

Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

1st REVISION

Analysis of results from the Public Consultation

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Introduction

The “Code of Conduct for Responsible Nanosciences and Nanotechnologies Research” (CoC) adopted on 7th February 2008 being due to be revised after two years, a public consultation has been opened on 21st October 2009 with a deadline set to 3rd January 2010 (See Form in Annex I)). The present analysis is based on the contributions received on 4th January 2010. Although the rather small numbers of respondents do not allow to extrapolate on the situation in Europe, they give nevertheless good indications on the perception of the Code of Conduct and the way it should be revised.

Contributions received

The public consultation has been opened to all stakeholders directly or indirectly involved or interested in Nanosciences and Nanotechnologies Research. In answer to the set of 8 questions (See consultation paper in Annex I), 49 valid answers were received (against 64 for the first consultation in 2007) from 17 countries¹ (4 of which outside EU). More than half of them claimed to represent their organisation (26 out of 49). 6 answers were substantiated by (existing or ad hoc) high quality papers representing for some of them a very significant amount of work.

First contributor in terms of numbers is Research with 19 answers, then Industry (18), Policy Makers (6) and Civil Society Organisations (6).

Two other substantial contributions have been received beside the web consultation (from an individual and from an industry). These two have also been considered when preparing the draft revised Recommendation.

Member States were consulted apart from this public consultation through a set of 4 meetings held in September and October 2009.

Information on the EC Public Consultation

The answers to the first question "How did you get to know the present consultation?" show that the main source of information has been the European Commission itself (65,3%). Within the secondary sources Public Authorities are cited 12 times (26,53%) and Media 6 times (12,24%). 'Others' is cited 4 times (8,16%; e.g. Blog reader, search engine,...) and Industry or industry association 3 times only (6,12%). CSOs, Science museums and Science centres are not cited at all.

¹ AUS, AT, BE, BG, CH, DE, SF, FR, IE, IT, NL, PT, SP, SW, TK, UK, US

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Lessons from Yes/No questions

Out of the 8 questions of the consultation, 7 were to be answered by 'Yes' or 'No' (see statistics and main messages in Annex II).

2. Did you know the existence of the Code of Conduct prior to the present consultation?

More than half of the respondents said they knew the CoC before the consultation. Industry contributors were more numerous to know it (66,67%) than Policy makers, CSOs and Researchers (resp. 50,00 / 50,00 and 47,37%).

3. If Yes, Do you or Does your company/organisation already follow the Code of Conduct?

Nearly 40% said they were applying it, Industry and Researchers being first (resp. 44,44 and 42,11 %) followed by CSOs and Policy Makers (resp. 33,33 and 16,67%). Therefore 88,9% of Researchers knowing the CoC said they follow it, 66,66% of Industry and CSOs, and 33,34% of Policy makers.

Comparison to 2007 consultation: In raw numbers, 88 % of the respondents agreed in 2007 that the Code of Conduct would bring an added value in Nanosciences and Nanotechnologies Research and 86% were ready to adopt such a code (although with some reserve for some of them). Nevertheless, for the issues of Scope (Q2), Principles (Q4) and Restrictions (Q6), figures showed a nearly half-half divide in reaction to the ideas exposed. 100% of researchers and policy makers (although the latter category was not significant with only 3 respondents) agreed that the Code would bring an added value and all of them (but 1 researcher on 19) indicated they would follow the Code. For Industry, Civil Society or Individuals, the agreement dropped respectively to 83, 80 and 85 % which was still a good approbation. The 2010 figures are coherent with 2007 ones although the figures are eroding for CSOs and dramatically for Policy makers.

4. Do you agree with the following statement? "The Code of Conduct brings enough added-value in the EU 'nanoresearch-landscape' and do not need to be revised"

Very few (22,45%) think that it should not be revised, bringing enough added value as it is. None of Policy makers would like the CoC to remain as it is (0%!), Industry and CSOs would like to revise it also (16,67% being for the status quo) followed by Researchers (36,84% being for the status quo).

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5. Compared to the 7 principles underlined in the Code of Conduct, would you suggest adaptation or change to the principles?

A majority (61,22%) would amend the set of principles founding the CoC. There also, CSOs and Policy makers and Industry would like to change or amend the set of principles (resp. 83,33 / 83,33 and 66,67%) against 42,11% only for Researchers who would then rather agree to keep the set as it is.

Comparison to 2007 consultation: If 100 % of Policy Makers agreed in 2007 on the Principles suggested, they were only 79 % of Researchers, 54 % of Industry and the rate dropped to 0 % for Civil Society! The set of principles had been changed in order to take on board the contributions. Obviously CSOs, Policy makers and Industry are still not satisfied.

6a. Do you believe that there are more fields of nanosciences and nanotechnologies where research should not be conducted?

A minority (32,65%) would extend the fields where research should be prohibited. This figure hides strong disparities, 83,33% of CSOs being in favour of more prohibition for research. Policy makers, Researchers and Industry would not extend the prohibitions but to different degrees (resp. 16,67 / 21,05 and 33,33%).

Comparison to 2007 consultation: The divide was also obvious for restrictions to be applied to N&N. Only 33 % of Industry and 37 % of Researchers agreed that there should be restrictions. The rates climbed nevertheless to 67 % for Policy Makers and 100 % for Civil Society!

6b. Do you believe that there are more fields of nanosciences and nanotechnologies where research should be more appropriately regulated?

A small majority (53,06%) would extend the fields where research should be more regulated. There also the general percentage hides a contrasted situation where 100,00% of CSOs would like to see research more regulated (followed by Policy makers at 66,67% and Researchers at 57,89%) against 27,78% for Industry.

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7. Do you think that the scope of the Code of Conduct should not be limited to research?

Three quarters of the respondents (75,51%) think that the CoC should not be limited to research. This high figure is coherent with the general agreement of the 4 categories: 100,00% of Policy makers would like to see the Code of Conduct not limited to research, 89,47% of Researchers, 66,67% of CSOs and 55,56% of Industry.

Comparison to 2007 consultation: Only 67 % of Policy Makers, 54 % of Industry and 53 % of Researchers agreed in 2007 on the scope of the CoC and the rate dropped to only 10 % for Civil Society. There seems to be a clear evolution towards and expansion of the CoC beyond research.

Lessons from comments and attached documents

The above statistical analysis gives already a good flavour of the spirit animating the respondents. Ideas emanating from written comments (see summary in Annex III) and attached documents (including websites) will be considered when drafting the revised Recommendation. Analysis below is performed by type of respondents.

Researchers (19)

Researchers have added only short comments to the Y/N questions (despite the fact that a majority of them would like to see the CoC revised) making it difficult (if not impossible) to find commonalities between them.

Industry (18+1)

Industry contribution is not only the most numerous but also the most argued. Nevertheless, the message coming out of Industry comments is not homogeneous, going from a complete "laissez-faire" to a great need of guidance and even some mandatory measures.

On the positive side the CoC is welcome as an "effective hybrid regulation mechanism" that can be used as a "basis for global dialogue", "prevent trade conflicts and stimulate equal protection of workers and consumers". Positive comments come notably from two European organisations (EuCheMs and CEFIC).

On the negative side it is viewed by some respondents as "totally unnecessary" or "inapplicable" considering the "present writing". Most negative comments come from national organisations arguing that national guidelines and regulations are in place (e.g. DE). The fact that there is already a regulation that can apply to N&N Research is reminded several times (but some contributions are just 'cut and paste' of others). The un-specificity of principles is underlined. Respondents remind also that Sustainable Development includes the economical aspects and that the positive side of N&N should be more visible.

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Policy makers (6)

Contributions from organisations considered as Policy makers may not have a statistical significance given the small number of them (1 German NCP for Nanotechnologies, 1 German Development agency, 1 Australian Ministry and 2 international organisations) but tendency and wording are important.

The German NCP "welcome(s) the Commission Recommendation as an important document to foster a general European-wide debate of possible ethical and safety implications of nanotechnologies and nanosciences (N&N)". This positive introduction is followed by a number of constructive suggestions to improve the text (that will be taken up as much as possible in the revised Recommendation). The German VDI TZ GmbH is suggesting a wording to replace the 'Accountability' principle by a 'Responsibility' principle.

The World Anti-Doping Agency (WADA) expressed strong concerns regarding future application of N&N Research to doping in sports.

The International Risk Governance Council (IRGC) provided extensive documentation on N&N risk governance, underlining that the issue of definition was an urgent one and that the CoC should be expanded beyond research to responsible sales and marketing (a suggestion shared by the Australian Department of Health).

CSOs (6+1)

As for Policy makers, contributions received from organisations considered as CSOs may not have a statistical significance (3 CSOs for the defence of animals, 1 consumer organization and two individuals) but there also, tendency and wording are important.

The three 'animal CSOs' are very coherent and can help precise the wording of the CoC on this aspect (that was already in the 2008 version).

The two individuals are targeting the issue of implants for tracking, surveillance, identification and remote control of people. A contribution is notably supported by useful documentation on US initiatives to cope with this issue ("Bodily Integrity Act" campaign in the US).

The consumer organization is pushing for expanding the scope of the CoC beyond research in order to ensure a responsible use of N&N.

Contacts

Mr. Philippe Galiay, DG RTD-L3, European Commission, (Philippe.Galiay@ec.europa.eu)

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ANNEX 1: Consultation Paper

On 7th February 2008 the European Commission adopted a Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research. This recommendation was followed on 26th September 2008 by Council Conclusions on Responsible Nanosciences and Nanotechnologies. Both documents suggested that the Commission Recommendation and the Code of Conduct should be revised after two years.

Therefore, in view of the said revision, planned for February 2010, the Commission is opening a new public consultation in order to receive new inputs from all people and organisations involved or interested by Nanosciences and Nanotechnologies research in Europe, and notably research, policy makers, industry, media and civil society organisations.

You may see the consultation form on SINAPSE: http://europa.eu/sinapse/directaccess/science-and-society/public-debates/nano-recommendation-2010_revision/. It will be open from Tuesday 20 October 2009 up to Sunday 4 January 2010.

Document attached:

1. Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research
2. Council Conclusions on Responsible Nanosciences and Nanotechnologies

Questions:

1. How did you get to know the present consultation?
 - a. From the European Commission?
 - b. From another public organisation?
 - c. From a Civil Society Organisation?
 - d. From an industry or industry association?
 - e. From a science museum or science centre?
 - f. From the media?
 - g. Other? [Comment]
2. Did you know the existence of the Code of Conduct prior to the present consultation?
[Y/N]

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3. If Yes, Do you or Does your company/organisation already follow the Code of Conduct? [Y/N] [Comment]
4. Do you agree with the following statement? "The Code of Conduct brings enough added-value in the EU 'nanoresearch-landscape' and does not need to be revised." [Y/N] [Comment]
5. Compared to the 7 principles underlined in the Code of Conduct, would you suggest adaptation or change to the principles? [Y/N] [Comment]
6. Do you believe that there are more fields of nanosciences and nanotechnologies where research:
 - a. Should not be conducted? [Y/N] [Comment]
 - b. Should be more appropriately regulated? [Y/N] [Comment]
7. Do you think that the scope of the Code of Conduct should not be limited to research? [Y/N] [Comment]
8. Do you wish to add a personal comment further to the 7 questions above? [Comment]

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ANNEX II: Statistics regarding Y/N questions

Overview:

All 49 contributions (% of Y and number of contributions)	% Policy	% CSOs	% RTD	% Industry	% All
2. Did you know the existence of the Code of Conduct prior to the present consultation?	50,00%	50,00%	47,37%	66,67%	55,10%
3. If Yes, Do you or Does your company/organisation already follow the Code of Conduct?	16,67%	33,33%	42,11%	44,44%	38,78%
4. Do you agree with the following statement? "The Code of Conduct brings enough added-value in the EU 'nanoresearch-landscape' and do not need to be revised"	0,00%	16,67%	36,84%	16,67%	22,45%
5. Compared to the 7 principles underlined in the Code of Conduct, would you suggest adaptation or change to the principles?	83,33%	83,33%	42,11%	66,67%	61,22%
6a. Do you believe that there are more fields of nanosciences and nanotechnologies where research should not be conducted?	16,67%	83,33%	21,05%	33,33%	32,65%
6b. Do you believe that there are more fields of nanosciences and nanotechnologies where research should be more appropriately regulated?	66,67%	100,00%	57,89%	27,78%	53,06%
7. Do you think that the scope of the Code of Conduct should not be limited to research?	100,00%	66,67%	89,47%	55,56%	75,51%
Contribution type (guest) - (personal: 0 - Organisation: 1)		6			53,06%
Contribution type (guest) - (Other: 0 - Policy makers: 1)	6				12,24%
Contribution type (guest) - (Other: 0 - Research: 1)			19		38,78%
Contribution type (guest) - (Other: 0 - Industry: 1)				18	36,73%

First raw findings (all respondents taken together):

1. The CoC was known by 55% of the respondents and 39% of them said that they are already applying it.
2. A vast majority (about 88%) thought that the CoC needs a revision, with more than 60% suggesting adaptation or change in the principles.
3. One third only (32,65%) think that prohibition of research in terms of fields should be extended and slightly more than 50% (53%) wish that research be more appropriately regulated.
4. Three quarter of the respondents think that the CoC should not be limited to research.

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Striking figures (per category of respondents):

1. 0% of Policy makers think that the CoC should not be revised!
2. 100 % of policy makers think that the CoC should not be limited to research!
3. 100 % of CSOs think that research should be more appropriately regulated!
4. 70 % of industry knew the CoC before the consultation!

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ANNEX III: Summary of comments

Industry

3 Ionna Psalti (EuCheMS)

Principles convincing; effective hybrid regulation mechanism; can be used as a basis for global dialogue; accommodate REACH substitution principle; launch Joint Programming Initiative on Standardization, detection and toxicological effects of nanoparticles; maintain voluntary approach but go for more targeted mandatory approach in areas of concern; compliance for relevant R&D projects should be considered; increase transparency and active information by industry; increase public communication on the CoC itself; include more guidelines on how industry can disclose information, on how to demonstrate societal advantage, on how to maintain dialogue on risks and expectations; provide guidelines for interaction between researchers and best practices; set a CoC on distribution and use of nano-objects through life-cycle; set a voluntary reporting scheme on material characteristics and toxicological effects of N&N; naturally occurring NPs should be covered; support detection and monitoring of NPs; Set guidelines on effective monitoring and evaluation mechanisms; guidelines for timeframes and indicators of national programmes; guidelines as to timeframes in monitoring nano-objects; guidelines as to mandatory registration systems; guidelines to provide information on the release of nano-objects from industrial products; guidelines on risk governance frameworks with clear steps for evaluating potential risks of nanomaterials.

4 Peter Hatto (Chair of ISO TC 229 and CEN TC 352)

Revise 'comprehensible'; revise 'accountability'; use ISO definition; need for robust risk assessment protocols before requesting it for funding.

9 Bruno Hubesch (CEFIC)

Thanks to the EC for helping setting up the stage!; change order of principles; define precaution as in COM(2000)1; add 'quality of science', 'sustainable development and human right to adequate standard of living'; text on 'integrity' not reflecting the situation; fundamental research should not be restricted; include 'responsible communication of scientific data and assessments'; the CoC should be better balanced in terms of risk-benefits; it would be advisable to have a CoC for research in general; regulations fully covering N&N based products and their use are in place and should be considered.

10 Hans-Juergen Wiegand (EVONIK)

"Laissez-faire" – Regulation already in place; any CoC should be in line with Responsible Care Global Charter of chemical industry companies; consider opportunities of N&N; CoC not suitable for implementation as too general; a comprehensive and effective legal environment for risk assessment and risk management is already in place; science should be open to all technological options under the principles of good scientific practice; no restriction on fundamental research; a mandatory CoC would hamper competitiveness; CoC should be revised in order to better assess scientific quality of research and improve protection of IPR and of confidential business information.

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14 Carolin Kranz (BASF)
Idem CEFIC!; see BASF CoC;

17 Martin Reuter (German Chemical Industry Association)
Code not suitable; precaution as per COM(2000)1; sustainable development in three pillars; guidelines are being developed by DE; be in line with responsible Care; consider the opportunities; no added value as a comprehensive and effective legal environment is in place already; no restriction on fundamental scientific research; a mandatory CoC would not be applicable; CoC would hamper research and restrain European competitiveness; mandatory code not necessary as national authorities have already established best practices (ex DE); idem EVONIK...

21 Günseli Ozkan
No comment.

27 Ineke Malsh (Malsh TechnoValuation)
Too general to be implemented by researchers; is there a need for CoC?; no clearly unethical or unsafe areas identified yet; current regulation applicable, but how?; main added value is foster international dialogue, prevent trade conflicts and stimulate equal protection of workers and consumers; See Observatory Nano and ICPC-Nanonet.

30 Charles Laroche
No comment.

32 Andrew Auty (Liability (Oxford) Ltd)
Comprehensible to all legitimate stakeholders; Replace 'people' by 'stakeholder' for sustainability; in the principle, include economical risk (e.g. in accountability).

33 Manfred Felske-Zech
"Saarbruecken statement"?

34 Thomas Brendel
No comment.

43 Mike Eaton (European Technology Platform – Nanomedicine – UCB Celltech)
Totally unnecessary code; safety should be a prerequisite to all research projects

44 Ivan Lovric (ETP - MINAM)
Forbid research on human cells, tracking and surveillance of humans.

45 Pentti Eklund (ETP - MINAM)
No comment.

47 Sebastian Nollau (ETP - MINAM)
Very un-specific principles; there should be practicable, focussed and specific regulation for all kind of research; it would be good to extend the CoC to industry but it would be another document.

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48 Christian Wögerer (ETP - MINAM)
Better regulate medical issues.

49 Massimo Rogante (Rogante Engineering Office)
Add to Innovation Principle 'Moreover the eventual benefits to environmental and human health protection consequent to the adoption and the development of N&N should be underlined and the particular merits achieved by the authors should be recognised and awarded by the EC and the related Member States'; an appropriate CoC should be proposed to users of research results.

Supplementary contribution

Jean-Philippe Bourgoin (CEA)
Add to the CoC information, training and reflection of researchers; connotation too negative for the time being; not specific enough; clinical trials are needed (4.1.17); be more practical in the writing of guidelines; researchers should not be liable; violation of HR cannot necessarily be foreseen; priorities are doubtful; present writing is counterproductive; CoC is inapplicable.

Researchers

7 Ahmet Yukselturk
Translate the survey!; should be forbidden for warfare; regulate inclusions in human body;

8 Augusto Morais
No comment

13 Rolf Vermeij
Extend CoC to all research;

15 Albert Romano-Rodriguez (Univ. Barcelona?)
Study impacts on human beings

16 Emilia Balabanova
Standardization, labelling

18 Nicola Goldberg (UKRC)
Little evidence of possible hazards; Scientists should be aware of potential risks and behave accordingly.

22 Norberto Patrignani
No comment

23 Mark Robertson
Adaptability will be required; must cover use of nanoparticles in industry and must not be overridden by trade secrecy laws;

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24 David Bennett
Go beyond research; limited effectiveness and impact if no teeth

25 Davide Mattia
Beef up innovation; how to get long-term safety data?;

26 Alvin Holder
No comment

28 Hugh Byrne
Definitions are too vague;

29 Thomas Melillo
Language issue for Principle 1;

31 Friedrich-Karl Lücke
Regulate food science

35 Tanja Meyer
No comment

36 June Freeland (UK Nanotechnology Safety Forum)
Concerned with Occupational Health and Safety (Exposure)

37 Enrique Llaudet
"More detail on handling"

38 Dante Gatteschi (Italian Interuniversity Consortium on Materials Science and Technology)
No comment

40 Teresa Fernandes
Plan regulatory review

46 Albert Sill
No comment

Policy makers

1 Martin Vogt (VDI – German NCP)
Recommendation welcome; CoC not really Nano specific; Freedom of research; Definition Nano; delete 'comprehensible'; more communication.

6 Olivier Rabin (WADA-AMA)
N&N research on human enhancement should be regulated; use of N&N for enhancement of human performance should be considered malpractice and/or professional misconduct; the CoC should not be limited to research.

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39 Jamiu Ogunbanwo (Dept. of Health, AUS)

Add 'Public Awareness, Educational and Enlightenment program'; extend the CoC to manufacturing, distribution and retail, production.

41 Christopher Bunting (IRGC)

Plan regulatory review as science progresses; what to do with the results of risk assessment research?; military conducted research can be a problem; definitions are needed urgently; the CoC should expand to responsible sales and marketing.

42 Wolfgang Luther (VDI TZ GmbH)

Replace 'Accountability' by 'responsibility': "Researchers should take into due regard as far as possible the social, environmental and human health impacts that their N&N research may impose on present and future generations".

CSOs

2 Samantha Dozier (PETA)

Incentives for animal testing alternatives; minimize the use of animals in safety assessment; encourage scientific journals to publish those who abide by the CoC; share information on results of animal testing in order to reduce it; favour in-vitro and in-silico methods.

5 Suzanne Merz

Note on TiO₂;

11 Anouk Jansens (Dutch Society for the Replacement of Animal Testing)

Give more attention to animal free techniques; prevent research if animal testing is involved; regulate animal techniques; extend the scope to regulatory testing; research data collected through animal testing should be shared by companies so as to avoid duplication; validate screening test which do not involve laboratory animals.

12 Ursula Sauer (Animal Welfare - ALTEX)

Prevent animal experiments in N&N; fund developments of non-animal tests methods; Lisbon treaty provision of Art. 13; an authorization procedure should be implemented; the scope should be extended to cover issues such as the need to determine the ethical acceptability of new products types as well as the likelihood of achieving the goals pursued; change paradigm from in vivo to in vitro test methods.

19 J.M. Rogez

A European organisation for the control of nanotechnologies is absolutely necessary; development of systems should receive authorization in order to avoid problems and dangers for human rights; financial sanctions should be necessary if the CoC is not respected; we must not accept chips in the body; if there is a problem it should be stopped easily; it is necessary to be sure that it will not be developed by malicious people or companies for bad uses; CoC, international organisation and financial sanctions are necessary for all countries not in Europe.

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20 Rob Reid (Which?)

Include 'transparency'; effective debate about the future direction of nano; it is not known where research are conducted and being used; UK voluntary scheme is not working; EC must do more than a CoC in order to ensure public engagement; more appropriate measures need to be taken at the production stage; EC must take responsibility for ensuring nano is used in a responsible way; more appropriate regulation is required to cover product development and commercialisation; CoC far too limited to ensure responsible development of nano; regulation of nano outside research must be covered by EU legislation; EC should not rely on CoC to ensure consumer safety.

Supplementary contribution

Raymond Bell (UK)

CoC is not addressing issue of ICT implants for tracking, surveillance, identification or remote control of individuals; research on non-medical applications of ICT implants should be regulated by MS (as medical applications are by EC).