New, Final NanoFATE Travel Report and Dissemination Input

Name:	Nina Schneider	**Organisation:**	SYMLOG – 262 rue Saint Jacques 75005 Paris France
Title of event travelled to:	EU Workshop: **'EU 2nd Regulatory Review of Nanomaterials'**		
Date of Event:	30th January 2013		
Location:	Brussels, Belgium		

Purpose of event:

This EU workshop (WS) was organized following the publication of the EU 2nd Regulatory Review of Nanomaterials in October 2012.

The aim of the WS was to present and discuss the main findings of the Review with representatives from the European Parliament, Member States and stakeholders.

- ➔ About 250 participants attended the workshop;
- ➔ Workshop was fully recorded (**webstreaming link**)
- ➔ Presentations are available online (see page 11 of this file)

As background: On 3 October 2012, the European Commission adopted the Communication on the Second Regulatory Review on Nanomaterials. This Communication constitutes the follow-up to the 2008 Commission Communication on regulatory aspects of nanomaterials. It assesses the adequacy and implementation of EU legislation for nanomaterials, indicates follow-up actions and responds to issues raised by the European Parliament[1], the European Economic and Social Committee[2] and the Council[3]. As part of the Second Regulatory Review, the Commission also adopted a Staff Working Paper on Nanomaterial Types and Uses, including Safety Aspects. The Staff Working Paper presents available information on types and uses of nanomaterials and analyses relevant information on the safety of nanomaterials.

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[1] Resolution European Parliament on Regulatory Aspects of Nanomaterials (2008/2208(INI), 24.4.2009)
[2] Opinion European Economic and Social Committee; INT/456 of 25.2.2009, Nanomaterials
[3] Conclusions on "improving environmental policy instruments" of 20 December 2010

Your role at the event

No NanoFATE or other academic presentation was given at this official Review event.

Nina Schneider from Symlog (NanoFATE Dissemination partner) attended the WS with the following objectives:

- ➔ Get a feel for the latest state of regulatory decisions and progress on nanomaterial legislation
- ➔ Disseminate NanoFATE project by handing out a 2-page leaflet (+ disseminate and recruit people for our NanoFATE Survey: 'Societal perceptions of nanotechnologies')
- ➔ Identify new contacts for our project dissemination strategy and plans (e.g. identify people for later project workshops, augment e-mail distribution list for NanoFATE communications)

Title of Presentations Given: N/A

Relevant people met with at the event and their organisation – Why they are interesting to others in NanoFATE and/or for our dissemination:

Speakers of the workshop

. Antti Peltomäki	Deputy Director - DG Enterprise & Industry
. Karl Falkenberg	DG- DG Environment
. Gwen Cozigou	DG Enterprise & Industry
. Gernot Klotz	European Chemical Industry Council (CEFIC)
. Eric Poudelet	DG Health and consumers
. Wim de Jong	Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR, Vice Chairman
. Kenneth Dawson	University College Dublin, Ireland
. Bjorn Hansen	DG Environment
. Armindo Silva	DG Employment
. Satu Hassi	Member of the European Parliament (MEP) (Greens)
. John Newham	Chemicals Regulation Policy Unit, Department of jobs, Enterprise and Innovation, Ireland
. Steffi Friedrichs	Nanotechnology Industries Association
. Vito Buonsante	Center of International Environmental Law (CIEL)
. Herbert von Bose	DG Research and Innovation)
. Krzyztof Maruszewski	Joint research Center (JRC)
. Otto Linher	DG Enterprise and Industry
. Catherine Mir	Head of Department for Nuisances Prevention and Quality of the Environment - Ministry of Ecology, Sustainable development and Energy, France
. Franz Fiala	The European consumer voice in standardisation ANEC
. Florian Schellauf	Cosmetics Europe

Workshop (floor) audience:

A large audience attended the workshop gathering big companies (e.g. Apple, Coca-cola, Henkel, 3M, EADS, etc.) as well as Industry Federations and associations, NGOs and consumer associations, people from various Ministries (Member States) and other national Protection Agencies etc.

Summary of event (outcomes, results etc. that you want to signal to NanoFATE partners):

Rather (very) little was said about Environment and/or exposure and/or fate of nanoparticles.

Main questions/concerns during the workshop

→ Is the new definition of nanomaterials accurate enough?
→ Should nanomaterials be considered in the same way as any other (chemical) substance?
→ What framework/tools should be used to identify, register and assess nanomaterials?
→ Will Europe succeed in being an open place for innovation *(this is a big concern of the Commission)* by tackling the risks appropriately, with a simplified regulatory framework that creates no unnecessary burdens on industry, meeting the EU safety standards while allowing growth and job creation in the context of an economic crisis?

Main outcomes of the workshop

The workshop discussion was quite animated. Much debate remains on the approaches of tackling nanomaterial safety and on the conclusions of this 2nd EU Review on Nanomaterials. (In the light of this workshop), it appears that consensus among the actors/stakeholders is not yet/always found and the positions and/or levels of discussion could be summarized as follows:

1/ Regarding the regulatory framework to be used → Views diverge.
- Those who think that REACH is the appropriate framework to deal with the safety of nanomaterials AND that it (only) needs adjustments of its Annexes.
- Those who think that an adjustment of the REACH Annexes IS NOT sufficient.

2/ Regarding the overall approach of tackling the safety issues of nanomaterials → Views diverge.
- Those who defend the (total) precautionary approach.
- Those who think that the approach should be proportionate (based on current experience of nanomaterials).

3/ About the 'case by case' approach → Clarification needed
- In its conclusions the EU Commission recommends the case by case approach but it seems that it is not quite clear what a nanomaterial case is. The need to define and characterize this case by case approach was raised during the workshop.

4/ Alongside the case by case approach, the issue of application → Strong concerns here (in particular from the science perspective).
- Question: to what extent does the safety assessment of a nanomaterial depend on the application? In other words how to be sure that a nanomaterial being assessed as relatively safe when used in an application *A* will also be safe in an application *B*?

5/ Lack of common ground between the various actors (Industry, Policy, Civil society) → Problem and lack of trust.

Sample of reactions on the above questions/issues:

Regarding the regulatory framework to be used , i.e. the Commission's suggestion to use REACH and modify/adjust REACH Annexes

Reactions from the Greens group in EU Parliament (*excerpt from presentation*)

- ➔ Modifications of the Annexes or guidance alone will NOT address fundamental shortcomings:
  - Substances < 1 tonne/year stay out of scope
  - Lack of definition means no clear legal requirements
  - Inadequate volume triggers for data requirements/registration deadlines mean too little data too late
  - Lack of exposure data will remain, due to inadequate hazard classification

- ➔ Knock-on effects of REACH deficiencies : REACH only requires data on exposure for hazardous substances
  - No hazard identification, no exposure data!
  - One will not get exposure data by tweaking the annexes
  - If we do not fix REACH, downstream legislation will stay deficient, and potential risks are NOT addressed upstream

- ➔ Outlook and recommendations:
  - Review of REACH is unlikely to lead to legislative amendments of REACH
  - Commission should make a proposal to fix the deficiencies of REACH by a stand alone "mini-REACH" for nanomaterials

- Commission's action on nano definition was triggered by deficient AND diverging definitions of nanomaterials in EU laws: Member States should continue to take national action for an inventory – preferably in a slightly *diverging* manner - to trigger EU action

Reactions from CIEL/Client Earth (*excerpt from presentation*)

Do we need extra regulation? YES

→ The poor results from REACH and a legal analysis of show us that changes are required to address the need to:
- lower the tonnage thresholds for nanomaterials,
- implement the one-substance/one-registration principle of REACH and ;
- allow appropriate risk assessment for nanomaterials.

→ Annexes changes are not enough. A change in Annexes may have some effects only if it clearly includes nanomaterials features as identifiers and if it would lead to requirement of specific risk assessments (CSA) of nanomaterials. But wouldn't solve other problems.
A new comprehensive nano regulation is needed.
Proposal: The regulation would:
- Apply to all legislation relevant to nanomaterials;
- State the difference between nano and bulk materials;
- Establish an EU-wide register for nanomaterials;
- Establish a medical surveillance program for workers.

Reactions from ANEC (*excerpt from presentation*)

➔ What information do consumers need?
Questions:
- Are consumers adequately protected from (nano) chemicals in products?
- Are consumers/policy makers adequately informed about (nano) chemicals in products?
- Was the COM 2nd Nano Regulatory Review helpful?

➔ REACH is not the solution
Article related problems:
Registration/Authorisation – do not lead to product limits!
Restriction path laborious and time consuming - no quick adaptation
Substance-by-substance evaluation:
excludes bans of groups of substances (e.g. CMR)
excludes a positive list approach (as in FCM regulation)
excludes non-toxic effects of chemicals (e.g. smell) or proxy indicators (e.g. TVOC) or functional aspects (e.g. FRs)
No systematic checks of chemicals in articles
Inadequate consumer information provisions

➔ 2nd Nano Regulatory Review
COM position unacceptable
- joint open letter by NGOs including ANEC – strong disappointment and deep concerns
- disregards scientific opinions
- grossly fails to address the current regulatory loopholes
- ignores EU Parliament resolution of 2009
- runs counter to opinions of many Member States
- looks like industry paper

➔ Alternatives
Chemicals in products

• Strengthened regulatory framework is needed, e.g. for materials in contact with water supply or food, products for children, construction products, products leading to indoor emissions, clothing, textiles, PPE, furniture, …..
• Full transparency – obligatory full declaration of chemicals
Nano specific provisions
• REACH modification (definition, nano form as new substance, no phase-in, changed tonnage triggers, CSA always required…)
• Adaptation of product regulation – no consumer exposure unless independent assessment confirms safety (approval), in some cases labeling (where provisions already exist)
• Mandatory nano reporting obligations - product database

Precautionary approach VS Proportionate approach.

Position of the DG Enterprise and Industry (*excerpt from speech*)

Much of the past discussion on nanomaterials has been based on incorrect assumptions.
We know much more about the hazards of nanomaterials than the public debate lets us believe and much of the data suggest that many of the nanomaterials are of rather low toxicity. This doesn't mean that there are no safety issues. However it means that our response has to be a case by case approach. Our response must be proportionate to the potential risk. And this is what the Commission proposes. There should be no misunderstanding: the Commission definitively intends to take action in nanomaterials whenever it is regarded as necessary. We want to use tools which deliver results quickly and effectively and we do not want to create new regulatory burdens where we are not convinced that it is justified.

Position of the DG Environment (*excerpt from speech*)

We have assessed REACH and our conclusions are clear: REACH has the potential but there are a number of deficiencies and specificities that we need to address when it comes to arrange the technical details of importance to nanomaterials. We think that a technical revision of REACH will make the best assessments for nanos and this will continue to be a priority action for the Commission. However, there will be nanomaterials that will not be covered by REACH as it is presently defined due to their low volume. We will have to discuss, think and assess how to deal with these issues, in particular nanomaterials with very low volume.

(workshop participant) from the Greens group at the EU Parliament (*excerpt from comments*)

In the Commission's communication it says clearly that we should avoid generalization from certain materials to others but I had the feeling that in the introduction of the Deputy Directory General, exactly this was done! You were referring to some amorpho silica (?) and carbon black and that there wouldn't be any evidence of the effects of those but what does that tell us about carbon nanotubes, about nanosilver? Very little! In the communication you state that nanomaterials are similar to normal materials and that some may be toxic and some maybe not. This is not a basis to decide on regulatory decisions. Coming to my question: The heading of this session is the knowledge base and it was made clear that the pace of innovation is so fast that we do not have the sufficient information that alone [provides] safety information for the legislator to make really decisions. M Falkenberg stressed the need to create public confidence. Why does the commission think that they can get the necessary knowledge for action without any further legislative changes and possibly even without an inventory?

➔ **Response from Gwenn Cozigou** (*excerpt from comments*)
The commission shows that it wants to defend a case by case approach. We are actually doing what we can and we have analyzed and come to the conclusion that we have the framework (REACH) and that it might have to be adjusted and we will also do that (we have prepared a preparatory work on that). This said, we have to be proportionate as well. The idea is not to prohibit everything until we know everything. As to the registry, it is going to be subject to an impact assessment and we will

come back to that once this impact assessment is done.

(workshop participant) Women working for ECOS (*excerpt from comments*)

The commission says that it can be concluded through the OECD results that nanomaterials can be assessed as other chemicals and that we only need minor adjustments. But we see that there is still a lot of work to do in this area: there are new tests, guidelines to be developed, others need to be adapted. We have even seen today that we are facing important issues for the characterization and identification of nanomaterials, also for the exposure assessment. So there are key elements related to the risk assessment that are not yet solved which means that we are still in a situation of lack of knowledge about the hazard of these substances. We wonder why in the meantime we do not have these tools to know more about nanomaterials; why the commission in this lack of knowledge is not taking a more precautionary approach instead of assuming that no data means no harm. We would rather put the burden on the industry to prove their data. No data, no market. This is the position from NGOs.

➔ **Response from Gwenn Cozigou** (*excerpt from comments*):
1. As the commission said, there is no reason that nanos are more hazardous than in non nano forms. This should be at the origin of our thinking.
2. We are extremely active on different fronts in order to increase knowledge and there is work going on REACH annexes. That being said, one has to think if he wants to kill a technology in order to be sure that we have an encompassing approach. We have an encompassing approach, we want to have a case by case approach but we also want to work with method.

➔ **Additional reaction from Gernot Klotz** (*excerpt from comments*)**:**
From the industry side 'no data no market, I would even support that because if you go in innovation, of course you have data! The debate here is rather do we have enough data but just to be clear, if we invest in certain product development, we also want to know if they are safe. If we look at the presentations of Mr Dawson and De Jong, we can say that there are a lot of data available. We can still have a discussion as to whether that is enough or if we need another study. But in principle I think we can do and assess this.

➔ **Kenneth Dawson** adds to the above questions/discussions (*excerpt from speech)*:

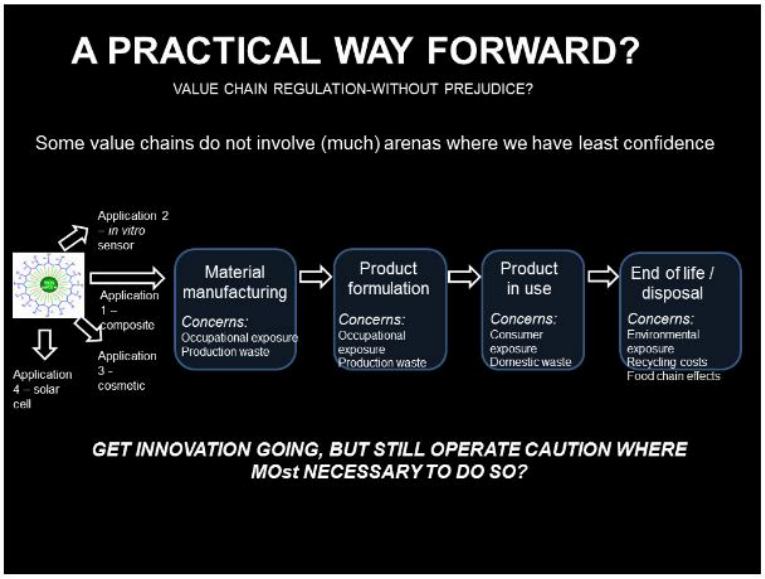
It does seem to me that one of the earlier speakers from the audience had remarked that what we know about earlier materials tells us relatively little about new materials. I think that this is correct and it was a point I did try to stress : we do need to continue to look at all these situations and constantly renew and question them. It seems to me that it is a good argument to look at things case by cases because we simply cannot be sure based on old legacy materials that have been tested on us what is going to happen in the next generation.

About risk assessment case by case and per applications of nanos

Bjorn Hansen: Data generation and testing for nanomaterials are possible based on current risk assessement requirements > Assuming that data are provided for each nano 'case'. What 'case' means will have to be identified and defined.

Kenneth Dawson (*excerpt from speech and presentation*):
'The challenge we face is not just about legacy, it is very fundamentally about innovation and how we handle innovation. What it looks like is that if you ask us to look at all these new materials [shows nanoflowers] and answer the question 'are they safe in every possible application or circumstances?' I think we will be overwhelmed. On the one hand we are mastering the field but on the other hand I don't think that in the current climate we will be able to handle the challenge. I ASK you to consider the possibility that we could look at different materials for different applications. And on an applications basis, perhaps begin to make judgments. For example, an additive in window glass might be a relatively safe product and might be a relatively easy assessment to make. That same

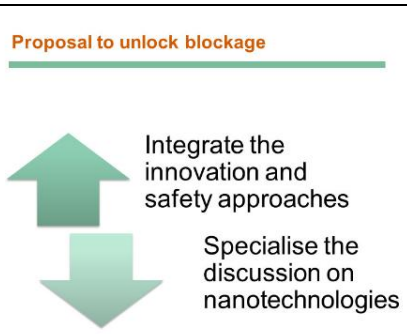
nanomaterial in baby food might be a catastrophic decision and you cannot answer those 2 questions at the same level I think.'



About lack of common ground between the various actors (Industry, Policy, Civil society) → Problem and lack of trust.

Gernot Klotz (*excerpt from speech*)

Europe faces unique societal changes. The effort to keep our standard of living is increasingly under competition, also against other regions. The deployment of enabling techs is not only an industry issue; it is an issue for society. Since many years we have intensive stakeholder dialogues and discussions but we are still stuck in a kind of Mikado situation (public policy – social trust – instruments). There is a lack of common ground between the various players. The societal trust is not there or is decreasing because of the public policy. The investments are missing because of the policy and the social trust.
Nano deployment needs complex systems to work together: need for trust in smaller companies, big companies, consumers etc. If one part of this chain gets lost, the deployment will not happen with all the consequences. Are we in this situation?= every stakeholder looks to its own targets and fights an epic battle. This is happening while in other regions, the world is speeding up the deployment and will soon flood the EU market with products based on nanomaterials and nanotech, all uncontrolled and not including the safety standards such as the ones the EU would like. A battery is not a baby bottle. If we treat nanomaterials only as a technology, we all take decisions on all applications with all tangible consequences. A politician asked me a few weeks ago: can we not stop production for three years until we are clear about certain questions? I respond: Do you accompany me to my employees to tell them 'you are out of job for three years till we know'?! We have to think about how we can speed up things together. We have to embark with new innovative ways to deal with topics and give EU the chance to have its standards on innovation AND integrated safety leading at a global level. How to unlock this situation?



There is not one nanotech but different technologies depending on the applications. So let's talk about nanotech and tackle them in a different way with an integrated risk strategy. Innovation is not only about industry and technologies. It's about mind set change. I urge all of us to move out of our castles and discuss nanotech and innovations with […] safety approaches. We cannot afford to miss this and not to use this approach. Let's be innovative on how we move forward and –regulation-, let's be clear, is one of many parts but it is also about trust and working together for industry and society as large.

Other relevant information for other NanoFATE members:

Available in this section:

1/ Quick overview of the conclusions of the second Regulatory Review. By Speaker Bjorn Hansen – Head of unit Chemicals in DG Environment

2/ Full agenda of the meeting and all presentations available via active links.

3/ FYI: New EU Project 'NanoREG' will start in few weeks.

1/ Quick overview of the conclusions of the second Regulatory Review. By Speaker Bjorn Hansen – Head of unit Chemicals in DG Environment

Why this 2nd Review?:

→ Initial review was made in 2009. Parliament, EESC and council requested additional
→ (what to test and how?) Sources for the reviews were/are:
SCEHIHR 2009. As there is not yet a generally applicable paradigm for nanomaterial hazard identification, a case by case approach for the risk assessment of nanomaterials in still warranted.
OECD 2012 "the approaches for testing and assement for traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials"

Conclusions on REACH and Nano
→ REACH registration and proof of safe use can work for nanomaterials.
> Case by case approach should be respected
> Each type of nanomaterial should be clearly described
→ Data generation and testing for nanomaterials are possible based on current risk assessment requirements
> Assuming that data are provided for each nano 'case'. What 'case' means will have to be identified and defined.
> Good description of test conditions and type of nanomaterial.

Did REACH registration work for nano?
> As of Feb 2012

- Voluntary tick box nanomaterial ticked in 7 registrations and 18 notifications
- Many more registered substances are obviously nanomaterials or have nanomaterial forms
> Registration dossiers generally unclear whether and how they cover nanomaterials
> therefore more specific requirements in REACH annexes are necessary

Work plan and timetable
> Focus on REACH annexes – Comitology [process by which law is modified in committee]
> Evidence base: JRC nano support + new study (Dec 2012)
> CASG Nano (sub group working on REACH) to be consulted (April 2013
> Public consultation (Feb – May 2013
> Impact assessment Board (Sept 2013)
> If appropriate draft measures within this COM Mandate

→ The Nano Review also covers a number of other legislations
> Worker protection: ongoing investigation in the workplace- changes to worker protection legislation necessary? ; EU OSHA publications and website review annexed to SWP
> Consumer product safety legislation: overview of latest developments on cosmetics, novel food , medicines, medical devices, food contact legislation
> Labelling of ingredients, in particular available to the consumer
> Environmental legislation

In our in-depth study in the environmental *acquis*[1] that is related to nanomaterials our conclusions is that if we get certain paces of information then the environmental *acquis* can work well for nanomaterials and this piece of information is exactly that piece of info that is generated through the registration process. So there is a dependency on REACH producing the results that it should but if it does then indeed and in general the environmental *acquis* works - even if here and there there are little things to be fine tuned, it doesn't look too bad.

EU nanomaterial registry?
> French legislation
> EU web platform for 2013 – references to all relevant information sources
Impact assessment for registry nanomaterials below the REACH tonnage volumes and outlined here:
"to identify and develop the most adequate means to increase transparency and ensure regulatory oversight, including an in-depth analysis of the data gathering needs for such purpose. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorization schemes".

Next steps
Own initiative report by EP
Council conclusions?
Discuss with stakeholders

2/ Full agenda of the meeting and all presentations available via active links.

Opening

Antti Peltomäki, Deputy Director General, European Commission, DG Enterprise and Industry

Karl Falkenberg, Director General, European Commission, DG Environment –speech not yet available

[1] The environmental *acquis* – "that which has been agreed upon" - comprises approximately 300 European legal instruments, mostly in the form of directives. In broad terms the *acquis* covers environmental protection, polluting and other activities, production processes, procedures and procedural rights as well as products.

Session 1: The Market Potential and Knowledge Base

Gwen Cozigou, European Commission, DG Enterprise and Industry - **The potential of nanomaterials to create growth and jobs**

Gernot Klotz, CEFIC - **Nanomaterials as a key enabling technology**

Eric Poudelet, European Commission, DG Health and Consumers - **Assessment of nanomaterials in food, health and consumer products**

Wim de Jong, SCENIHR, Vice-Chairman - **SCENIHR´s opinions on nanomaterials**

Kenneth Dawson, University College Dublin, Ireland - **How hazardous are nanomaterials?**

Discussion on Session 1 - [(92:10 – 107:56)]

Session 2: The Policy Response

Bjorn Hansen, European Commission, DG Environment - **The main conclusions of the Second Regulatory Review**

Armindo Silva, European Commission, DG Employment - **Worker protection legislation and nanomaterials**

Satu Hassi, Member of the European Parliament - **Initial reactions and planning in the Parliament**

John Newham, Department of Jobs, Enterprise and Innovation, Ireland - **Planned follow-up to the Second Regulatory Review by the Irish Presidency**

Steffi Friedrichs, Nanotechnology Industries Association - **Why is existing regulation sufficient to ensure safe use of nanomaterials and what can industry do to generate trust?**

Vito Buonsante, EEB/ClientEarth - **Is there a need for more regulation on nanomaterials and why do we need to treat nanomaterials differently from other chemicals?**

Session 3: Panel Discussion on the Policy Response

Panel Discussion moderated by Philippa Jones, Chemical Watch: **What can the European Union do to fully use the innovation potential of nanomaterials while ensuring their safety?** - [speech (268:45 – 340:28)]

Panellists:
Bjorn Hansen, European Commission, DG Environment
Gwen Cozigou, European Commission, DG Enterprise and Industry
Dick Jung, Deputy Director Safety and Risks of the Ministry of Infrastructure and the Environment, Netherlands
Peter Smith, CEFIC
Steffi Friedrichs, Nanotechnology Industries Association
Vito Buonsante, EEB/ClientEarth
Aida Ponce, ETUC

Session 4: Further Development of the Knowledge Base

Herbert von Bose, European Commission, DG Research and Innovation - **Fostering safe and**

responsible nanotechnology innovation and supporting science-based regulation

Krzysztof Maruszewski, European Commission, Joint Research Centre - **Addressing needs for information on nanomaterials**

Otto Linher, European Commission, DG Enterprise and Industry - **The Commission's plans for an impact assessment on the most adequate means to increase transparency**

Catherine Mir, Ministry of Ecology, Sustainable Development and Energy, France - **What are the objectives and impacts of the planned nanomaterial registry in France?**

Franz Fiala, ANEC - **What information do consumers need?**

Florian Schellauf, Cosmetics Europe – **The view of the cosmetics industry on nanomaterial registries**

Discussion on Session 4 - [(435:00 – 451:30)]

Closure

Fabrizia Benini, European Commission, Member of Cabinet of Vice-President Tajani

3/ FYI: New EU Project 'NanoREG' will start in few weeks.