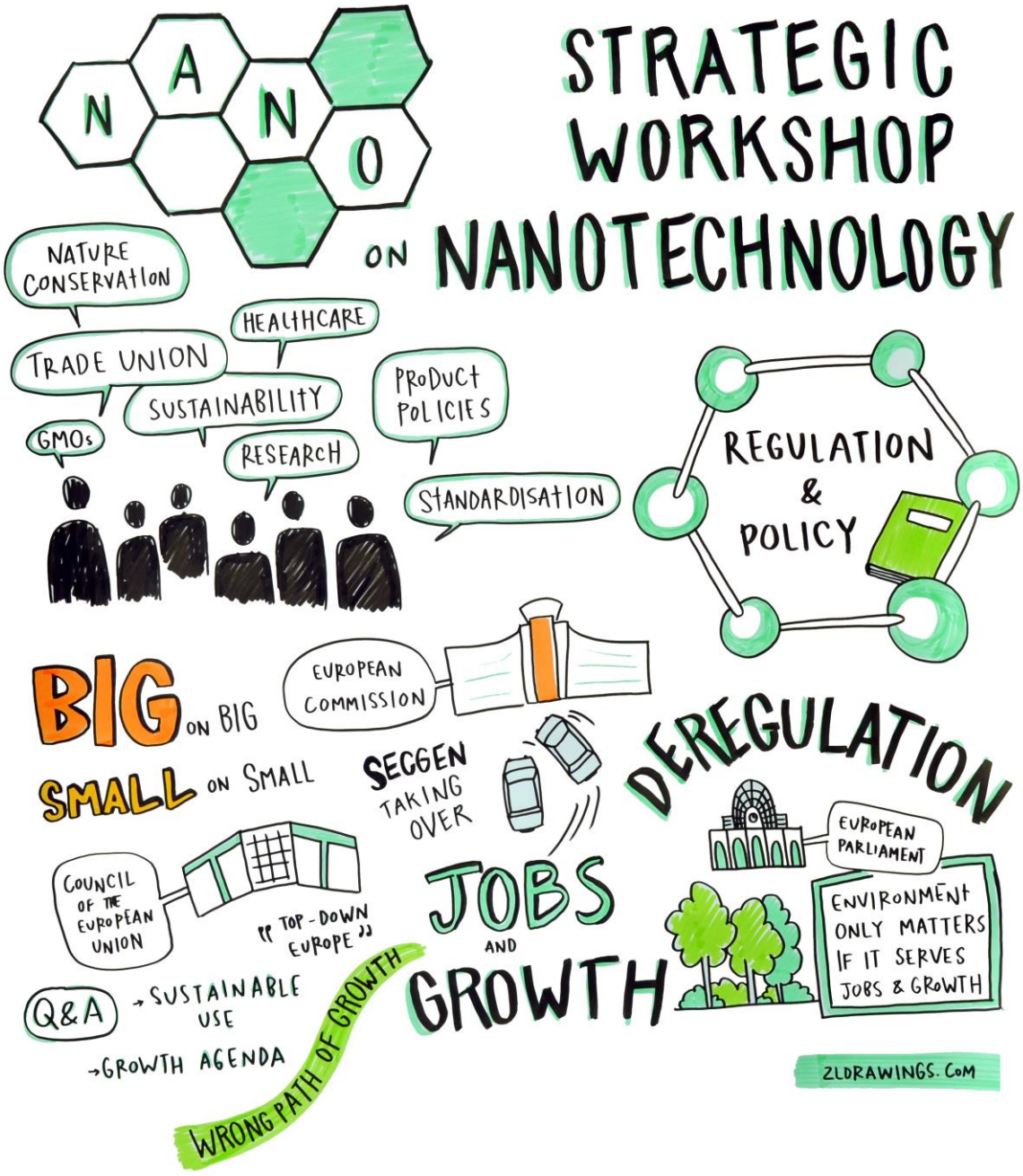
STRATEGIC WORKSHOP ON NANOTECHNOLOGY

Bridging the gap between policy and science
Event Summary

Tuesday 10 February 2015 – Brussels, Belgium



Topic:	Page
1. Welcome and objectives	**2**
2. Keynote speaker, Axel Singhofen, The Greens	2
3. Technical challenges in nano policy making	**3**
4. Technical challenges and the role of "technical bodies"	6
5. Morning Conclusions	**7**
6. Nanomaterials Food Factory - Role Game	8
7. Ensuring risk assessment of nanomaterials to establish a precautionary based regulatory framework	**8**
8. Toxicity and eco-toxicity of nanomaterials	9
9. Risk management of nanomaterials	**10**
10. Conclusions and Next Steps	11

1. Welcome and Objectives

David Azoulay (The Center for International Environmental Law, CIEL)

The objectives and focus points of the session were summarised in the following points:

- Increase the capacity of civil society in understanding the challenges posed by nanomaterials (NMs) in products, including food and food contact materials
- Discuss current policy and regulatory priorities
- Present specific technical difficulties to regulate and minimise the risks of NMs
- Provide updates on the work at OECD, ISO and CEN level

2. Overview of the Current Nano-Regulatory and Policy Context

Axel Singhofen, Advisor on Health and Environmental Policy, The Greens

The keynote speaker, **Axel Singhofen Advisor of Health and Environment Policy for the Greens in the European Parliament (EP)**, delivered a passionate speech about the new institutional balance of power between the new European Commission with their (lack of) environmental agenda and the European Parliament and its impacts on current and future environmental policies.

Significant structural and policy changes have taken place in the Commission. The new Directorate General for Environment is now responsible for two areas; Environment and Maritime Affairs & Fishery. The immediate concern is that important environmental issues will inadvertently be neglected. Axel Singhofen stressed that new environmental policies go towards the direction of deregulation and of putting many laws under assessment, e.g. on air quality, nature conservation, etc. He also criticised the decision of withdrawing the circular economy package, even though the parliament repetedly has voted for it; a package from which both the environment and the society could have benefited from. The explanation lay in the fact that the responsibility of the Commissioner for Environment, Mr. Vella, is directly connected to the agenda of Mr. Katainen, who is in charge of jobs and growth. Singhofen announced that whilst jobs and economic growth are the Commission's top priorities, the environment and nanotechnology are not, and in effect the three pillars of sustainability (economy, environment and society) are no longer reflected in the Commission's policy making. Singhofen continued by questioning the process of democratic decision making in the EC,

which now appears to have taken a top-down approach, where environmental ministers cannot succeed in getting their views echoed at a higher level within the council.

With regard to NMs in food and information requirements, MEPs put forth an amendment to the existing definition to bring it in line with EFSA recommendations, i.e. a threshold of 10% particle distribution in the nano-range scale in contrast to the 50% proposed by the Commission. In addition, a moratorium on the use of nanomaterials in food was proposed until trustworthy testing methods are available. Singhofen also mentioned legislative proposals in the pipeline. The Commission proposed to exclude additives (at nano-scale range) from the ingredient lists of food, but the European Parliament opposed a veto to the delegated act to ensure more information is available for consumers through the labelling of NMs. As a result, the Commission will have to come forward with a revised proposal. The EP has also opposed to have the wording "intentionally" next to "manufactured nanomaterials". This is an important aspect as it will ensure that all manufactured nanomaterials are to be treated according to existing health and safety rules, including releases from by-products and diffuse emissions. The Greens are pushing for an inventory of nano-containing products, including food products and food contract material. However, as DG Grow is not supportive of the idea and see limited benefits for an inventory at EU level, they have boycott it.

Singhofen also announced that EC is close to an agreement with regard to REACH Annexes. The impact assessment board will meet in April 2015.

Singhofen concluded his speech by discussing how nano-related policies are viewed within the Commission, suggesting that it will not be one of their priorities. Overall, he predicts that the Commission is not keen on changing the definition of NMs nor to prepare a legal proposal for establishing an EU registry for products containing NMs. Two legal proposals are currently expected by the Commission: the review of the Reach Annexes to include nano-specific requirements for physical-chemical characterisation and toxicological profile of NMs, and the response to the EP request from 2009 concerning the need for an inventory for products containing NMs.

Finally, the speech was concluded with a note on TTIP. Singhofen argued that the U.S is fundamentally against REACH and he does not see any reason of including them in something they are opposed to.

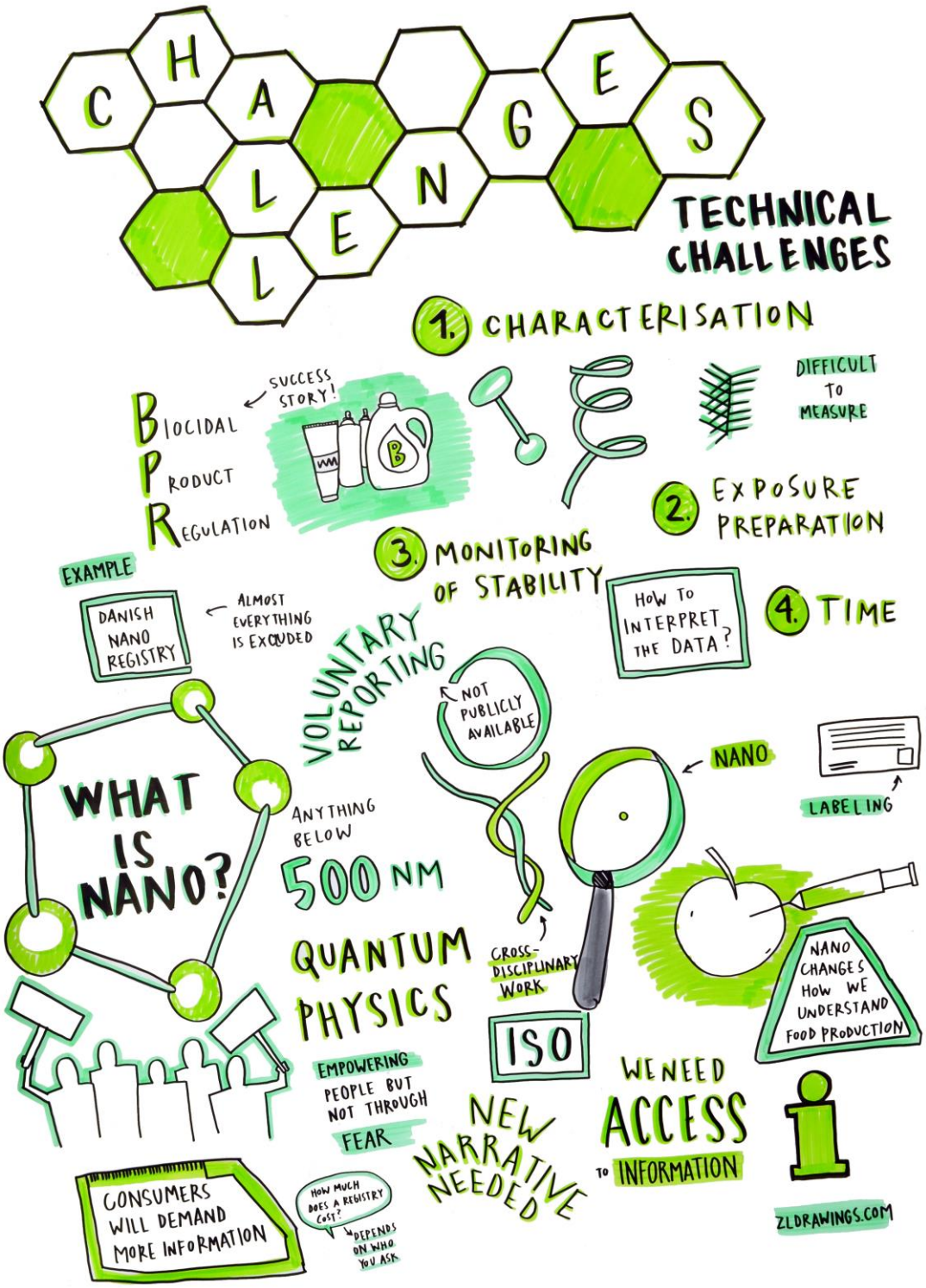
3. The Importance of Technical Challenges in Nano Policy Making

Dr. Steffen Foss Hansen, Ass. Professor, DTU Environment and Nanotechnology

Dr. Steffen Foss Hansen from the Technical University of Denmark (DTU) explained the science behind nano-materials and how characterisation, definition, measurements and risk assessment are relevant to understand the need for regulation. He emphasised the vast technical challenges how relevant they are to the development of policy and the regulatory framework for nanotechnology.

Biocidal Products Regulation (BPR) was used as the main example, due to its ground-breaking nature when dealing with NMs. BPR is the first legal text with a definition on "nanomaterial". Additionally, BPR's authorisation process required industry to present a separate dossier (with all data

requirements) as opposed to REACH. Dedicated risk assessment is needed when NMs are used in biocidal products.



In his presentation, Dr Hansen elaborated on the various technical challenges faced by his DTU research team towards making a scientific risk assessment for a product containing NMs:

Material characterisation:

Characterisation of NMs deals with measurement techniques and harmonised laboratory procedures to establish the nano-structures at hand, their physical-chemical characteristics and potential behaviours. The latter is especially relevant when NMs are included in complex matrices (mainly solid or liquids) such as food and drinks.

A prominent example referred to was Zinc oxide (ZnO), which can be observed in the laboratory in 17 different forms, all sharing the same molecular formula. What makes each of them unique is their shape, size, and molecular structure which in effect determines their reactivity and behaviour when released in the environment. One thing NMs have in common is their highly reactive nature due to their very small size.

Potential issues:

- Various characterisation methods, often a combination of them is needed to provide different characteristics;
- NMs in complex matrices appear as non-spherical particles and in the form of aggregates/agglomerates;
- Currently not able to measure size for non-spherical nanoparticles with the methods we currently have;
- Size is an important characteristic influencing NM toxicity.

Exposure preparation, toxicity testing and time (dynamic testing system):

There are four different methods to prepare a sample, resulting in different visual representations of the nanoparticle in the sample solution (solvent, stirring with water, encapsulation, sonication). All methods will somehow affect the shape and size of NMs.

Knowing how a sample is prepared is necessary to interpret toxicity results. The sample media and particle concentration have potential effects on the solution's stability. Since nanoparticles change dramatically over time, toxicity testing has to be carried out accordingly.

Due to a dynamic test system it is challenging to understand how and in which way particles interact. In most cases, after 48-72 hours sample stability goes down to zero, thus significantly limiting the possibility to study long-term effects. Higher concentrations of NMs in samples might also impact the stability of the sample solution. To summarise:

Important to know:

- How was the sample prepared;
- Minimisation of particle aggregation seems the best approach to deal with changes over time;
- Determining the residue and density is crucial for exposure assessment.

Potential issues:

- Sampling methods will affect shape and size of nanoparticles;
- When nanoparticles are put in media there is a decrease of absorbance with time;
- The bigger the concentration of nanoparticles, the less stability of the solution;
- Limited guidance available;
- Lack of access to information for products containing nanoparticles hinder the possibility to conduct risk assessment;
- REACH, the regulatory framework for registration and authorization of chemicals is often considered sufficient by regulators and industry while it appears that the complexity of nano is beyond our regulatory capacity.

The inability to handle these technical challenges in a common, agreed, scientific way hampers policymaking. At the moment, it is difficult to establish Command & Control regulation. In the current legal framework, it is not foreseen to share the challenges of REACH with scientists and academics and this is somehow preventing us as a society to make progress in properly regulating nanotechnologies.

In his concluding remarks, Steffen Foss Hansen mentioned the example of the Danish nano-registry, which will not support the further access of data on NMs and their potential impacts in consumer products. Almost all product categories containing NMs were excluded for being registered, except of biocidal products with the objective of keeping the registry manageable. The real reason appears to be that there is one person from the Danish EPA who has a special interest in the specific products and their potential impacts when containing nanoparticles.

The Danish EPA were criticised by civil society for making simple things look difficult, for their lack of transparency, and for having the intention to not make the registry publicly available.

4. Technical Challenges and the Role of "Technical Bodies"

Ian Illuminato, Friends of the Earth

Ian Illuminato from **Friends of the Earth,** presented technical challenges and the role of technical bodies in addressing the application of NMs in consumer products, including food. According to him, when looking at NM behaviour we are moving into the realm of quantum mechanics. This raises many concerns, mainly on potential effects in the human body.

Currently, in the standardisation of nanotechnology, the technical committee ISO TC 229 and its' working group 3 is dealing with the health, safety and environmental aspects, for example persistence and occupational hazard due to exposure to NMs. He emphasised on the importance of promoting standards that focus on the above issues and on the inclusion of many researchers across disciplines.

What is positive until now is the large output of standardisation deliverables showing the market relevance of nanotechnologies, the many liaison members contributing to the process and a continuous contact with a number of scientists and regulators, making this an unquestionably valuable learning process for NGOs.

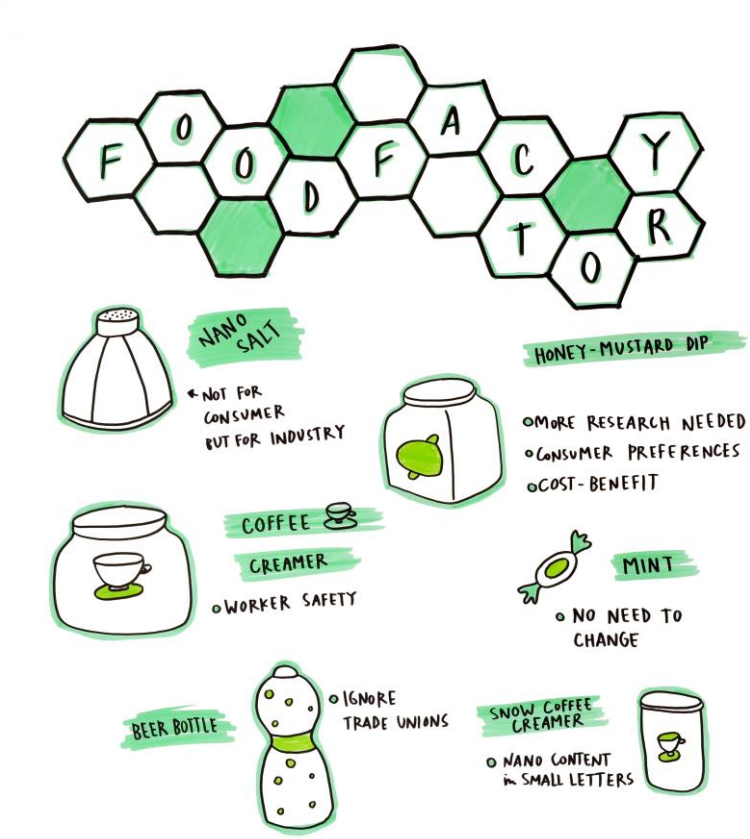
On the negative side, standardisation processes are time consuming, expensive and results come after years of work. Given the complexity of the issue and the interests at stake, the lack of knowledge on the part of important stakeholders is undoubtedly also a barrier in such discussions.

Ian Illuminato concluded his presentation by reminding the audience that civil society should not take extreme standpoints, and instead communicate with all stakeholders, even those on the other side of the table, and to be careful not to overuse media.

5. Morning Conclusions

David Azoulay, CIEL

David Azoulay concluded the morning sessions with a few thoughts, noting that despite the many challenges NGOs and other stakeholders face in this area, we are all part of the solution to address these challenges. It is important to discuss the challenges within the broad stakeholder community in order to overcome them and to constantly build up knowledge on emerging nano-issues.



6. Nanomaterials Food Factory – Role Game

The workshop attendees were split into groups and asked to think of the implications of innovating and modifying a food product to include NMs, and then introducing it to the market from the perspective of the manufacturer. Products which were discussed included salt, mints candies, honey mustard, and coffee creamer powder. Discussions amongst groups showed that from a manufacturers' perspective, the potential consequences for introducing nanomaterials in food products is minimal.

7. Ensuring Risk Assessment of Nanomaterials to Establish a Precautionary Based Regulatory Framework

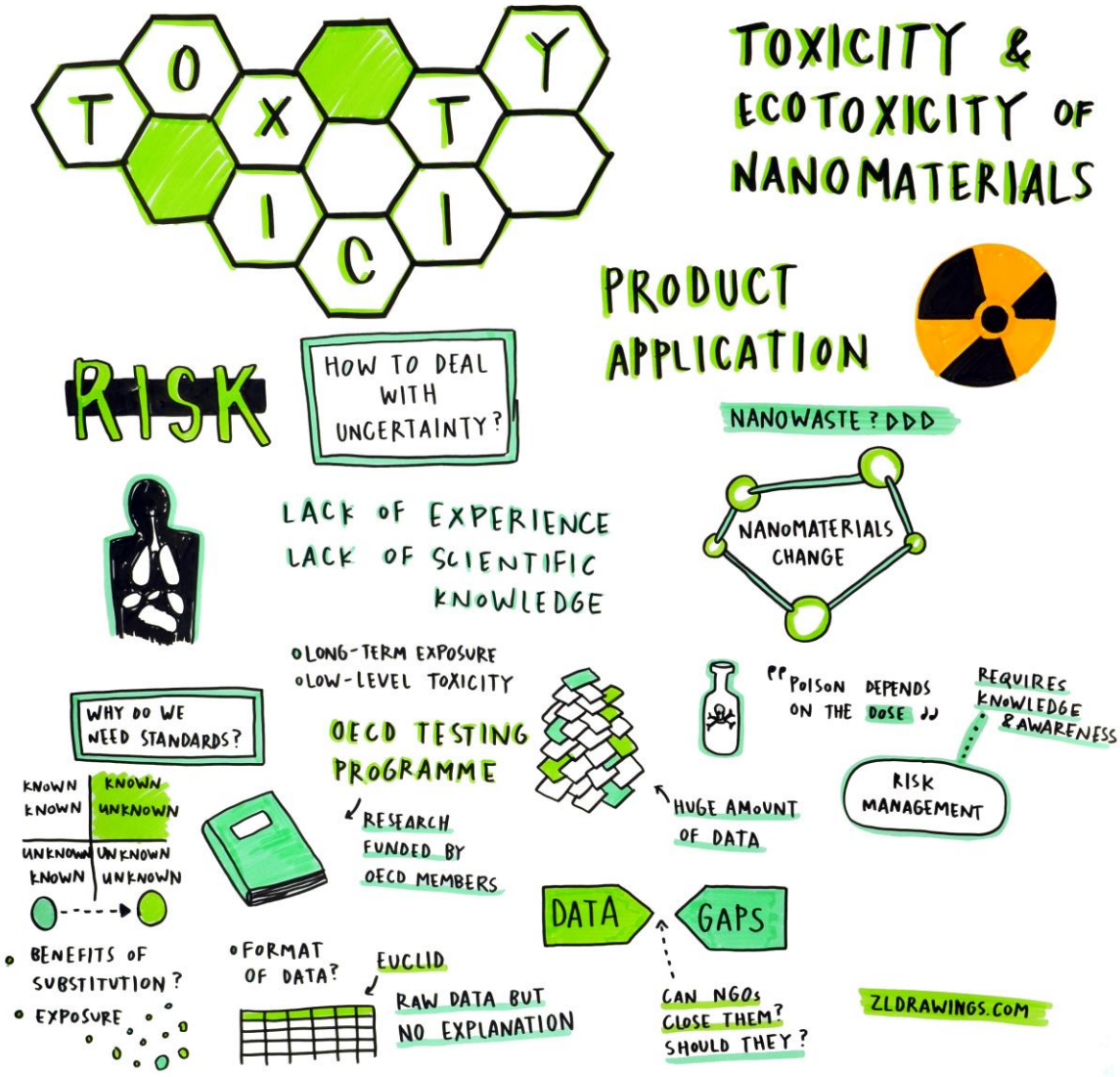
David Azoulay, CIEL

David Azoulay (CIEL) presented the CIEL-ECOS-ÖI project, which aims to ensure that risk assessment methodologies and risk management tools help guide regulators towards the adoption of a precaution-based regulatory framework for the responsible development of nanomaterials in the EU and beyond. Engaging the audience in the challenge, he asked: "why it is so difficult for NGOs and scientists to work together?" He argued that due to their limited resources, NGOs cannot partake in lengthy and elaborate scientific research which may or may not produce results, and furthermore, may produce results which challenge our own assumptions and positions. Scientists, on the other hand, face the issue of producing controversial results and materials on the health and environmental impacts of NMs, which may affect future funding and collaboration opportunities.

He continued explaining why this collaboration includes CIEL, ECOS and Öko Institut (ÖI), highlighting ECOS' experience working with experts in the technical committees where standards are prepared and ÖI's hybrid nature of true scientists with a devotion to scientific appropriateness. As the project partners cannot say that they speak for the entire NGO community, the involvement of other organisations equipped with the correct tools is pursued with this workshop and the steering committee. Furthermore, capacity building is a vital aspect of the project in order to combat the beliefs that nanotechnology is too technical a topic. Azoulay stressed that with two years left of this project,

there is still time to collaborate, create new tools and have a significant impact on what is going on both in terms of reflection to adapt the regulatory framework to the challenges that NMs pose and in terms of engaging with technical work done to detect, characterise and assess health and environmental impacts of NMs.

8. Toxicity and Eco-toxicity of Nanomaterials



Andreas Köhler (ÖI) gave a presentation on specific project activity concerning further understanding toxicity and eco-toxicity of NMs. He presented the various types and discussed the potential hazards due to their physical and chemical characteristics. However, he stressed that hazards is an inappropriate word to use in this context. Due to the lack of knowledge there is to identify hazards in regulatory toxicology, 'risk' is preferred in this context. Risk is to be considered as a function of

exposure. Therefore, reduction of exposure is a safety measure. When we have a product containing a NM, what we do not know is if the NMs will stay in the product matrix or if there will be a potential release. The key objective in this case is to safeguard humans and the environment, ensuring they are free from harm. As certain industries buy nanomaterials as ingredients or inputs to their products, they have not had to consider any potential risks of nano-scale material up until now, and are lacking in both experience and scientific knowledge to measure exposure in the workplace and potential health and environmental impacts.

NMs may rapidly change once they are released into the atmosphere or in water and soil with many aggregation and chemical composition being possible if they are exposed to human bodies or natural organisms. A different NM may cause the exposure and harm than the one originally put in the product. It is therefore important to consider 'hazard characterisation' of NMs in products – low concentrations of NMs can still have a large impact if exposed to human beings of the environment for long time. There are many uncertainties regarding this and it will not change easily. Unfortunately, there is no sharp size related thresholds for nano-toxic effects. Possible toxicological effects can occur due to oxidative stress (free oxygen radial formation), inhalation, mechanical interaction with NMs, endocrine disruption effects and geno-toxicity (including cellular uptake).

NMs can enter the body via different exposure routes, namely inhalation via the lungs, and through ingestion and skin contact. There are scientific debates regarding which exposure routes are relevant for groups of NMs.

The OECD has in the last four years worked towards establishing a large testing programme for NMs, where many endpoints have been investigated. In other words, effects which can be tested and observed. NGOs have often complained about the lack of data available for risk assessment for NMs, and with the final OECD publication of the testing programme data we still expect uncertainty, but on a different level. Now the questions are: 'How will we deal with the data and be able to draw certain conclusions/recommendation to ensure proper risk assessment of NMs?' 'Will this change the debate on how to deal with uncertainty and available toxicological data?'

NGOs objective is to maintain momentum on the need for further environmental health and safety obligations concerning the use and release of NMs in the life cycle of products. In order to achieve this, NGOs must become aware of toxicological knowledge and how to interpret it for societal stakeholders in order to become more effective in future regulatory demands and discussions such as the revision of Reach Annexes expected in the second quarter of 2015.

9. Risk Management of Nanomaterials

Andreas Hermann (ÖI) gave a presentation on the risk management of NMs highlighting the many gaps and challenges which society faces. With so much data and material it is important to ask if there are any issues with grouping and characterising them or with transferring data from one material to another to determine potential exposure scenario. The known characteristics for NMs (i.e. toxic ions, quantum forces, etc.) are not enough for grouping alone. Additionally, as NMs transform throughout their life cycle, it is difficult to be consistent. A multi-perspective approach to grouping has recently been presented to answer these questions looking at the whole life cycle of NMs. It is linked to IATA

work, a combination of step-wise collection (collecting information, looking at it, and moving on) and the evaluation of information. The approach is due to be officially presented in 2015, and can then face the problem of full transparency, to know which data has been excluded and included. The approach is very promising but it is doubtful that it will resolve all data requirements.

10. Conclusions and Next Steps

David Azoulay (CIEL) wrapped the day up with some conclusions of the workshop and presenting the next steps. It was noted that there are many issues which were not mentioned, such as how to overcome the resource challenge as a civil society, what to do in the short term etc. It was concluded that the discussions of the workshop did not attempt to oversimplify the issues. Retaining the complexity of the topic is important in order to have a chance to influence the discussion going on. This is because the discussion will very often travel back and forth between large perspectives and minute details and we need to navigate between these two. We're not bad at being the moral compass

at those discussions, identifying the societal changes we want to see based on our convictions, but very often we have to talk about the complexity, without getting lost in the details.

We also identified a couple of areas where there is room for further improvement, where we should move and push forward, such as air, water and soil as a proxy to ensure the health of the environment. We spoke about influencing public research activity - another area that we identified, has room for further engaging NGO's in the nano debate and moving the discussion in the right direction.

The fact that the regulatory environment that we are revolving on is becoming increasingly difficult is a sign that we have been doing good work. It does not mean that we should not try to adapt to the changing environment, and that we need to stick to the way we do things. We must consider alternative ways to approaching this discussion.

How do we deal with all the OECD data derived from the testing programme of 11 different nanomaterials? This is an issue for all of us to consider. It is very important for us to acknowledge the complexity of this question in order to decide how we move forward.

If you have any questions regarding the CIEL-ECOS-ÖI project or would like to know more, please do not hesitate to contact the project partners:

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