

**Katja Lähtinen, Helena Valve, Timo Jouttijärvi,
Petrus Kautto, Sirkka Koskela, Pekka Leskinen,
Kimmo Silvo**

SYKE - Finnish Environment Institute

Marja Pitkänen, Heli Kangas, Pauliina Tukiainen

VTT - Technical Research Centre of Finland

**Piecing together research needs: safety,
environmental performance and regulatory
issues of nanofibrillated cellulose (NFC)**



CLEEN LTD

ETELÄRANTA 10

P.O. BOX 10

FI-00130 HELSINKI

FINLAND

www.cleen.fi

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Katja Lähtinen*, Marja Pitkänen**, Helena Valve*, Timo Jouttijärvi*, Heli Kangas**, Petrus Kautto*, Sirkka Koskela*, Pekka Leskinen*, Kimmo Silvo*, Pauliina Tukiainen**

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Piecing together research needs: safety, environmental performance and regulatory issues of nanofibrillated cellulose (NFC)



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Abstract

Control over matter on the atomic scale or nanoscale enables the creation of devices and structures with ground-breaking characteristics. Novel materials are expected to improve ecological efficiency, enhance quality of life and generate economic growth. In forest industry, there are numerous potential uses for nanofibrillated cellulose (NFC). However, the life cycle safety and environmental impacts of NFC are largely unknown. Due to this, incorporating the environmental considerations into research and development work is needed at the very beginning of NFC-based value chain development. The purpose of the study was to identify the most critical research needs relating to product safety, environmental performance and regulation challenges of producing and using NFC in intermediate and end products. The project was to bring together a wide spectrum of top experts to contemplate existing results and to prioritise unanswered questions relating to NFC production and usage in different phases of value chains. According to the results, identified research needs can be divided into two main topics: testing and test procedures and environmental behaviour of NFC. The development on-time regulation and standards was considered as important, but in many cases it was noted to be proceeding at a slow pace. Due to this, proactive communication with customers, authorities and consumers were considered to be an important question that requires research inputs. It was emphasised that research results on safety issues and environmental product characteristics, for example, are needed for reliable communication between different actors. The debates also opened up practical questions about the appropriate modes and arenas of cooperation between different stakeholders. Moreover, as became very evident in the debates during the pre-study, dialogue around new technologies and their implications are needed not only between administrators, scientists and private enterprises, but also more widely across the whole society.

Helsinki, June 2012

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1 Introduction

Control over matter on the atomic scale or nanoscale enables the creation of devices and structures with ground-breaking characteristics. Novel materials are expected to improve ecological efficiency, enhance quality of life and generate economic growth (e.g., Ince et al. 2011). Currently, the search for technological solutions for cost-efficient nanocellulose production is intense both in Europe and North America. From the Finnish perspective, new nanotechnology-based operations such as the manufacturing of nanofibril cellulose (NFC) from chemical wood pulp can be seen as examples of technologies that may offer economically, environmentally and socially significant advantages: they are considered to increase the resource efficiency of current products and to support the possibilities of developing new products, resulting in an increase in competitiveness in the global markets.

Evaluating the life cycle and safety effects and regulation needs of emerging technologies is always a challenge. Simultaneously, information on those aspects is crucial when developing new products and seeking out their new industrial applications. Nanocellulose is an example of a new material, the life cycle safety and environmental impacts of which are largely unknown. It has been elicited that some nanoparticles could induce toxic responses with different grades of severity depending on several factors, such as their intrinsic properties and their involvement in different activities. At the same time, adequate and accurate information on the impacts and risks of nanomaterials is needed for the planning of regulation for controlling their production, use and disposal. It is also in the interests of the companies who produce and use nanomaterials to prevent any unwanted, unforeseeable environmental consequences that might occur during the life cycle of nanomaterials. Therefore, environmental considerations should be incorporated into technical innovations and product development at the very beginning. This requires new kinds of environmental management systems and governance.

As a result of the ongoing research and development (R&D) work in the fields of nanocellulose production technologies and the usage of nanocellulose in different end products, companies need information in order to adjust their operations and decrease business risks. Information is needed both on the safety and environmental impacts on NFC as well as potential regulatory changes related to NFC. At the same time, regulation should not prevent innovative and environmentally beneficial R&D in NFC and NFC-based products. Due to the close connection between the above-mentioned exceptional uncertainties and R&D in the field, it is apparent that environmental aspects should be considered in the early stages of searching for new technical innovations and product development in NFC. However, since straightforward regulations do not currently exist, especially for NFC production, responding to the safety and environmental challenges requires approaching issues related to corporate social responsibility (CSR) (e.g. GRI 2011) as an option for recognising new kinds of tools and management practices at companies producing and using NFC (Kuzma and Kuzhabekova 2011).

2 The pre-study: towards collective screening of research needs

There are numerous potential uses for NFC in forest-industry production processes and end products including, for example, composites and construction materials, porous materials, paper and board, coatings, functional surfaces and functional additives (Klemm et al. 2010). In the future, NFC may complement or substitute currently used raw materials in manufacturing processes of already existing products, or it may be used as a material for manufacturing entirely new, currently non-existent end products. However nanotechnology is still a relatively new

application area in forest industries. In addition, despite the efforts within REACH and by national authorities in Europe, there are currently no applicable regulations, for example, for NFC production.

Despite the lack of general regulation on nanomaterial production, environmental, health and safety (EHS) issues should be incorporated into the early stages of R&D related to the production and use of nanomaterials. As a result of this, NFC should be dealt with in regulations (Figure 1). The prevention of troublesome surprises that might occur when NFC-based products are launched onto the markets, used by consumers, recycled and/or disposed of is in the interests of both companies and the public sector. The importance of proactive CSR within companies is especially important in a situation where the behaviour of nanocellulose in different environmental contexts is largely unknown.

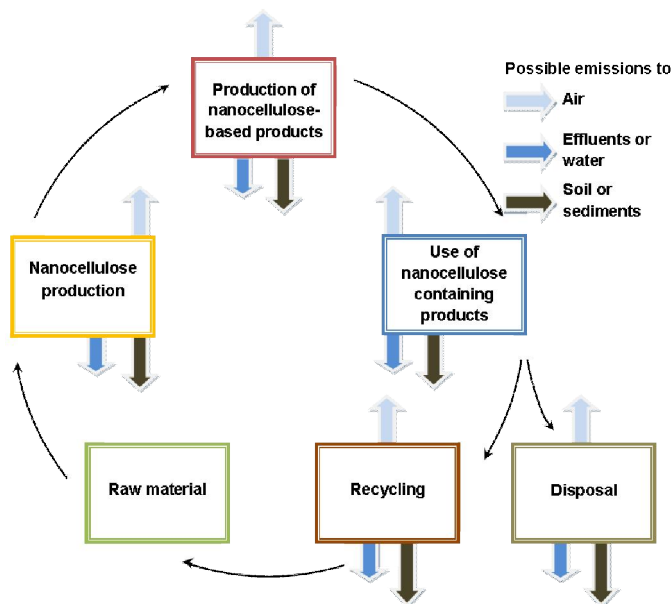


Figure 1. Life cycle phases of the value chain for NFC production and NFC-based products. Depending on the production processes and end products, the EHS impacts and regulation needs may vary within and between different unit processes.

The motivation of the pre-study, named "The safety and environmental performance of nanofibril cellulose (NFC): research needs and methodological challenges" was to identify the most critical research needs relating to product safety, environmental performance and regulation challenges of producing and using NFC in intermediate and end products. The project was to bring together a wide spectrum of top experts to contemplate existing results and to prioritise unanswered questions relating to NFC production and usage in end products. The debates were arranged into three key themes as illustrated in Figure 2.

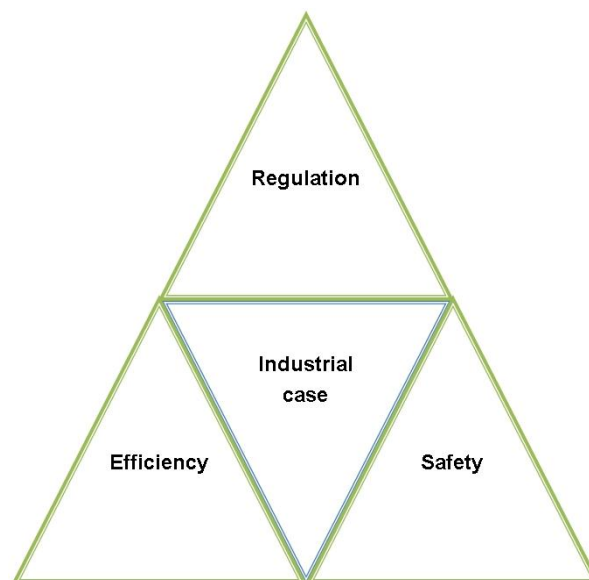


Figure 2. The entity of interlinked issues important for recognising the crucial issues related to the development of nanocellulose production value chains from the perspective of industries.

The project organised three stakeholder meetings (see Table 1). This report presents the main lessons from all the debates, focusing particularly on analysing the output of the January 2012 workshop.

Table 1. Interactive events arranged and analysed in the project.

Event	Goals	Themes	Participants
Meeting June 2011	Setting the stage: what are the key questions of the pre-study, key participants, ideas for organisation of the events and debates.	Product safety Environmental performance	Industrial partners (UPM, Stora Enso) Administrators (TUKES) Scientists (from VTT and SYKE)
Meeting for Scientists November 2011	Enlarging the network of participating scientists. Discussion about a potential joint research proposal.	Product safety Environmental performance	Scientists, e.g. from: BioSafe Oy, FIOH, LUT, M-Real, Pöyry, SYKE, UEF, UPM, Stora Enso and VTT
Workshop January 2012	Two-day workshop, where the presentations given by the experts on different themes served as stimulus for working group discussions .	Product safety Environmental performance Regulation	Industrial partners, administrators and scientists from more than 15 organisations

The pre-study was performed in cooperation between two Finnish Strategic Centres for Science, Technology and Innovation (SHOKs) – Forestcluster and the Cluster for Energy and Environment (CLEEN). Representatives of the Forestcluster EffNet programme participated as nanotechnology experts by providing NFC safety information, characterisation expertise/knowledge and connection to international standardisation and EHS aspects of nanocelluloses. The role of the CLEEN MMEA programme was to provide a viable methodological basis to evaluate the human and environmental safety issues of NFC production and NFC-based products. In addition, the outcome of the pre-study will be used as a basis for a post-doctoral study "Nanosafety on trial(s): Understanding politics and potentials of product-oriented environmental policies" funded by the Academy of Finland.

During the pre-study, a total of three workshops were arranged in June 2011, November 2011 and January 2012. In the workshops scientists, industry representatives and administrators discussed topical and open issues related to focus area of the research project. The two events held in 2011 provided background information for the January's two-day workshop, where presentations given by the experts on different themes served as stimulus for more in-depth working group discussions. In January's working group discussions, the participants of the workshop were organised into three groups, which concentrated on each of sub-project themes: product safety, environmental performance, and regulation. In this report, the outcomes of the workshop held in January 2012 are first presented in detail by themes. After that, the topics emphasised in the separate group discussion are cross-sectionally combined into general theoretical and empirical development needs and research questions.

3 The characteristics of NFC and NFC-based value chains

The term "nanocellulose" is widely used to describe a range of quite different cellulose-based nanomaterials. These differences are not only due to a wide variety of available raw material sources, for example wood, crop residues and bacteria, but also to different top-down and bottom-up production methods, and optional physical and chemical modifications (Klemm et al. 2010).

Nanofibrillated celluloses (NFC) are generally produced by the fibrillation of cellulose fibres into nano-elements by intensive mechanical treatments. The resulting material is not homogeneous, but consists of fibres of different degrees of fibrillation and with a wide size distribution. The thickness of NFC nano-elements is typically in the range of 20–40 nm, while the length is in the microscale. Fibrillated celluloses are highly branched and flexible, and have a high aspect ratio. NFC has some unique properties, such as great strength, shear thinning behaviour, network and film formation capability and a highly reactive surface. Due to these properties, NFC is a potential raw material for a wide variety of applications, such as a strength additive in composites and papers, a rheology modifier in paper coatings, paints and adhesives, and a barrier material in packages. The appearance and structure of NFC is presented in figures 3 and 4.

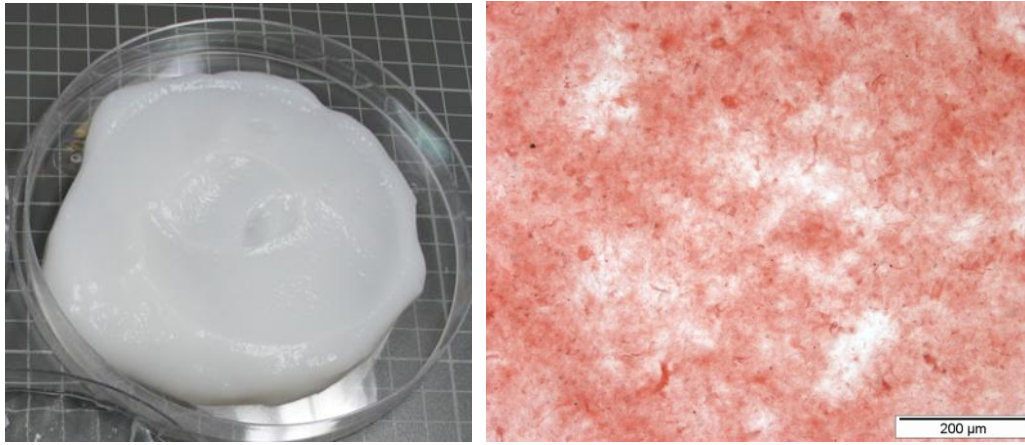


Figure 3. Appearance NFC manufactured by mechanical treatment (left), optical microscope image of NFC (right) (Pöhler et al. 2010).

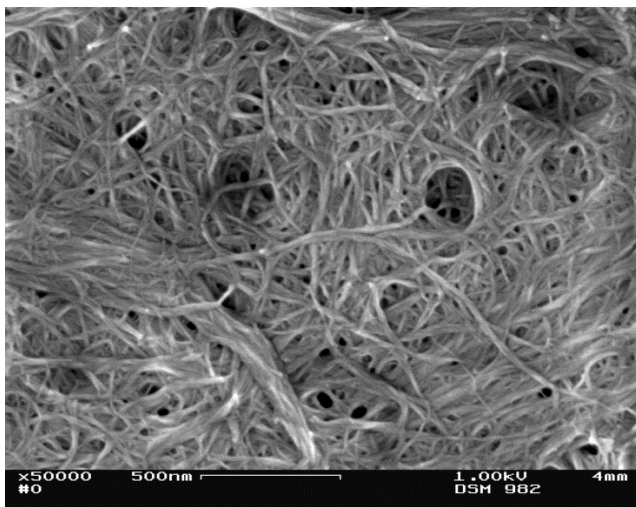


Figure 4. Scanning electron microscope (SEM) image of NFC. Magnification 50,000x, scale bar 500 nm (Pöhler et al. 2010).

Contrary to branched or entangled microfibrils produced by pure mechanical treatment, individual nano and microscale fibres can be obtained through enzymatically or chemically assisted mechanical treatments. Well-known chemical pre-treatments employed in the manufacture of NFC are TEMPO (2,2,6,6-tetramethylpiperidine-1-oxyl) -mediated oxidation and carboxymethylation. In these pre-treatments, the surface charge of fibres is increased by oxidation and mechanical disintegration is used to separate the fibres. The width of the nanofibres is in the range of a few nanometres, and the length a few micrometres. Nanofibres have a high aspect ratio and they are not branched (Figure 5, photo on the left). When cellulose fibres are subjected to acid hydrolysis, cellulose microfibrils are cleaved in a transverse direction, along the amorphous regions. After mechanical separation by sonication or by ultrasound, a rod-like material referred to as cellulose whiskers or nanocrystalline cellulose (NCC) is produced. These whiskers have a relatively low aspect ratio and are typically 2–20 nm in width with a wide length distribution ranging from 100 to 600 nm and even >1 μm in some cases (Figure 5, photo on the right). Cellulose whiskers are individual elements with no branching.

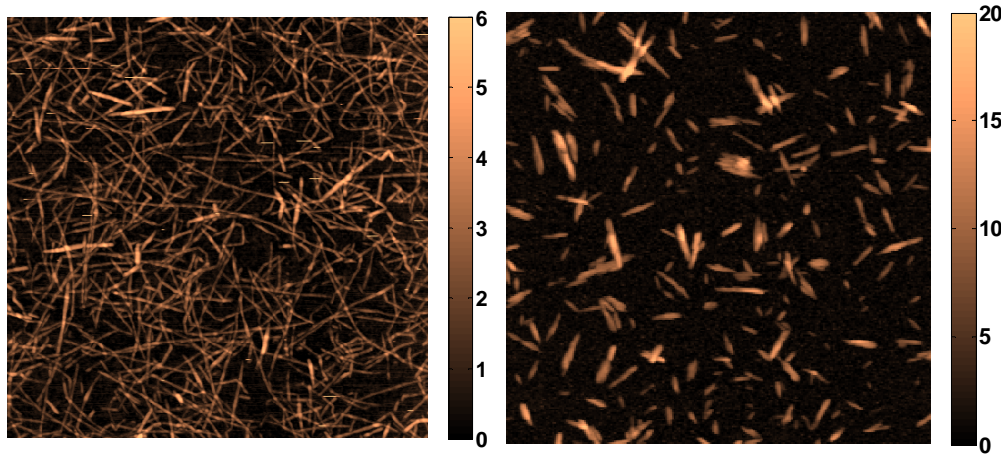


Figure 5. Atomic force microscope (AFM) images of a) individual nanofibres obtained by TEMPO-oxidation (left) (Pöhler et al. 2010), and nanocrystalline cellulose from cotton (right). Image size 2x2 μm .

Bacterial cellulose (BC) is produced by bacteria such as *Acetobacterium xylium*, through cellulose biosynthesis and by the building up of bundles of microfibrils. BC is secreted extracellularly by the bacteria as ribbon-shaped fibrils, less than 100 nm wide, which are composed of much finer nanofibrils with a width of 2–4 nm (Figure 6).

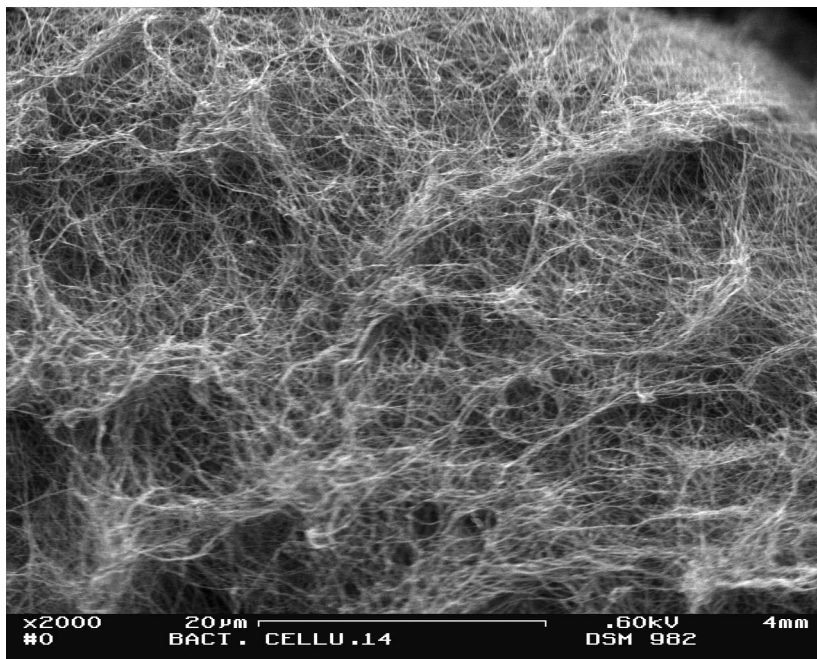


Figure 6. SEM image of bacterial cellulose. Sample kindly provided by Alexander Bismarck, Imperial College of London.

4 Evaluation of human and environmental safety of NFC and NFC-based products

4.1 Introduction to product safety

Nanomaterials will improve the performance of many products in the future but at the same time they exhibit unknown properties and thus may expose humans and the environment to new risks. Nanocelluloses are one of the most abundant and sustainable nanomaterials with a wide industrial application potential, and thus they provided an inspiring case for the pre-study. Wood pulp and powdered cellulose are generally recognised as being safe and they can be used, for example, as a raw material for food contact materials or even as food additives. However, as with other nanomaterials, their biological impacts on ecosystems and humans cannot be evaluated merely on the chemical characteristics of the cellulose. For example, the size, shape, aggregation properties and many still unknown factors may affect the interactions of NFC fibres with cells and other living organisms (Pitkänen et al. 2010).

Thus, alongside the expected positive impacts and totally new properties achieved by using NFC in different types of products, specific characteristics of nanomaterials may also cause new risks for humans and the environment. In order to shed light on the unknown properties of NFC, the objective of the first theme of the pre-study was to identify topics and dimensions relevant to evaluating the product safety of NFC and NFC-based products related to the exposure of nanofibrillated celluloses in different kinds of ecosystems and humans.

At present, some studies looking at the toxic properties of nanocelluloses are available. FPInnovation in Canada studied the toxicity of nanocrystalline cellulose in detail (O'Connor 2009, Kovacs et al. 2010, O'Connor 2011). The test protocol contained a battery of acute and chronic whole organism tests, cell viability and cellular uptake tests. Based on FBInnovation's results, it was concluded that NCC does not indicate any ecotoxicological concern. Bacterial cellulose nanofibres were tested using comet and *Salmonella* revision assays (Moreira et al. 2009). Bacterial cellulose nanofibres did not show genotoxicity under the test conditions. Based on these studies, nanocrystalline cellulose NCC does not cause ecotoxicological concern, and bacterial cellulose nanofibres did not show genotoxicity under the test conditions.

Vartiainen et al. (2011) assessed the health and environmental safety aspects of microfibrillated cellulose (MFC). To evaluate the health effects, mouse macrophages and human macrophages were exposed to MFC, and the viability and cytokinetic profile of the cells were studied. No inflammatory effects or cytotoxicity on mouse or human macrophages were observed under the conditions tested. The results of toxicity studies suggested that the MFC is not cytotoxic and does not have any effect on the inflammatory system in macrophages.

Pitkänen et al. (2010) assessed the *in vitro* cytotoxic and genotoxic properties of two different types of nanocelluloses: nanofibrillar cellulose (NFC) and whisker-type ultrafine cellulose (UFC). The analysis indicated absence of cytotoxic and genotoxic properties for the nanocelluloses tested. The only weak indications of toxicity were found for the finest size-fractionated NFC samples, which showed an indication of transient morphological changes in one cell line (human cervix carcinoma (HeLa229) cells) in the Highest Dolerate Dose (HDT) test. In the study the actual cause of morphological changes remain unclear.

In conclusion, according to current research results the studied nanocelluloses do not cause cytotoxic, genotoxic or ecotoxic concerns. However, in order to receive more unambiguous

information on the safety impacts of nanomaterials such as nanocelluloses, internationally agreed standardised methods applicable for studying the material characterisation and implementing their safety experiments are needed to ensure their safety. In addition, the recognition of possible risks caused for humans and ecosystems in the different phases of NFC-based value chains is a prerequisite for assessing the effects of NFC in different types of final products.

At January's workshop, Professor Jussi Kukkonen (University of Eastern Finland) delivered a presentation on the topic: "Ecotoxicology and nanomaterials: Is there a need for testing?" Kukkonen presented many relevant questions that need to be answered before the safety of different kinds of nanomaterials and nanoparticles could be ensured. Kukkonen emphasised that there are many unknown factors and uncertainties in evaluating the toxicity and effects of nanomaterials. The risks in the reliability of assessments are connected to the selection of the right measurement targets to evaluate the potential effects and dose metrics in terms of concentration, surface area and number of particles. In addition, it still needs to be resolved how environmentally relevant conditions could be generated in test circumstances to be able to expose the organisms to the impacts of nanomaterials. Currently there are very few research results available on the toxicity and safety effects of nanomaterials, although a database on their EHS impacts is expanding. In addition, the number of species tested is very limited and there is no information available on the chronic toxicity impacts (e.g. the impact of reproductive function, behaviour and immunity) and bioaccumulation and biomagnification potential of nanomaterials.

4.2 Discussing product safety: Lessons learned

In the workgroup discussions it became clear that there are many unresolved issues in evaluating the human and environmental safety of nanomaterials in general and thus NFC and NFC-based products. Despite several current research results mentioned above, at the moment it is not fully known whether NFC fibre nevertheless has some properties that might have harmful impacts on humans or ecosystems. In order to ensure that the proposed measurements are applicable for nanocellulose and to deepen the understanding of the safety of NFC fibre, specific properties of nanocelluloses need to be taken into account when test methods and testing protocols are developed. In addition, more information is needed with regard to the similarities and differences of NFC when compared, for example, to MCC pulp. One central question that came up in the group discussions concerned how the properties of NFC and its behaviour in biological systems differ from MCC and pure powdered cellulose that are generally used as a food additive (E460). In addition, since there are also natural nanoparticles in the environment, such as in humus, the potential differences between "natural" substances and NFC were also addressed in the discussions.

The exposure for human beings caused by producing and using NFC was one of the key topics in the discussions. However, the current consideration of exposure and exposure routes is still at a theoretical level to some extent, since both NFC production and the usage of NFC in intermediate and end products are still under R&D. It is known, as with other products, that the exposure routes of workers involved in NFC production processes and consumers buying NFC-based end products are inhalation, digestion and skin contact. In the workgroup discussions, it was supposed that the amount of NFC exposure might be higher for workers in the plants than for end-consumers. Possible exposure routes were considered to be dust formation of dried NFC and the formation of aerosols containing NCF. Compared to workers, the exposure was assumed to be smaller for consumers depending on the end product characteristics (e.g. packaging material, paper or food).

The discussion participants emphasized that current knowledge of the behaviour of NFC in ecosystems is very limited. Furthermore, it can be said that no information exists on NFC's effects on special natural circumstances, for example in boreal regions. The stability of nanomaterials in different kinds of ecosystems would be a crucial way of assessing the environmental behaviour of NFC. In addition, for example, chemical modification of pure nanocellulose gives numerous variants that most probably behave in different ways in biological systems and in the environment, increasing the uncertainty of its impacts. For instance, participants discussed how the behaviour of NFC, which is an anionic particle, might be changed in biological systems and the environment when cationic groups are added in modification. More information is needed on these aspects, although currently some information exists on modified nanocelluloses and the changes in their properties caused by modification. Information on different kinds of emissions caused by manufacturing processes, final products, recycling and waste was found to be crucial for developing safety evaluations. Compared to usage, recycling and waste management, information on emissions caused by production processes can be considered more important due to the magnitude of operations in plants. In waste water treatment of production processes, the capacity and performance of waste water treatment plants in catching the nano-size materials were emphasised as important factors for controlling NFC production. Regarding emissions, recycling was also considered to be an important part of product safety. It was assumed that although most of the NFC material was supposed to remain in the pulp during recycling, small amounts of NFC were also supposed to be released into the water during the processing of recycled fibres.

Currently the focus of research is mainly on potentially dangerous nanomaterials, which may create an image that all nanomaterials, including NFC, are harmful. The special properties of NFC, for example, aim to flocculate, affect the applicability of different safety testing procedures and should be taken into account when developing measurement systems for assessing the safety impacts of NFC. In the group discussions it was emphasised that both the physical and chemical properties of NFC should be measurable. In addition, the possibility of using references from food and pharmacy industries was emphasised. It was assumed that industries using nanocellulose-based substances or microfibres could provide information both on the characteristics of their nano-fibre raw materials and applied safety testing methodologies.

Industrial processing may affect whether NFC still exists in nano-form in consumer products, during recycling or waste water treatment. In the group discussions this was regarded as a very important question: consumers and the environment are only exposed to nanocellulose when nano-sized material exists in the end products. Another issue that was emphasised is the chemical and microbiological purity of nanocellulose. For example, the use of chlorinated substances during NFC production may have an effect on the usability of NFC for food additives. It is not clear whether the recyclability of NFC-based products is similar to currently existing commodities. In all, the importance of efficient NFC production processes was emphasised both from the perspective of environmental friendliness and cost efficiency.

The safety impacts of NFC are global and thus international collaboration is required for developing and comparing research methodologies as well as data gathering. Furthermore, the reliability and validity of methodologies and data sources can be tested in cooperation with international organisations. In terms of regulation, it was mentioned in the group discussions that standards and legislation set for other industries (e.g. guides for pharmaceutical and cosmetic industries) could be employed in assessing the impacts of NFC. It was felt that the regulation process is too slow for the development of a reliable assessment framework for NFC and NFC-based products. Due to this, proactive communication with consumers, customers and authorities was found to be necessary in order to meet the information needs in the industry. It was also

mentioned in the discussions that although information on the safety effects on NFC is necessary, the risk of overreaction in the markets exists and because of this, the provision of timely information on NFC-related issues is crucial.

4.3 Future research needs in the theme of product safety

At the end of the group discussion, participants summarised and prioritised the topics that were brought up during the discussion and identified the main research needs. One main issue concerned the information needs. The capability to communicate reliably with customers, authorities and consumers was regarded as important for companies to be able to foresee, be prepared and meet their information needs. In terms of information gathering, an appropriate organisation for managing the data gathering and "storage" was also discussed.

In the discussions one crucial issue was identified: What properties of nanocellulose may endanger safety? Are there such properties and in what circumstances? Related to this, assessing the exposure of workers and consumers to NFC was considered as important.

As a summary, the topics that were brought up were as follows:

- The measurement method to determine what form the material (NFC) is in the product. Is it still in nano-form in the products? Relevant indicators and measurement methods to determine the amount of nanocellulose in end products are needed.
- In order to assess the amount of migration of nanomaterials and nanocelluloses from food contact materials to food, the effective migration tests and test procedures that are also suitable for nanocelluloses are needed to determine the possible migration of nanocellulose.
- Exposure of workers during NFC production and NFC-based products. This calls for relevant measurement methods, for example, to determine dust formation during production, the formation of aerosols and other possible methods of exposure.
- The basic question of the properties of nanocellulose that may endanger the safety was emphasised. This generates a need to understand the phenomena that makes materials toxic to humans and environment in more depth. In this context, the influence of the chemical modification of nanocelluloses to the toxicity is discussed. More information is needed to fill in the knowledge gaps.
- More information is needed on the environmental behaviour of NFC, in particular on the efficiency of current waste water treatment plants. In addition, the environmental behaviour of nanocelluloses during disposal and recycling is almost unknown.

Comprehensive communication with customers, authorities and consumers was also highlighted. Participants agreed that research results of safety issues are needed for reliable communication. Building up a joint databank was suggested by participants.

5 Environmental performance of NFC-based value chains

5.1 Introduction to environmental performance

Environmental performance of NFC production needs to be approached not only from environmental and economic perspectives, but also in terms of social aspects (Kuzma and Kuzhabekova 2011) in line with the general objectives of sustainable development (e.g. UN 2008) and CSR aspects (e.g. Li and Toppinen 2011). Currently, the challenge for both companies and public authorities is the lack of unambiguous indicators, measurement systems and the empirical assessment results of the environmental, economic and social impacts of processes used in manufacturing nanocellulose-based products (e.g. Hessel et al. 2008, Vartiainen et al. 2011).

Promoting sustainable production in pulp and paper industries is expected to support the evolvement of a symbiotic relationship between the successful market development of forest companies and the green economy. The global objectives of sustainable development may help forest companies to recognise pathways for achieving product innovation and market growth that enhance the use of environmental friendly and renewable resources in advanced processes. Nanocellulose-based products are considered to play a crucial role in seeking new options for developing value chains of forest industries (Ince et al. 2011, Klemm et al. 2011). The focus of the second theme of the pre-study was to approach the contents of environmental performance in NFC-based value chains and to tackle the issues crucial in assessing the environmental performance of the NFC production system from the primary production of raw material to processing, end use and waste/recycling.

In the January workshop, research scientist **Elina Saarivuori** (Technical Research Centre of Finland, VTT) gave a presentation on the topic "Environmental management and sustainable use of nanocellulose" with a special focus on a new product development phase. Developing a framework for evaluating the sustainability of nanocellulose production may be considered an iterative, evolving process, with the different phases of product development starting from idea generation and proceeding step-by-step to commercialisation and product management. As a result of progressive advancement in a developing evaluation system, unforeseen issues can be clarified in the course of product and concept development. In addition, in an iterative development of a nanocellulose sustainability assessment system, new data that was unavailable prior to the start of product development is also generated during different phases of product development.

In Saarivuori's presentation, the minimisation of health- and environment-related risks and the provision of information for promoting healthy and safe manufacturing processes were emphasised as the benefits of sustainability evaluations. In addition, knowledge of the sustainability of nanocellulose products may also be used for reducing non-scientific claims of their risks and benefits, for demonstrating the commitment of companies to CSR issues and further increasing the public acceptability of nanocellulose products.

In her presentation, Saarivuori introduced suitable methods for assessing environmental impacts of production systems such as life cycle assessment (LCA), carbon footprint, water footprint and life cycle risk assessment and environmentally-extended input-output (EEIO) analysis (Leontief 1970). With regard to corporate social responsibility issues, economic and social sustainability effects of production systems may be combined with the environmental evaluation methods, for example, with input-output (IO) analysis (Leontief 1936), life cycle costing (LCC) (e.g. Gluch and Baumann 2004) and social life cycle assessment (SLCA) (e.g. Hunkeler 2006). Saarivuori

emphasised that in employing sustainability assessments, the usability of the methodologies listed above may be challenged due to the nature of nanomaterials and the new production technologies used in their processing. These affect both the data availability and the reliability of measurement results.

The methodologies available for evaluating simultaneously environmental, economic and social sustainability dimensions were also approached in the presentation given by Project Manager **Timo Jouttijärvi** (Finnish Environment Institute, SYKE). Alongside Saarivuori's presentation, Jouttijärvi's topic in the workshop was also linked to the topic of environmental performance. In case of new nanocellulose-based products, areas of major change may include primary production (e.g. shifts in raw material acquisition as well as in production of energy and chemicals), process technologies and performance of production systems (e.g. usage of emerging techniques, emissions and positive/negative impacts of unit processes within systems), and characteristics of nanocellulose and paper products, as well as the consequences of their usage (e.g. technical properties, usability/recyclability, safety). As a result of these changes in production systems, the whole value chain will be changed, which further affects the value-added of the products as well as the regulative environment.

Data availability and the need for developing suitable assessment methodologies are not the only challenges linked to evaluating the environmental performance of NFC-based production systems. In his presentation, Jouttijärvi emphasised the need for deepening the knowledge of the relative importance of different sustainability dimensions in NFC value-added chains (Figure 7). In some life cycle phases of NFC production and usage, unknown and immeasurable impacts within a particular sustainability dimension may be more critical than in the other sustainability dimensions, but without reliable information they are impossible to assess.

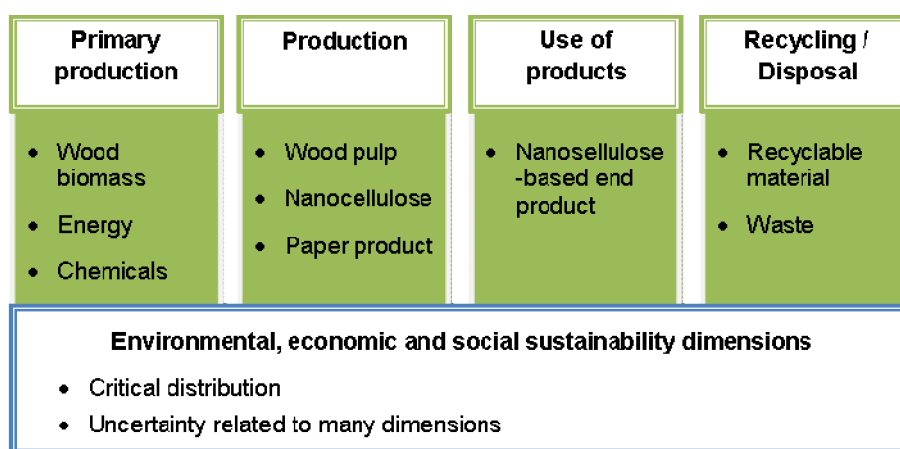


Figure 7. The sustainability measurement criteria for different parts of NFC-based production systems are not necessarily of equal importance and there are different risks associated in evaluating the sustainability effects.

5.2 Discussing environmental performance: lessons learned

The issues approached in the workshop group discussions among scientists, industry representatives and administrators were similar to the topics that were emphasised in the presentations of Saarivuori and Jouttijärvi. In general, people in the group discussions felt it important to have profound, reliable and valid information on the sustainability impacts of NFC-based production, including the whole value chain from primary production to end use, recycling and waste management. In addition, in sustainability evaluations, the discussion participants emphasised the significance of wide-scope measurements where, along with environmental and

economic criteria, social aspects were also addressed. In the discussions, from the societal point of view, knowledge of environmental effects was considered to be the cornerstone for making decisions relating to the production of NFC-based products. Furthermore, profound information on environmental impacts was found to be closely connected to enhancing economic and social sustainability.

In production systems, NFC-based products may either be substitutes for old raw materials of existing products, or they may constitute entirely new products. In industrial management, the possibilities of increasing resource-usage efficiency were stressed as the primary starting point for manufacturing NFC-based products. The increase in resource-usage efficiency provides opportunities for both the decrease in production costs and the enhancement of environmental performance that provide further grounds for supporting company-level competitiveness. In contrast, the possibility for supporting competitiveness by processing products with higher end product prices is far riskier, due to the capricious nature of consumer preferences. Consumers' purchasing decisions may change rapidly and they may be affected by many unpredictable and even false statements occurring in the market arena. In addition, since the decisions of consumers also affect the purchases of business customers, in NFC-based product manufacturing relying primarily on new value-added, generation opportunities would induce high business risks.

Involvement in NFC-based products requires significant investments in R&D as well as in new production technologies, and thus failures in new business branches would also be reflected in the vitality of processing traditional products. Due to this, the role of regulation was emphasised as crucial in the group discussions for managing overall business risks in pulp and paper industries. So, in this respect, the responsibility of ensuring environmental performance was placed on the shoulders of public authorities in the discussions. In addition, negative information or even false claims linked to the environmental and social sustainability effects of NFC-based products could widely reflect the acceptability of companies' operations that would further influence their competitiveness. Thus, regulation could be a tool for companies for receiving information on the most crucial measurement targets that need to be addressed when new products are to be launched onto the markets. In addition, the possibility of relying on regulation would support the transparent communication of product characteristics that is crucial both for companies and authorities. On the other hand, transparency does not necessarily refer to information reliability: as a result of proactive information there may be deficiencies in the knowledge-base that may cause inaccurate or even erroneous conclusions of, for instance, product environmental performance.

The need for advancing profound sustainability assessment in the context of NFC-based production systems was not questioned in the group discussions. However, defining the criteria for describing environmental performance including the social dimension seemed to be challenging, not to mention proceeding further to the definition of concrete indicators, the recognition of data sources or specifying methodologies that could be used for the wide-scope sustainability assessments. In the discussions, the emissions and costs currently being measured in traditional pulp production were brought up as an optional reference to the indicators that would be suitable for assessing the impacts of new NFC-based production systems. In fact, according to some industry representatives, processing NFC-based products does not necessarily essentially differ from the manufacture of traditional pulp products.

Particularly connected to the general criteria of social sustainability, impacts on human health during product manufacturing, end use, recycling and waste management were strongly emphasised in the discussions. In this context, the discussion participants recognised strong links

between environmental performance and product safety evaluations. The possibility of employing, for example, the scientific advice (e.g. EFSA 2011) provided by European Food Safety Authority (EFSA) to develop measurement systems for evaluating the effects of NFC-based products for employees and consumers was brought up in this context.

When discussing the sustainability impacts of NFC-based production systems, the fact that both the harms and benefits should be approached in balance was emphasised. In addition to the possibilities of enhancing environmental friendliness by substituting the use of non-renewable resources with renewable ones, in paper products the use of NFC might decrease the dusting of paper. In the phase of end use, a decrease in paper dusting would have direct positive health effects that would further enhance social sustainability. In order to achieve profound knowledge of environmental performance of NFC-based products, all relevant aspects should be recognised and approached by valid measurements.

5.3 Future research needs on environmental performance

In the group discussions the need for implementing the assessments from the perspective of whole value-added chains was emphasised. In the assessments, the availability of reliable data was considered a major challenge compared to defining appropriate measures for environmental performance assessments. In fact, the participants assumed that the environmental impacts of producing NFC will probably not differ considerably from that of current chemical wood pulp production. Therefore, the existing sustainability indicators were also assumed to be appropriate for measuring the environmental performance of NFC, especially in the primary production of raw materials and the industrial production of NFC. However, some challenges may occur when evaluating the environmental performance occurring in the end use (consumers) of NFC-based products as well as in their recycling and disposal. Thus, it is possible that new sustainability indicators may be required in the future for assessing the potential positive and negative impacts of NFC usage, but it is not clear since the products, consumers and markets are currently unknown. In all, based on the group discussions it can be assumed that the uncertainty of measurements increases both in terms of data availability and the development of measures in the final phases of NFC-based value-added chains.

6 Regulation and product-based environmental policy

6.1 Introduction to regulatory development

The third overarching theme of the pre-study focused on regulatory developments and their relation to emerging forms of environmental management and corporate responsibility. Figure 8 presents the heuristic scheme employed to study this theme.

Today, the regulations that are designed to control the use of nanomaterials and harmonise safety testing are still very much under development. Nevertheless, a lot of effort is employed in addressing the issue. The regulations under development will have direct influence on the assessment and testing of NFC applications (arrow 1 in Figure 8). On the other hand, the public organisations drafting the test guidelines and draft regulations depend on the expertise and experiences of the industrial actors (arrow 4). As a result, Figure 8 highlights the symbiotic nature of policymaking, pointing to the interdependency of business and government (Mazey and Richardson 2001, Coen and Grant 2006, Coen et al. 2010, Wilson 2006).

Moreover, as arrow 3 in Figure 8 illustrates, health and environmental issues should be integrated in product development (Kelty 2009, Kulinowski 2006, Macnaghten 2010, McCarthy

and Kelty 2010, Tischner et al. 2000). The demands have generated commitments to product-oriented environmental policy (Commission of the European Communities 2001, 2003, 2008, Kautto 2008, Dalhammar 2007). New regulatory approaches extending the responsibilities of producers have been proposed particularly to govern nanotechnology (Levi-Faur and Comanesthter 2007, Ludlow et al. 2007).

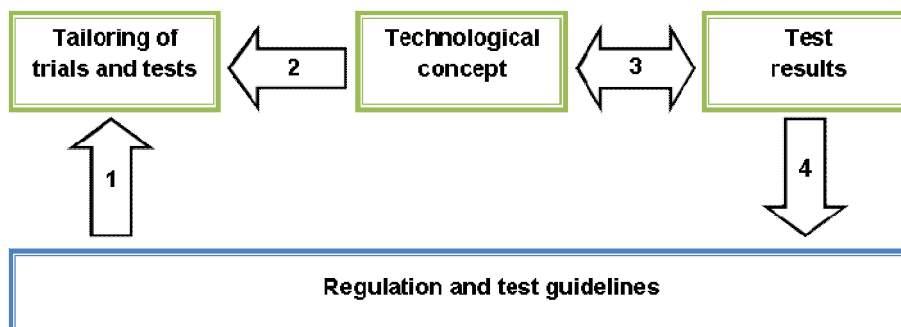


Figure 8. Co-development of product development, testing and regulation (1=Regulations under development, 2=Concept specific experimental design, 3=Integration of health and environmental issues to product development, 4=Expertise and experiences of industrial actors)

Regulation and its possibilities to support the integration of safety and environmental concerns in product development were discussed, to varying degrees, in all three meetings organised in the pre-study. Whilst some issues and topics were integrated in the common agenda, being raised in one meeting to the next, the nature of the debates changed along the way. In the beginning, many of the industry representatives and scientists were mainly "interested in learning what is going on" in the international forums. In the final workshop, however, the costs and benefits of regulation were more openly deliberated. At the same time, the problems of some regulatory strategies were critically evaluated and alternatives were probed. At all times, the focus was on safety regulation in particular. This meant that the discussions necessarily overlapped with the product safety theme.

In the workshop in January, senior scientist **Jukka Ahtiainen** (Finnish Safety and Chemicals Agency, Tukes) provided an overview on the state of the art of regulatory developments. In his presentation, Dr Ahtiainen updated us on the work that is going on in the two international focal points, starting with the OECD Working Party on Manufactured Nanomaterials (WPMN) and proceeding to activities organised under the EU Commission.¹

The aim of the OECD work is, above all, to create guidance for existing test guidelines and possibly new test guidelines for the safety testing and assessment of manufactured nanomaterials. At the moment, a total of 13 nanomaterials, or groups of nanomaterials, are under scrutiny. The common objective is to create dossiers that present the intrinsic properties of these materials, focusing on their physical and chemical characteristics, ecotoxicology, environmental fate and health effects. Funding for the work is provided by OECD Member countries. At the moment the Nordic Council of Ministers sponsors the testing of silver and iron nanoparticles. Typically countries operate as main sponsors, co-sponsors, or contributors following their national interests. For example, South Africa proposed nanogold to the programme and also committed to financing the related activities. However, as Dr Ahtiainen pointed out, such linkage of interests and commitments is not totally without problems. The OECD Working Party thus

¹Under the Commission, the work takes place in a subgroup of CARACAL = Competent Authorities for REACH and Classification and Labelling Environmental Management. This subgroup is named CASG-nano.

emphasises that the testing programme is not to be used in a purpose-oriented fashion, to intentionally "prove" that a material is safe.

In addition to the work on safety testing of a set of nanomaterials, the OECD examines the applicability of its chemical testing guidelines for nanomaterials. Referring to the results gained in this project so far, Dr Ahtiainen concluded that it seems evident that new means for analysing the physical and chemical characteristics of nanomaterials will be needed. Meanwhile many of the "endpoints" or measurement variables used in chemicals testing are also relevant for NMs. Having said that, Dr Ahtiainen nonetheless emphasised that metrics (e.g. mg/l) for dosing, and exposing and characterisation must be reconsidered. Guidelines for so doing are currently under development.

Questions related to applicability of pre-existing scripts also occupy a key position at the EU level. The special group of competent authorities has been set to evaluate the potentials of REACH² and CLP³ to extend and effectively fulfil the regulatory challenge. In addition, the group has had the demanding task of drafting a general definition for nanomaterials. According to the recommendation released in October 2011, the EC suggests that a nanomaterial has external or internal dimensions ranging from 1-100 nm, a surface specific volume that exceeds 60m²/cm³ and contains 50% particle number size distribution of this kind of material (particles). This definition applies to both man-made and natural NMs (particles, aggregates, agglomerates).⁴

Getting back to REACH, Dr Ahtiainen reminded us that the regulation applies equally to substances, their use and their multiconstituents. Moreover, "REACH obliges the registrant to ensure that his registration(s) demonstrate(s) that all forms of the substance in his dossier(s) can be used safely".⁵ However, it is also possible that independent registration for nanomaterials will be demanded and the link to their bulk forms removed. Alternatively, a totally new piece of regulation may be deemed necessary – discussions suggesting this have already been witnessed.

At the end of his presentation, Dr Ahtiainen raised the current topics of registration and labelling. During its Council presidency in 2010, Belgium proposed obligatory registers and labelling schemes for all EU countries. The initiative to support the traceability of nanomaterials was, at the time, supported by many Member States (including France, Sweden, Italy and the Netherlands, for example). Currently, France is considering national legislation that would designate the use, import and manufacturing of nanomaterials eligible for registration. However, as the speaker pointed out, such schemes might send a false signal to consumers, indicating that all nanomaterials are equally similar and problematic. This, of course, is not the case. Nevertheless, whatever happens with the official initiatives, the means of communicating with the public about NFC will also be needed.

²REACH implementation projects on nanomaterials (RIPoN 1,2,3)

³CLP = Regulation (EC) no 1272/2008 on classification, labelling and packaging

⁴In specific cases and where warranted by concerns for the environment, health, safety or competitiveness, the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%. Moreover, by derogation, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

⁵Today, bleached cellulose (CAS-no: 65996-61-4) is exempted from REACH registration according to REACH Annex IV. However, if grinded mechanically to NFC (without chemical modifications), it will probably remain exempted, but the rationale for so doing should be given by the manufacturer. Meanwhile, if chemically modified e.g. with covalent bounds, NFC would be considered a new substance, and this would lead to an obligation to register.

6.2 Discussing NFC and safety regulation: lessons learned

In the encounters bringing together industry representatives, scientists and administrators, regulatory development and their relations to NFC applications were intensely discussed. That holds true for the January 2012 workshop in particular. In this workshop it became evident that the development of safety regulation of nanomaterials, including NFC, is a *common concern*. Everyone appeared to be fearful of extra delays and explicit regulatory exceptions. Rather, from the point of view of many participants, the work seems to be proceeding at a frustratingly slow pace. When the workshop attendees were asked to identify objectives for the regulatory development and write them down, one of the responses received read: "What is the time schedule for guidelines? Lack of regulations – a hindrance to innovation and business development?"

In the focus group debates, too, the *benefits* of regulations and standards were brought up. According to the participants, the official demands could provide a background against which the appropriateness of industrial operations could be reflected. As one participant noted, safety is in any case an issue that must be somehow ensured: the clients who buy the material request guarantees. The same goes also for the consumers of the final products.

However, safety was not only deemed important because it is explicitly demanded or inquired about, but simply for its own right. This can be an ethical starting point. In addition, participants referred to attempts to minimise the potential of risks and surprises. News about negative effects would harm business: not only would individual products be at stake, but also entire brands. It was also pointed out that firms may be concerned about the image of a branch or industrial cluster, trying therefore to ensure that all operators fully commit to the joint rules.

Responsible behaviour may exceed immediate safety considerations (human and occupation health), also relating to the enhancement of overall sustainability and environmental performance. Again, doing so may prove cost-effective, allowing for reductions in energy costs, for example. It was also recognised that *product-based environmental policy* will be actively enhanced by the Ecodesign directive of the EU. However, the participants were not entirely convinced that integration of health and environmental concerns can be effectively promoted by potentially rigid process demands.

Despite the consensus on the importance of safety and sustainability issues, *costs and risks of regulation* were also discussed. In particular, when – or if – all nanomaterials are treated and discussed as a single, coherent group, from the NFC point of view the risk of *overreaction* evolves. Scientific tests carried out so far indicate that unmodified NFC does not pose any risks to human health and the environment. However, if regulatory codes and public discourses merge all nanomaterials together, thus making similar assumptions about them and posing similar demands on them, product development may be unnecessarily hindered. In addition, very strict restrictions on nanomaterial use may come with harmful side-effects. For example, the recycling of materials may be hampered.

The worry over overregulation probably also motivated the claims that were made to suggest that NFC is not a nanomaterial at all, or even if it is, under development is not a new material, but rather an old one that has been used for a long time in baking paper, for example. Both of these claims were critically assessed by other participants. According to a common view, NFC indeed fulfils the criteria of the EC definition for nanomaterials.⁶

⁶See also Vartiainen et al. 2011.

A close reading of all the debates also reveals that the participants had slightly different views on the ways product development, testing strategies and learning processes should be brought together. On one hand, as we had seen in Dr Ahtiainen's presentation, the challenges can be approached by aligning with the logic that REACH and chemical regulation follow. This would mean that NFC in its uncoated and unmodified form is taken as a common starting point. Experimentation could then be steered to produce a *tentative REACH dossier*. Doing so would not only help the companies working with NFC to anticipate the regulatory development, but also, thanks to the experiences gained, to actively participate in the policy discussions. The studies carried out so far already indicate that many test methods potentially suitable to other nanomaterials are not suitable for NFC.

On the other hand, many of the participants in the January 2012 workshop emphasised that 'pure' NFC may become an irrelevant safety concern if compared to the modified versions of NFC. The chemical and physical treatments may radically change the qualities of the material, resulting in potentially poisonous or otherwise harmful compounds⁷. Hence, many industry representatives suggested that from their point of view it makes sense to start analyses and studies by *focusing on the likely products* they will have.⁸ The first task then is to find out in what form the material is in the product. Furthermore, as a number of scientists pointed out, responsibility should be taken for the *systemic entity* that is emerging: the final product should be safe throughout its processing⁹, use and disposal. Central to this will be the interactions to which NFC will be exposed in different phases.

Finally, interesting and in-depth discussions focused on *communication and public engagement*. Again, people contemplated the issue from somewhat different perspectives. However, general concerns were raised about "unnecessary fears" and "irrational concerns". The public domain appeared thus as something inherently risky and in need of active management. Above all, at the January 2012 workshop the quest was for careful balancing: neither too much nor too little should be communicated. Doing and engaging too little might result in the emergence and overtaking of a "nano-monster" that dissolves important differences between nanomaterials, merely causing apprehension. Meanwhile, too detailed a declaration of all things not-yet-known would be unnecessarily alarming, too. This argument points back to the potential of overreaction. In several remarks the attendees raised concerns about reasonability. It is clear that NFC and its applications need to be carefully studied and analysed, but how far and for how long should the research go? When can something be declared safe? This worry was deemed particularly important due to the intuitive safety of the non-modified NFC. However, the public (in all its diversity) may not share such an intuition, asking instead for hard proof, the sufficiency of which may nonetheless never satisfy everyone. This, of course, raises a dilemma about the communicative strategies through which NFC is assigned capacities and qualities. However, many participants argued for openness and, indeed, for active engagement in one way or another. At the same time, a desire was expressed for the authorities to provide information about nanomaterials and their differences and applications.

⁷Under REACH the modifications are treated as separate value chains of NFC.

⁸In this context many panelists referred to the EU Packaging Directive.

⁹The importance of occupational health and industrial safety legislation was emphasised in all meetings arranged as part of the pre-study.

7 Mapping the way ahead

In several respects, the small-scale pre-study fulfilled the expectations of its researchers. Over the course of one year the project brought together a diverse set of top experts, out of whom some had no prior specific knowledge about NFC and its testing, development and regulation. In the joint research process it was possible to proceed from hesitant and careful speculation to more open airing of worries and ideas. At the same time some common questions and research needs became articulated.

However, what the pre-study also taught us were the limits of such an "NFC-in-general" approach. It is possible to identify research themes without links to particular industrial cases, but clarification of more precise questions would benefit from contextualisation. NFC receives its importance, meanings and impacts through diverse interactions that vary depending on the production process, use and waste management. Whilst the interactions that emerge and become dominant cannot be nailed down in advance, they can nevertheless be probed and categorised for analytical purposes. Hopefully the lessons then learned can also further affect product development: this is the rationale of the "safety-by-design" (Kelty 2009) and "product-oriented environmental policy" (Commission of the European Communities 2003) approaches.

On the other hand, the emphasis of interactions and relations does not decrease the importance of the testing of the intrinsic qualities of NFC and its modifications. This is the case, although in the pre-study such a "substance-based" approach was repeatedly supplemented by arguments that pointed to a more "product-based" research strategy. In the end, however, the two perspectives intertwine. This becomes evident, for instance, when contemplating waste management and the potentials of recycling. Whilst NFC will turn waste through specific processes and products, its basic qualities are critical when assessing the reactions and effects in different media and waste management processes.

Indeed, waste management and recycling were themes that were identified as research priorities in the pre-study. These themes further open up more specific questions about the behaviour of NFC during recycling process, such as whether the recyclability of NFC-based products is similar to the currently existing commodities or not, and will the NFC remain in pulp or released into water, etc. In the pre-study, other topics and phenomena in need of further toxicological and ecotoxicological research were identified. For example, a general question to get a deeper understanding of the fundamental phenomena that makes materials toxic to humans and environment in general was pointed out. A better understanding of the phenomenon behind the toxicity could efficiently reduce the need for safety testing of nanocellulose and its chemical modified forms, and help R&D to design safe products.

Identified research needs can be divided into two main topics: a) testing and test procedures, and b) environmental behaviour of NFC. Relevant indicators and measurement methods that are applicable to nanoselluloses are needed in order to determine in what form the NFC material is in the product: is it in the nano-form or not, and what is the amount of nanocellulose in the end product? In addition, suitable migration tests and test procedures for nanomaterials and nanocellulose are also needed to determine – or exclude – the migration of nanocellulose to food. Studying the exposure of workers during NFC production and products containing NFC, such as dust during production, aerosols, etc. also calls for relevant measurement methods. In the field of behaviour of NFC in water systems, the efficiency of current waste water treatment plants was highlighted. The environmental behaviour of NFC during disposal was also mentioned as a question that needs clarification.

When it comes to environmental performance more generally, the discussion carried out during the pre-study indicated that the sustainability of NFC and its product applications is definitely something that must be actively analysed and demonstrated. This requires paying attention to the potential development in resource efficiency: decreasing the usage of materials, complementing current materials, and/or substituting current materials and the unknown possibilities and obstacles in recyclability (are there differences in the recyclability of NFC-based products compared to the existing ones and if so, what are the differences?). In addition, the durability of NFC-based paper products, for example, may differ in their characteristics compared to the existing ones which may shorten or lengthen their life cycle, thus further affecting environmental performance. Therefore, from an industrial point of view, involvement in the production and usage of NFC creates new business risks that are related to the incomplete information on NFC production processes, possible uses of NFC in end products and their potential markets, as well as the unknown end product characteristics in terms of use, recycling, and disposal.

In addition to research themes and questions, the debates between the different experts helped to identify other strategic choices. NFC gained properties not only as a scientific, technical and commercial issue, but also as a societal one. These features became discussed mostly in the context of regulation and its development. It was agreed that product development, research and regulation cannot evolve, and should not evolve, separately. However, whilst acknowledgment of this will challenge the regulating public authorities, private enterprises also face new kinds of requests and options. These choices can be illustrated with the use of the continuum between integrative and innovative Corporate Responsibility (CR). Halme and Laurila (2009) draw this distinction in order to point to the different roles firms can take in relation to CR and product development. In innovative CR, the emphasis is on developing new business models for solving social and environmental problems and enlarging core business. Challenges in communication with customers, authorities and consumers were considered to be an important question that requires research inputs. It was emphasised that research results on safety issues and environmental product characteristics, for example, are needed for reliable communication between different actors. Therefore, industry representatives considered the possibility of developing a joint databank to gather and share the safety data of nanocelluloses and related materials.

The debates also opened up practical questions about the appropriate modes and arenas of cooperation between different stakeholders. Moreover, as became very evident in the debates during the pre-study, dialogue around new technologies and their implications are needed not only between administrators, scientists and private enterprises, but also more widely across the whole society. However, it is not clear how such communication could be fruitfully enhanced. Nonetheless, an analysis of the views, experiences and tools on which communicating and engagement must and could be based might provide at least tentative ideas and answers.

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