria and guidance about how to put its principles into practice and how to measure the compliance, both implicit and explicit adoption of the EU-CoC will remain a *lip service*, and equivalence with other (implicit) means of compliance cannot be ensured. Fostering and supporting "implicit adoption" of the current EU-CoC is thus unlikely to add value to the current situation. Pushing for an "explicit adoption" seems to be a necessary step.

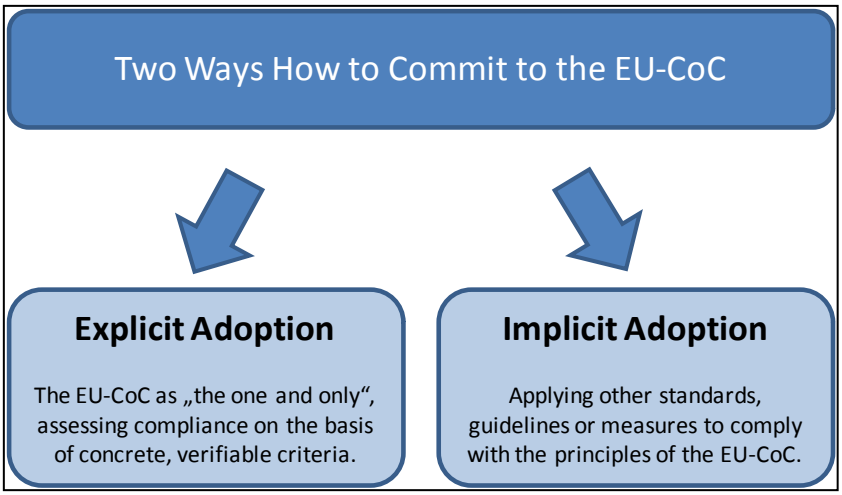

Figure 3: The two approaches identified on how stakeholders support and commit to the EU-CoC principles and guidelines[23].

In this context, it must be ensured that the level of compliance with the EU-CoC is assessed on the basis of sufficiently concrete, verifiable criteria. The development and integration of concrete and verifiable criteria into the EU-CoC thus represents a prerequisite to allow any meaningful form of adoption of the EU-CoC. Amending the EU-CoC with such criteria could convert it to a *verifiable standard* (comparable to an ISO standard) [24]. Organisations could voluntarily opt to be "certified" (checked for compliance) according to this standard. In the context of ISO standards, compliance with the criteria of the standard has to be *explicitly* demonstrated.

Whether the above "standard" approach can be attained, depends on the level of specificity that will be sought with the revision of the EU-CoC's guidelines. Defining verifiable criteria to be linked to the principles of the EU-CoC is a challenging task, due to the broad spectrum of issues covered by the EU-CoC's principles, the different stakeholder groups addressed, and the broadness of the nanotechnology theme. As it has become evident during the discussions on the existing EU-CoC as well as the work on the CodeMeter[25], the

[23] Graph from NanoCode WP2 Synthesis report, page 22.

[24] Not necessarily containing stringent requirements (e.g. for a certification process), but rather concrete guidance, see e.g. the voluntary International Standard ISO 26000:2010 "Guidance for Social Responsibility". http://www.iso.org/iso/iso_catalogue/management_and_leadership_standards/social_responsibility/sr_discovering_iso26000.htm

[25] In the NanoCode project, a prototype of an implementation assistance tool (the CodeMeter) has been developed. This tool has been tested with N&N research stakeholders and the findings have been compiled in section 3.4.2.

broadness would even be increased in the case of an extension of the scope of the EU-CoC to science, emerging technologies or innovation.

Instead of detailing the EU-CoC itself with concrete criteria, a viable option seems to have a general EU-CoC, containing general principles and some (still rather general) guidelines, and to complement it with implementation assistance tools to put it into practice (lower path in Figure 4). These assistance tools may be tailored to different target groups (e.g. public vs. private research, research or production stage) as well as to different technologies or application sectors, in order to provide the appropriate level of specificity and practical guidance.

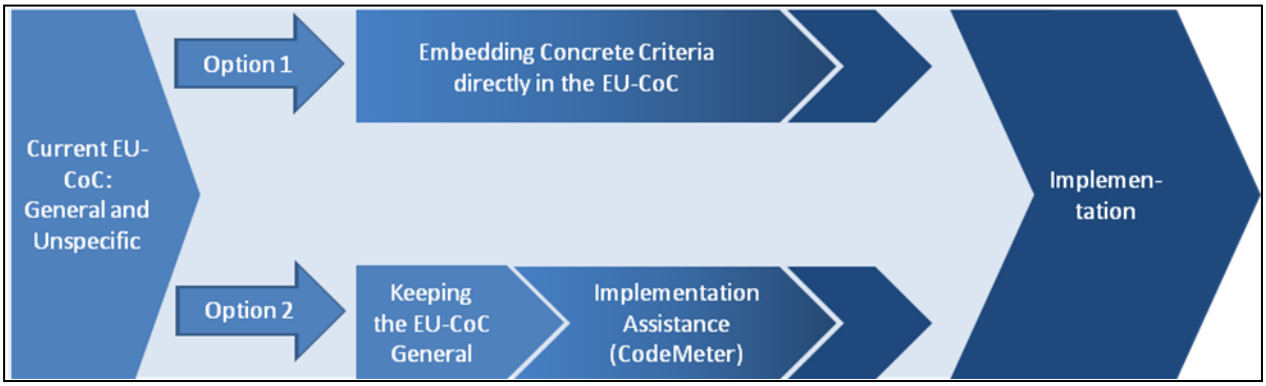

Figure 4: Options to increase the level of specificity of the EU-CoC.

As a starting point, those standards and good practices mentioned and used by stakeholders to ensure *implicit adoption* of the EU-CoC should be analysed and used to derive the criteria for the EU-CoC. For the development of the criteria, stakeholders and experts should be included. As presented in section 3.4.2, the CodeMeter provides a prototype of such an implementation assistance tool which has been tested with stakeholders.

Recommendations

- The EU-CoC should be revised with the intention to shift its functionality from the current general framework of behaviour to a voluntary standard. The need for explicit adoption should be part of the scope of the EU-CoC and should be taken into account in defining tools for its implementation.
- Concrete criteria should be developed in close cooperation with stakeholders and experts under consideration of existing initiatives and the experiences made with the CodeMeter prototype (section 3.4.2).
- Accompanying the EU-CoC with implementation assistance tools could help providing the adequate level of specificity and practical guidance to the EU-CoC. The CodeMeter should be developed and evaluated in parallel to the revision of the EU-CoC.

3.3 Content Issues of the Current EU-CoC

The EU-CoC is expected to be reviewed periodically (roughly every two years). The EU Member States should therefore be invited to cooperate with the Commission in order to review the EU-CoC and monitor the extent at which the addressed N&N research stakeholders have adopted the EU-CoC[26].

The NanoCode stakeholder surveys in ten countries provided insights into the level of awareness and adoption of the EU-CoC (section 3.1). The interviews and discussions with N&N experts in the context of national workshops were used to gather inputs and comments about those content issues in the EU-CoC that were considered to be in need of revision. Although the results of the NanoCode stakeholder consultation unveiled an overall very good agreement with the seven principles of the EU-CoC (see also section 3.1), certain aspects and requirements of the EU-CoC have been subject to intense and controversial debates particularly in the workshop discussions with the participating N&N experts. These considerations deliver the starting point for the upcoming revision of the EU-CoC.

3.3.1 Structure and Language of the EU-CoC

The structural peculiarities of the EU-CoC and the English as language of choice make it even more laborious to engage with the complex principles and contents of the EU-CoC. Those parts of the EU-CoC which are in front of the actual principles and guidelines are written in a distinct “Commission language” which has been reported sometimes difficult to understand and thus unnecessarily hampering an intuitive approach to the EU-CoC.

The order of the different content elements of the EU-CoC booklet[27] seemed to confuse the readers and makes it difficult to recognise the significance of the document for individual N&N stakeholders. It has been criticized that the principles and guidelines (the key parts of the EU-CoC from the perspective of the potential user) are only placed in the Annex of the document, behind the Commission recommendation. In addition, there is no introduction outlining whom the EU-CoC is for, what it is about, and what the benefits are in using it, and who is responsible for its dissemination.

In the context of deriving practical criteria to assess compliance with the EU-CoC’s principles and guidelines, it has proven difficult to identify a clear relationship between the principles and the guidelines of the EU-CoC (see CodeMeter in section 3.4.2). Some guidelines cover aspects of different principles. On the other hand, some principles do not seem to have an obvious counterpart in the guidelines section (see “Innovation” in section 3.3.3). This complicates an intuitive top-down approach from the most general principles over the guidelines towards practical criteria, how the guidelines could be implemented.

The unnecessary barriers regarding language and structure of the EU-CoC can be relatively easily removed by changing the order of the content elements or produce a more reader-friendly version of the EU-CoC. Such revision would not put so much emphasis on the political process which led to the EU-CoC, but instead would focus on the actual principles and guidelines and the benefits of using the EU-CoC. These suggestions are suitable to achieve a quick improvement of the accessibility of the EU-CoC.

[26] EU-CoC recommendation No 5.

[27] 1. Foreword, 2. Commission recommendation, 3. Code of conduct, 4. Council Conclusions

Recommendations

- Both the choice of language used and the particular structure of the content elements in the EU-CoC booklet[28] should be addressed in the revision of the EU-CoC and be better adapted to the primary target audiences of the EU-CoC. An introduction, outlining who is addressed and what the benefits of using the EU-CoC are should be added. A proposal for the structure is presented in Annex 4.1.
- The lack of cohesion between the principles and the guidelines is inherent to the entire EU-CoC and could only be removed through fundamental revision of all guidelines. If such deep revision is envisaged, ordering the guidelines according to the topics of the principles is recommended.

3.3.2 The "Accountability" Principle

In spite of the good overall agreement with the principles of the EU-CoC, 17% of the NanoCode survey stakeholders disagreed with the "Accountability" principle (N=297). Holding N&N researchers accountable for impacts that their N&N research may impose on present and future generations, as formulated in this principle, was considered unjustified and unrealistic by many N&N stakeholders. It was suggested that the EU-CoC should provide a clear indication that scientists must not be held responsible for what is done with their work by other actors in the medium term or in a more distant future.

Qualitative stakeholder comments underlined the interpretation that consequences of N&N research remain always uncertain and beyond the influence of individual researchers. This seems particularly true if basic research is considered where often no specific application is directly in the focus of the researchers. Some even feared that strict compliance with the "Accountability" principle would require many N&N research activities to be stopped, because negative consequences of research results in the future cannot be effectively prevented.

Objection against the "Accountability" principle was particularly strong in the German-speaking and French-speaking stakeholder communities. In Germany, revision of the "Accountability" principle was reported by some stakeholder groups to be a precondition to reconsider implementation of the EU-CoC.

In addition, the term "accountability" seemed to be subject to language-dependent interpretations and connotations. In relation to the German and French version of the EU-CoC, a connotation towards the juridical term of "liability" was reported – a notion that many considered particularly inappropriate in the context of a voluntary measure. However, the discussions in the UK showed that "Accountability" is rather used to express moral obligation than legal compliance.

Recommendations

- The explicit attribution of accountability to N&N researchers for potential impacts of their research on future generations seems unacceptable. The EU-CoC should be more specific so that it is clear *who needs to do what* to be "accountable". Scientists remain accountable for good scientific practice, but not for what is done with their work by others in the future. Particular care is needed in the translations.
- It is crucial to recognize that criticism about the "Accountability" principle has contributed to an overall rejection of the EU-CoC among a considerable number of N&N stakeholders. Fundamental

[28] http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf (text version) or http://ec.europa.eu/research/science-society/document_library/pdf_06/nanocode-apr09_en.pdf (booklet)

revision and/or clarification of this principle is therefore pivotal to the success of the revision and further implementation of the EU-CoC. The objecting stakeholders should be included in the revision and reformulation of this principle.

3.3.3 The "Innovation" Principle

There are only vague indications in the guidelines of the EU-CoC regarding the meaning of the "Innovation" principle[29]. It remains unclear who is addressed by this principle (Member States, research funders, or researchers?) and what is expected to be done to be responsible in terms of "Innovation".

Due to these ambiguities, particularly N&N research stakeholders considered the "Innovation" principle to be unnecessary in the context of N&N research. They argued that research intrinsically strives for innovation and that there was no need for such principle. In the context of the entire EU-CoC, however, the "Innovation" principle seems to be meant to primarily address Member States which are invited to ensure that research must pursue innovation to the benefits of the society and the individuals.

Given the ambiguity of the term "Innovation" and the lack of specific guidelines indicating concrete actions to fulfil the "Innovation" principle compliance with it seem difficult. On the other hand, "responsible innovation" is considered as a possible extension of the scope of the EU-CoC beyond N&N research and therefore this aspect deserves particular attention (section 3.3.3).

Recommendations

- A clarification of the roles of the different target groups of the EU-CoC and further specification of suggested actions in relation to the "Innovation" principle should be provided.
- It is recommended to establish unambiguous links between the "Innovation" principle and the guidelines section. Some of the keywords mentioned in the "Innovation" principle ("novelty", "creativity", "flexibility", "planning ability") could therefore be taken up again in the guidelines section.

3.3.4 Stringency of Some Guidelines

In relation to some of the "guidelines on actions to be taken" (section 4 of the EU-CoC), some concerns were raised about their stringency and their perceived sweeping character and actions are advocated to lessen this aspect. In particular:

- Guideline 4.1.17: *"As long as risk assessment studies on long-term safety is not available, research involving deliberate intrusion of nano-objects into the human body, their inclusion in food (especially in food for babies), feed, toys, cosmetics and other products that may lead to exposure to humans and the environment, should be avoided."* It has been pointed out that this rule could be too broad and could de-facto lead to a moratorium on certain types of research in nanomedicine and nano-enabled personal care products, certainly an unintended effect. Further criteria and indications to clarify how to apply this guideline need to be developed and provided.
- Guideline 4.2.6: *"N&N research organisations and researchers should launch and coordinate specific N&N research activities in order to gain a better understanding of fundamental biological processes involved in the toxicology and ecotoxicology of nano-objects man-made or naturally*

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

occurring". In the light of the range of stakeholders addressed by the EU-CoC, it seems unrealistic to require all N&N researchers to "launch and coordinate" nanotoxicology research. The role of accompanying research activities and social sciences research (e.g. the FP7 Science in Society research programme) could be included to provide more adequate options for the different types of N&N research stakeholders.

3.4 Fostering the Implementation of the EU-CoC

This section of the MasterPlan addresses options how the implementation of the EU-CoC in practice could be supported. Possible incentives motivating stakeholders to implement the EU-CoC are discussed in section 3.4.1. In section 3.4.2, the experiences made with the prototype of an "implementation assistance tool" (the so-called CodeMeter) will be presented. Suggestions for an improved communication and dissemination strategy will be provided in section 3.4.3.

The possible options concerning the implementation of the EU-CoC will become relevant after key decisions concerning scope (section 3.2) and critical content issues (section 3.3) have been taken. Only then will any further attempt to promote the EU-CoC have good chances of success.

3.4.1 Embedding the EU-CoC in the Governance Context: Incentives and Disincentives

As it is defined in its scope and aim, the EU-CoC is a voluntary policy instrument. It is meant to be complementary to existing regulations[30]. As a fully voluntary framework of general principles of behaviour it cannot be expected to replace enforceable, unambiguous and verifiable rules and actions. Consequently, the EU-CoC will hardly lead to full coverage among all relevant stakeholders. Nevertheless, different options have been discussed how the voluntary EU-CoC could be embedded within and linked with existing governance structures, and feedbacks from the NanoCode consultation strongly suggest that some form of enforcing mechanism should be introduced to support widespread implementation of the voluntary EU-CoC.

Although the instrument of a voluntary code of conduct was regarded adequate to implement the principles of the EU-CoC, many perceived it crucial to link the EU-CoC with some sort of incentives or disincentives that could be used to encourage N&N stakeholders to notice, adopt and apply the EU-CoC.

A number of options have been identified in the consultation, ranging from weak forms of incentives to stronger enforcing and monitoring mechanisms (disincentives). These could be implemented with the following measures:

- **Positive Label**: Introducing a "label of EU-CoC compliance" could serve as a weak form of establishing societal pressure to adopt the EU-CoC and creating increased visibility of N&N stakeholders that are compliant with the EU-CoC. On the way to create such a label, the EU could provide assistance to implement the label, provide a platform to enhance its visibility, define the labelling process, and support the attempt to integrate the label criteria into international standards and norms.
- **Priority in Public Research Funding**: Giving priority in the funding of N&N research to those applications that include a detailed account of how the institution/applicant will ensure compliance with the EU-CoC (such as ethical reviews of EU projects)[31].

[30] Commission recommendation on A code of Conduct for responsible nanosciences and nanotechnologies research & Council conclusions on Responsible nanosciences and nanotechnologies research, Annex lead-in and "Scope and Aim".

[31] A relevant example is given by ethical reviews applied to research projects in the FP7 health area. In the case of research on animals, it is required to demonstrate application of the 3R-principle (reduce, refine, replace) regarding animal testing. Projects demonstrating to apply this principle (e.g. through alternative testing methods) have priority compared to others (see http://www.healthncpnet.eu/jahia/Jahia/pid/32).

- **Compliance for Public Research Funding**: Compliance with the EU-CoC might be made a precondition to be eligible to receive public funding for research[32]. The Netherlands have so far announced to introduce mandatory contractual obligations to comply with the EU-CoC in their national funding scheme for N&N R&D[33]. It must be said, that this option has also met substantial objections
- **Whitelist / Blacklist**: Using a publicly available compilation of best-practice cases to add an incentive for organisations to adopt the EU-CoC. On the contrary, "naming and blaming" approaches ("blacklist") have been suggested in the knowledge that industry is particularly sensitive to issues concerning reputation, or fear of losing it.
- **Turn the EU-CoC into a standard for quality control: T**he EU-CoC could be included in standard rules related to quality control systems (to be applied in one or more steps of the supply chain). The EU-CoC would need to comply with the format of a standard, to allow certification and auditing.

All of the above ideas only work if they are based on a transparent evaluation process. If the EU-CoC should be embedded into such a context (e.g. in the research funding process), it needs to be revised to include specific, practical and verifiable criteria. As a rather general framework of desirable behaviours as it is now, the EU-CoC is not adequate to take such part.

Establishing incentives and, in particular, enforcing mechanisms will inevitably move the EU-CoC away from the basic idea of a fully voluntary measure. Moreover, the need to link the EU-CoC to enforcing mechanisms should also be assessed in the light of the desired degree of implementation that should finally be reached within the EU-CoC's target groups. If non-compliance is not tolerated, a voluntary measure is not the tool of choice (not even with incentives).

Recommendations

- The EU-CoC should be kept voluntary and it should not become a surrogate for enforceable (legal) regulations.
- A number of implementation options have been identified, from weak forms of incentives to strong enforcing and monitoring mechanisms. These include: Introducing a label on EU-CoC compliance; giving priority to research complying with the EU-CoC in the public research funding process; making compliance with the EU-CoC a precondition to receive public funding for research; developing a whitelist / blacklist of EU-CoC applicants; or turning the EU-CoC into a standard for quality control.
- Objective monitoring and verification need to be enabled by revising its guidelines in order to become more specific, practical and verifiable, or by providing implementation assistance tools.

[32] In the recommendations of the European Commission in the EU-CoC, several hints are given that the EU-CoC has indeed been foreseen to play a role in providing "funding criteria" in the procedure of granting public funding for research projects and in the formulation and implementation of research strategies: "That Member States consider such general principles and guidelines on research to be an integral part of institutional quality assurance mechanisms by regarding them as a means for establishing funding criteria for national/regional funding schemes, as well as adopting them for the auditing, monitoring and evaluation processes of public bodies." (EU-CoC Recommendation No 3), and "That Member States, in their bilateral agreements on research strategies and activities with third countries and in their role as members of international organisations, take due account of this Recommendation when proposing research strategies and taking decisions, and duly coordinate with other Member States and the Commission." (EU-CoC Recommendation No 7)

[33] WP 2 Country Report: The Netherlands. Available on www.nanocode.eu

3.4.2 Prototype of an Implementation Assistance Tool: The CodeMeter

The NanoCode consultation identified a strong need for supporting materials to assist stakeholders in interpreting and implementing the EU-CoC in their respective research environment. The CodeMeter has therefore been designed as a tool for *voluntary self-assessment* of compliance with the EU-CoC with the main objectives to:

- **Enhance the Practicability of the EU-CoC**. Break the EU-CoC's general principles and guidelines down into more concrete criteria and practical indicators which give indications about the level of compliance of the research carried out with the EU-CoC. A list of the criteria used in the prototype of the CodeMeter is presented in Annex 4.2.

- **Support Reflection and Learning.** N&N researchers are supported in reflecting ethical, legal and societal consequences of their N&N research. The CodeMeter therefore includes explanatory notes on key aspects of the EU-CoC (e.g. definitions, further information, and examples) and provides hints about how the compliance with the EU-CoC can be improved.

- **Enable Verification and Monitoring.** By providing concrete criteria, monitoring of the level of performance against the EU-CoC becomes possible.

Due to the heterogeneity of target audiences of the EU-CoC it seems inadequate to address all stakeholders with a "one-fits-all" approach. In the current prototype, the target group of the CodeMeter has thus been limited to people with a role in planning, managing or coordinating activities in N&N research and development (R&D), its safety, quality or corporate responsibility. The prototype of the CodeMeter has been implemented as an electronic questionnaire and was evaluated by selected N&N research stakeholders during national workshops in partners' countries.

The CodeMeter is based on a selection of those EU-CoC guidelines which are considered applicable to the chosen target group. Each guideline is related to one or more questions (or criteria) with a score assigned. For each question, further information about the topics of the respective guideline as well as relevant information links are presented. The final scoring is calculated by loading the scores of each question on one (or several) of the seven EU-CoC principles and represented on a seven-dimensional spider net graph, with each EU-CoC principle at the end of one axis[34] (figure 5). In the end, hints how to improve are suggested.

[34] The prototype version of the CodeMeter is based on 14 (out of 27) guidelines of the EU-CoC. A total of 23 questions/criteria (4 to 6 criteria for each of the 7 principles) have been developed.

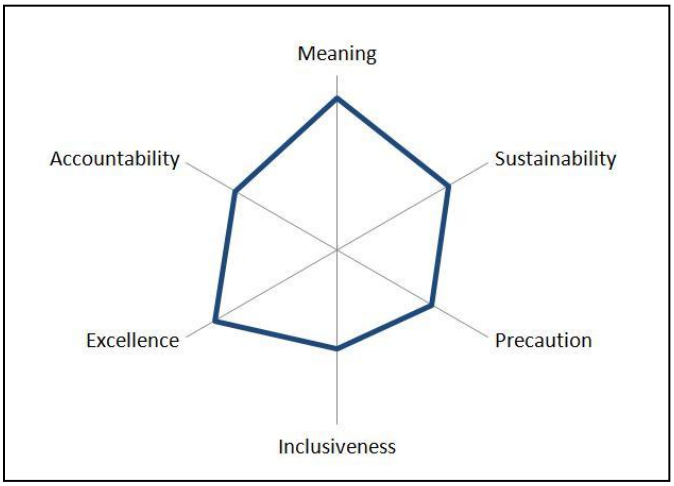

Figure 5: Spider net representation of a possible CodeMeter scoring.

The following list summarises the most important experiences made with the prototype of the CodeMeter in the test groups. In general, the feedback for the CodeMeter as implementation assistance tool was positive. N&N stakeholders appreciated the CodeMeter for enhancing practicability of the EU-CoC's principles and guidelines, and for providing a structured approach to the EU-CoC. The included "further information" and "hints how to improve" sections were rated to support a reflection and learning process. From the analysis of feedbacks, a number of key aspects for the further development of the CodeMeter were identified:

- **Stakeholder Specificity.** Even within the narrow target group chosen (see above), stakeholders observed that some of the criteria are outside the scope of their professional world, irrelevant or too academic. If the CodeMeter should not exclusively be appropriate for managing staff of research organisations, the underlying EU-CoC criteria need to be revised with regard to target group specificity. For instance, some criteria have been considered not readily applicable to private organisations (e.g. the requirements related to open access publishing), and some criteria have been considered beyond the insights of researchers in non-executive positions into organisational and formal procedures. In terms of increasing the flexibility of the tool towards unconventional, unexpected or stakeholder-specific it was therefore suggested to:

  - Add a "not applicable" option to each of the CodeMeter questions which can be ticked if a question is considered inapplicable by the respondent. Choosing the "not applicable" option would however need to be justified.

  - Add the option to choose "other", allowing participants to add and substantiate their own method of complying with a criterion.

  - Add gradual answers. The current CodeMeter only allows answers in the form of "yes" or "no". Setting the tick (or leaving it blank) determines the score achieved for a question. It was suggested to offer the possibility to scale one's answer (e.g. between 1 and 5).

  These changes are expected to add further flexibility, prevent false scorings and the "other" option could be used to extend and improve the CodeMeter tool based on used inputs over time.

- **Add Evidence**: In order to avoid "lip services" in the self-assessment, the statements made in the CodeMeter tool should be documented with "evidence"[35]. If the option to add evidence is given, data privacy will play a role as soon as these assessments would be required and exchanged (e.g. to acquire public funding for research projects).
- **Scoring System**. The CodeMeter prototype is designed as a learning and self-assessment tool. In order to use the CodeMeter for a formal assessment of compliance with the EU-CoC, definitions of thresholds and minimum levels of compliance would be needed. The comparability of CodeMeter scores could also be enhanced by introducing a system to compare a user's score to the mean performance of other users (benchmarking).
- **Principle-Guideline-Question Correlation**. The loading system used to build the spider net graph is not immediately comprehensible. A more straightforward system would be needed to ensure a clear and transparent evaluation process. To this purpose, however, a more stringent hierarchical correlation between principles and guidelines of the underlying EU-CoC would be required, allowing for a strict top-down approach (principle -> guideline(s) -> question(s) / criteria).
- **Data Privacy**: Data privacy could become a key aspect depending on the role the EU-CoC and the CodeMeter will take. On the one hand, as a tool for self-assessment and learning, all (confidential) data and evidence can be kept local. On the other hand, if the CodeMeter will be used to evaluate compliance (e.g. in the research funding procedure) and compare compliance among different users, some data and evidence would need to be transferred, stored in a central database and assessed by an external body (e.g. the funding body). In any case, data privacy should be disclosed transparently in the CodeMeter tool.

The need for a simple and well-structured implementation assistance tool is expected to persist beyond the revision of the EU-CoC, but due to the close link between the EU-CoC and the CodeMeter, the current prototype of the CodeMeter will need to be adapted according to the results of the on-going revision of the EU-CoC, depending on the scope, role and contents that are defined for the revised EU-CoC. However, the CodeMeter prototype offers the necessary flexibility to cover such developments, and the basic purpose of the CodeMeter (implementation assistance, self-evaluation) will probably remain a need.

Recommendations

- Due to the appreciation of the CodeMeter approach, it is recommended to follow up on this concept. As a voluntary tool for self-assessment and implementation assistance, the CodeMeter will also support researchers in reflecting ethical, legal and societal consequences of their research.
- The CodeMeter should be adapted to the results of the on-going revision of the EU-CoC, to the feedbacks from the prototype testing and be developed in parallel to the revised EU-CoC.

[35] such as participation certificates, publications, risk assessment reports, monitoring results, etc.

3.4.3 Enhancing Transparency and Communication about the EU-CoC

3.4.3.1 Raising Awareness

Raising awareness of the EU-CoC is a precondition and the first step on the path to implementation. As reported in section 3.1.1, awareness of the EU-CoC among N&N experts who participated in the NanoCode survey is around 50%, and publicly available information about the EU-CoC is rare. There is no official platform where information about the EU-CoC is presented, user experiences are exchanged, or help can be found regarding the implementation of the EU-CoC.

Besides the NanoCode project website, the only official page which refers to the EU-CoC is the European Commission's Nanotechnology webpage[36]. However, this webpage is available in English only and it does not provide any further information on the EU-CoC. On the European Commission's Cordis Nanotechnology webpage[37], no reference to the EU-CoC is made. This is particularly surprising in light of its focus on N&N research.

Developing a central information platform is crucial for several reasons. It would make the EU-CoC more readily accessible, rendering its goals, target groups, requirements more transparent, and communicating examples of applications of the EU-CoC. Such platform would also be ideal to inform about past, on-going and upcoming activities in relation to the EU-CoC. In particular, in the short term, it could present a response to the demand for a better follow-up of the various consultations and revisions that have taken place recently. The platform could also serve as the host for the Code-Meter tool (section 3.4.2).

3.4.3.2 Organising the Dissemination Process

The current means of dissemination of the EU-CoC have not been successful in terms of informing and motivating Member States, as well as N&N stakeholders in general, to support the dissemination and implementation of the EU-CoC (section 3.1.2). This is confirmed by the limited number of the consulted N&N experts (around 20%[38]) that were aware of dissemination activities from their national governments concerning the EU-CoC.

Once the revision of the EU-CoC has been shaped and its role in the governance context been determined, dissemination will become important again. Besides the mentioned information platform, a number of ideas and suggestions from the NanoCode stakeholder consultation are hereafter listed. The choice of dissemination means will also depend on the future role the EU-CoC will be given.

- **Academic Context**: "Road shows" or "days of science" at schools and universities could be used to improve awareness of the EU-CoC among young people, students and researchers.
- **Industrial Context**: European Technology Platforms (ETP)[39] could help to disseminate the EU-CoC to HSE managers, research group leaders and people in position of responsibility of research in research organisations

[36] http://ec.europa.eu/nanotechnology/index_en.html

[37] http://cordis.europa.eu/nanotechnology/home.html

[38] This is an average value. The situation is less straightforward when considering variance across countries: e.g. 33% in The Netherlands, 29% in Germany, 17% in France, 7% in the UK.

[39] European Technology Platforms are industry-led stakeholder fora charged with defining research priorities in a broad range of technological areas (Energy, ICT, Bio-based economy, Production and processes, Transport). http://cordis.europa.eu/technology-platforms/home_en.html

- **Education and Professional Formation**: Over the longer term, education and professional formation on N&N will be of increasing importance. Workshops for research professionals could support the implementation of the EU-CoC in practice. Initiatives on the EU-CoC within undergraduate and graduate courses could promote the discussion on ethical issues in the education of future researchers.
- **Marketing Materials**: Visually attractive flyers, available in all important languages, should be developed and used to reach more people and raise awareness of the EU-CoC. They could be distributed at conferences or events.

In the light of the strategic decisions to be taken (section 3.2) and other critical issues identified (section 3.3), increasing the dissemination of the (current) EU-CoC seems to be quite pointless. However, in the meantime, stakeholders should be better informed about the on-going revision process and be involved in the shaping of the future EU-CoC. The situation can be summarized as follows:

- Awareness of the EU-CoC is a precondition and the first step on the path to implementation. To date, awareness amongst the EU-CoC target groups is moderate and there are only few sources of information on the EU-CoC. There is no (official) EU-CoC platform or webpage.
- Dissemination did not effectively reach the target groups of the EU-CoC. There is a limited awareness of both the EU-CoC itself and governmental dissemination concerning the EU-CoC.
- There has been insufficient dissemination of the EU-CoC along the dissemination chain (European Commission, Member States, governmental bodies, organisations and individual N&N stakeholders). Key issues have been a lack of commitment and clear responsibilities for dissemination as well as controversial content elements of the EU-CoC.
- Recent and on-going consultations regarding the EU-CoC lack transparency in terms of the impacts they have on the further development of the EU-CoC.

Recommendations

- As a primary communication measure, an official EU-CoC platform should be launched, independent from strategic and content-related changes to the EU-CoC (see sections 3.2 and 3.3). This platform should inform about past, on-going and upcoming activities and transparently document the consultation and revision process. It could later host the CodeMeter (section 3.4.2).
- Other means of communication should also be developed, depending on the outcomes of the on-going revision, and be closely coordinated with the (renewed) dissemination activities. A number of options, related to different target groups, have been identified: Development of marketing materials; Dissemination through European Technology Platforms; Initiatives on education and professional formation.
- Dissemination activities should be supported by a reference point for the dissemination of the EU-CoC at the level of the European Commission as well as in each of the Member States.
- A clear and unambiguous commitment at EU level, accompanied by a series of (policy) actions to foster Member States and stakeholders to commit to and adopt the EU-CoC is necessary, in particular to push countries which lack of particular coordination actions and clear responsibilities at national level on nanotechnology-related issues. These are key barriers for the implementation of a tool such as the EU-CoC. Former dissemination structures (duties, responsibilities, coordination and

monitoring) should thus be reviewed to identify the reasons for the lack of success at EU and Member State level.

- Explicit responsibilities and goals for a targeted communication about the EU-CoC should be identified. Due to the interdisciplinary character of the EU-CoC, multi-agency collaborations are needed. Activities should be coordinated between European Commission and Member States government agencies.

4 Annex

4.1 Example of Revised EU-CoC Structure

1. Foreword **1**

Outline of the context and background of the (revised) EU-CoC, its role and relevance in the governance context.

2. Quick Overview **2**

Important characteristics of the (revised) EU-CoC: Scope and aim, target groups, benefits of using it. Instructions how to use (CodeMeter), links to contact, help and further information.

User testimonial: How did my organization benefit from adopting the (revised) EU-CoC?

3. Code of Conduct for Responsible Nanosciences and Nanotechnologies Research **4**

Presenting the general principles of the (revised) EU-CoC and their respective guidelines. If a strict top-down hierarchy (principles -> guidelines -> criteria) can be established, this is further enhancing clarity.

Annex I Example of EU-CoC Implementation using the CodeMeter **10**

Annex II Political Context (Commission Recommendation and Council Conclusions) **12**

4.2 List of CodeMeter Criteria

The following table lists the set of criteria which have been implemented in the CodeMeter implementation assistance prototype. Due to the limited target group of the CodeMeter in comparison to the EU-CoC, not all guidelines have been used. For a detailed reference of the CodeMeter see section 3.4.2.

EU-CoC Guideline No	EU-CoC Guideline Content	Criterion No 1	Criterion No 2	Criterion No 3
4.1.2	*With due respect for intellectual property rights, [...] research organisations and researchers are encouraged to make easily accessible and understandable by lay people as well as by the scientific community all N&N scientific knowledge as well as related information such as relevant standards, references, labels, research on impacts, regulations and laws.*	During the last five years I have published a relevant part of my publicly funded N&N research in open access journals or other online public media.	In a dedicated section of my organisation's website, recently published N&N research results are presented to the interested public in a way which is easily comprehensible to lay people.	
4.1.4	*N&N research organisations and researchers should ensure that scientific data and results are duly peer-reviewed before being widely disseminated outside the scientific community in order to ensure their clarity and balanced presentation.*	In my organisation, a standardised procedure stipulates that scientific N&N research results are internally or externally reviewed before being widely disseminated outside the scientific community.	Before scientific N&N results are disseminated outside the scientific community, experts of the relevant disciplines are consulted to ensure clarity and balanced presentation of the publication.	
4.1.5	*Given its potential, [...] N&N research organisations should ensure that N&N research is conducted at the highest level of scientific integrity. Questionable N&N research practices (not limited to plagiarism, falsification and fabrication of data) should be fought as they may entail risks for health, safety and the environment, raise public distrust and slow down the dissemination of benefits from research. Individuals signalling impropriety in research should be protected by their employers and national or regional laws.*	My organisation systematically (e.g. with dedicated software) checks scientific data that will be published for falsification, plagiarism and fabrication of data or results.	Researchers in my organisation are instructed (at least upon taking up a post) about my organisation's values concerning integrity in research, about the consequences of improper behaviour and about how to behave in case they identify questionable research practices.	My organisation provides a point of contact where I refer to in case I identify questionable research practices. This contact guarantees discretion (anonymity) and protection of those reporting such incidences.
4.1.6	*[…] Organisations performing N&N research activities should demonstrate transparently that they comply with relevant regulations.*	I am personally aware of the applicable laws and regulations in my research sector, and I keep myself up to date about relevant regulatory developments.	My N&N research projects are (internally) evaluated in terms of regulatory compliance before submission of the proposal.	Responsibilities to ensure regulatory compliance of N&N research projects are explicitly assigned and transparently documented in my organisation (e.g. on the project or organisation web page).

4.1.8	*The broad directions of N&N research should be decided in an inclusive manner, allowing all stakeholders to enrich the preliminary discussions on these directions.*	My organisation, department or research group maintains some form of regular and open contact with other stakeholders to gather their views, inputs and concerns on its broad directions of N&N research.		
4.1.9	*[...] Research organisations and researchers are encouraged to consider, at the earliest stages and through participatory foresight exercises, the future implications of technologies or objects being researched. This could allow the development of solutions to meet potential negative impacts caused by the use of a new object or technology at a later stage. Consultations with relevant ethics committees should be part of such foresight exercises as appropriate.*	In the past five years, my organisation, department or research group organised or participated in at least one participatory foresight exercise to explore potential future implications of its N&N research.		
4.1.10	*N&N research itself should be open to contributions from all stakeholders who should be informed and supported so that they can take an active part in the research activities, within the scope of their mission and mandate.*	My organisation, department or research group is committed to integrate an interdisciplinary and multistakeholder view into its N&N research projects whenever possible and feasible (e.g. by including risk experts, social scientists, public bodies or NGO experts into the research teams or in the project phase).		
4.1.13	*[...] [N&N research] organisations should encourage fields of N&N research with the broadest possible positive impact. A priority should be given to research aiming to protect the public and the environment, consumers or workers and aiming to reduce, refine or replace animal experimentation.*	My organisation, department or research group is involved in N&N research that is contributing to achieving the United Nation's Millennium Development Goals, e.g. by developing N&N solutions for sustainable food and energy supply, for fighting major diseases, preventing climate change, or providing access to safe drinking water.	My organisation's, department's or group's N&N research contributes to a reduction or substitution of the use of harmful substances or scarce resources, or an improvement of inefficient processes along a product's lifecycle compared to current technologies.	Reducing, refining or replacing (RRR) animal testing is explicitly mentioned among the core values of my research organisation (e.g. in its mission statement).
4.1.16	*N&N research organisations should not undertake research aiming for non-therapeutic enhancement of human beings leading to addiction or solely for the illicit enhancement of the performance of the human body.*	In case my organisation, department or research group undertakes N&N research for non-therapeutic enhancement of humans, the corresponding research projects are supervised and closely monitored by medical and ethical experts.		

4.1.17	*As long as risk assessment studies on long-term safety is not available, research involving deliberate intrusion of nano-objects into the human body, their inclusion in food (especially in food for babies), feed, toys, cosmetics and other products that may lead to exposure to humans and the environment, should be avoided.*	Research involving deliberate intrusion of nano-objects into the human body or inclusion of nano-objects in products that are expected to lead to exposure of humans and the environment is only performed if long-term risk assessments are available or concomitantly conducted/initiated.	
4.2.1	*Students, researchers and research organisations involved in N&N research should take specific health, safety and environmental measures adapted to the particularities of the nano-objects manipulated. Specific guidelines on the prevention of pathologies induced by nano-objects should be developed in line with the Community Strategy 2007-2014 on Health and Safety at Work.*	At workplaces in my organisation, department or research group where nano-objects are handled, nano-specific safety instructions, safety guidelines, work instructions and/or health, safety & environment (HSE) measures are in place, which are adapted to the peculiarities of nano-objects.	
4.2.2	*N&N research organisations should apply existing good practices in terms of classification and labelling. In addition, as nano-objects might present specific properties due to their size, they should undertake research on systems (including e.g. the development of specific pictograms) aiming to inform researchers and more generally people likely to come into contact with nano-objects in research premises (e.g. security and emergency staff) so that they may take the necessary and appropriate protection measures in the course of their duties.*	I am familiar with the UN GHS hazard symbols, signal words, hazard statements and precautionary statements and they are applied according to CLP Regulation 1272/2008 (e.g. if samples of nano-objects leave the research premises).	
4.2.6	*N&N research organisations and researchers should launch and coordinate specific N&N research activities in order to gain a better understanding of fundamental biological processes involved in the toxicology and ecotoxicology of nano-objects man-made or naturally occurring. They should widely publicise, when duly validated, data and findings on their biological effects, be they positive, negative or null.*	My organisation, department or research group has been involved in research activities aiming at better understanding the release, fate and effects of nanomaterials in biological systems or in the environment .	In reporting scientific results about the toxicology and ecotoxicology of nano-objects, I include “null-findings” in my publications if these null-findings contribute to better understanding the fate and effects of nano-objects.

4.3 International Conference

4.3.1 Programme

PROMOTING RESPONSIBLE INNOVATION:
THE FUTURE OF
THE EUROPEAN CODE OF CONDUCT FOR NANOTECHNOLOGIES

Thursday, September 29th 2011, Hotel Silken Berlaymont, Brussels

PROGRAM

MORNING SESSION

Registration, coffee (starting at 8.15)

Chair: Elvio Mantovani, AIRI/Nanotec IT, Philippe Galiay, European Commission

8.50 - 9.00 **Welcome & Opening**

9.00 - 9.20 **Towards an Innovative and Responsible European Research Area**
***Octavio Quintana**, Director, European Research Area Directorate of the European Commission, European Commission*

9.20 – 9.40 **Principle and needs guiding responsible innovation**
***Daniel Bernard**, Senior Scientific Advisor, Arkema*

9.40 – 10.15 **The NanoCode project: the MasterPlan & CodeMeter**
***Elvio Mantovani**, AIRI/Nanotec IT – Italian Centre for Nanotechnologies*
***Christoph Meili**, The Innovation Society*

Coffee break

10.40 **Panel: Making the Code work**
Discussion on strengths and weaknesses of the Code and on key recommendations of the Nanocode Project

10.40 – 10.50 **What responsible innovation means, accountability vs. responsibility**
***Robert Lee**, Co-Director, ESRC Centre for Business Relationships, Accountability, Sustainability and Society (BRASS), UK*

10.50 – 11.00 **Pros and cons of the Code**
***Sylvia Maurer**, The European Consumers' Organisation (BEUC), Belgium*

11.00 – 11.10 **Can the Code be applied?**
***Yves Samson**, Director Nanosciences program, Commissariat à l'énergie atomique et aux énergies alternatives (CEA), France*

11.10 – 11.20 **Applying a voluntary code: the BASF case**
***Carolin Kranz**, BASF, Germany*

11.20 – 12.45 **Panel discussion and full plenum debate**

Moderator: **Antje Grobe**, University of Stuttgart

Lunch (12.45-13.45)

PROMOTING RESPONSIBLE INNOVATION:
THE FUTURE OF
THE EUROPEAN CODE OF CONDUCT FOR NANOTECHNOLOGIES

Thursday, September 29th 2011, Hotel Silken Berlaymont, Brussels

AFTERNOON SESSION

Chair: Elvio Mantovani, AIRI/Nanotec IT, Philippe Galiay, European Commission

13.45 **Extending the boundaries of the Code?**

Round table with representative of different Countries to illustrate the respective position about responsible innovation and discuss the possibility of extending the Code's principles and approach on a global scale and beyond research.

Moderator: Françoise Roure, French Ministry of Industry, chair of the OECD Working Party on Nanotechnology

Panellist:

- **Yoonsuhn Chung**, Korea Institute of Science and Technology (KIST), Korea
- **Bernardo Delogu,** DG Health and Consumer (DG Sanco), European Commission
- **Guanglu Ge,** National Center for NanoScience and Technology, China
- **Leon Gielgens**, Program Director Nanotechnology of Technology Foundation STW and NanoNextNL, The Netherlands
- **Wolfgang Luther,** VDI-Technologiezentrum, Germany
- **Linda Nielsen,** University of Copenhagen, Denmark and European Group on Ethics
- **Jack Stilgoe,** University of Exeter, UK

Questions and answers

16.40 **Closing remarks and future initiatives**

17.00 **Conference closing (chair)**

Information and registration details

www.nanocode.eu

4.3.2 Main Findings during the International Conference

Support for the Basic Idea of the CoC and Status of Implementation

- Support for an easy, simple and short format of the EU-CoC.

From N&N Research to an "Innovation" Code

- The extension of the EU-CoC from nanotechnology to research or responsible innovation in general was supported.
- The EU-CoC should remain a general code which could be complemented by subcodes and / or assistance tools for each technology.
- It has to be decided on which level a revised or new EU-CoC should be implemented (European vs. international level).
- The EU-CoC could possibly be extended beyond Europe and in this case cooperation with the OECD was suggested.

From a Framework of Behaviours to a Standard

- The EU-CoC could become, in the long run, a standard.

Structure and Language of the EU-CoC

- The wording of the principles in general has to be done with care especially for the different national contexts.

The "Accountability" Principle

- There is a consensus that a redraft of "Accountability" as a principle within the EU-CoC is necessary.

Embedding the EU-CoC in the Governance Context: Incentives and Disincentives

- Support for an awareness raising, reflection tool that should remain voluntary.
- Is considered to be rather a systematic approach than a specific guideline whereby the process is more than the result itself.
- It was recommended to foster governance with the EU-CoC rather than implement regulation.

Prototype of an Implementation Assistance Tool: The CodeMeter

- The CodeMeter as an instrument for self-assessment of compliance with the EU-CoC was acknowledged.
- The CodeMeter should support the EU-CoC as a model of reflection and a basis for dialogue.
- The enhancement of the benchmark function of the CodeMeter application was suggested.

Organizing the Dissemination Process of the EU-CoC

- The CodeMeter - in its main idea well-perceived - should be further applied as a learning tool in the dissemination process of the EU-CoC.
- The EU-CoC should be included in the education of scientists.
- It was suggested to create networks where different kinds of stakeholders including industries are together and integrate them in the decisions about the future of the EU-CoC.
- Foster dialogue between society, researchers and industry.
- A specific EU-program was suggested to disseminate basic information and to keep lay people aware of the state-of-the-art in the N&N fields.