Risk assessment of nanofibrillated cellulose in occupational settings

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Juulia Rouhiainen, Pöyry
Virpi Väänänen, FIOH
Irina Tsitko, VTT
Jesse Kautto, Pöyry

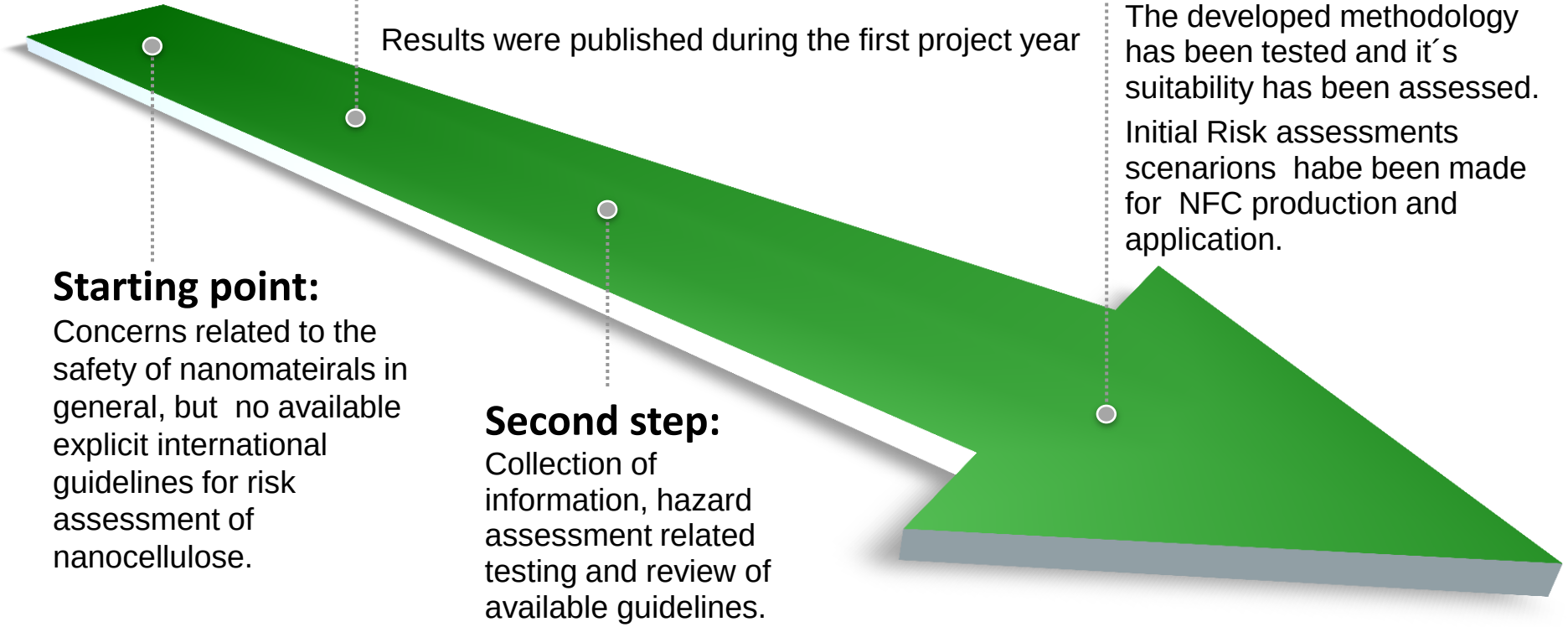
1. Introduction

First step:
Review of the state-of-the-art of risk assessment and publicly available reports on nano-related studies on health, safety and environment.
These results were used as the basis for the definition of a risk assessment methodology for this project.

Results were published during the first project year

End point:
The developed methodology has been tested and it´s suitability has been assessed.

Initial Risk assessments scenarions habe been made for NFC production and application.



Starting point:
Concerns related to the safety of nanomateirals in general, but no available explicit international guidelines for risk assessment of nanocellulose.

Second step:
Collection of information, hazard assessment related testing and review of available guidelines.

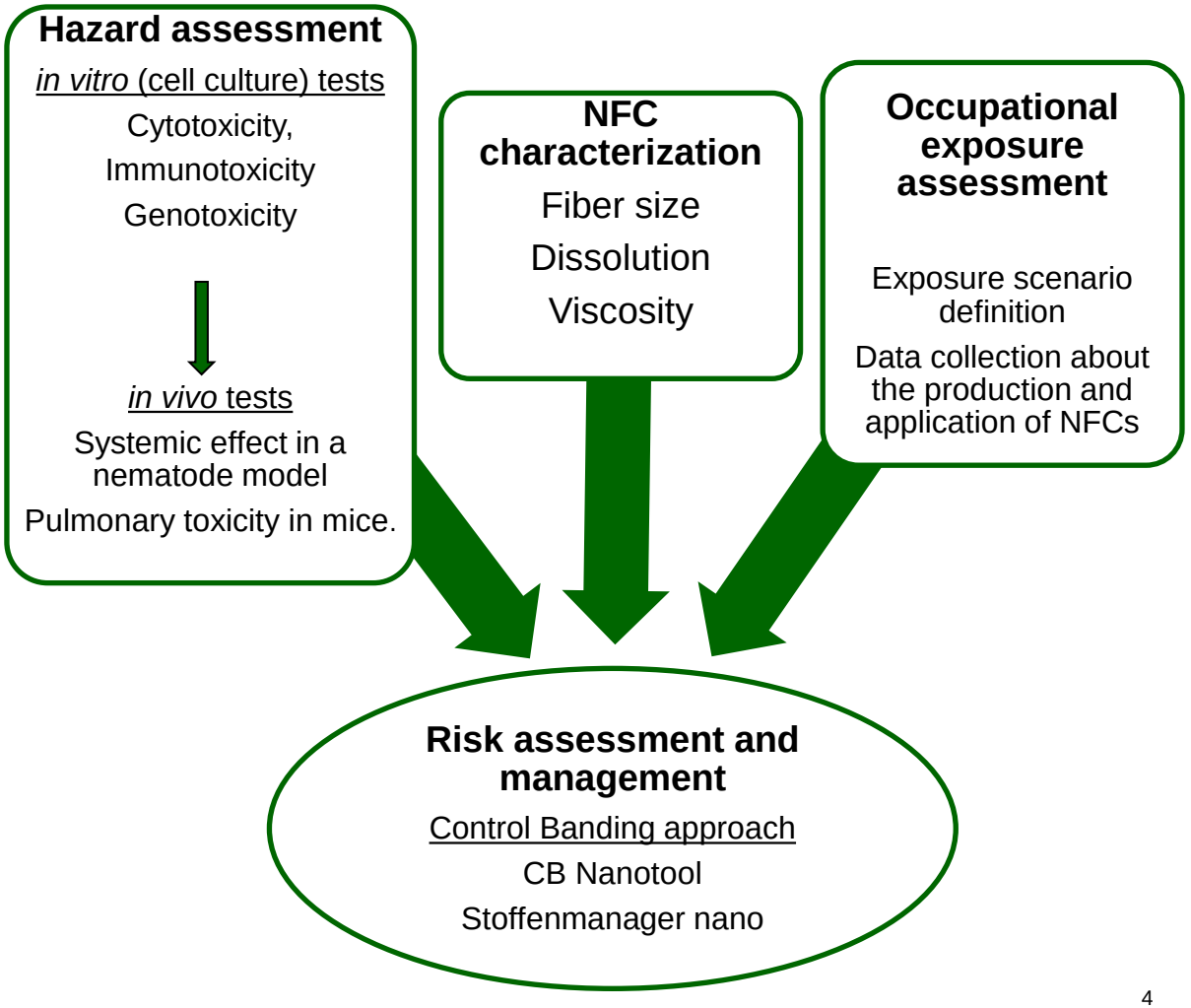
2.1 Risk assessment methodology

Risk = hazard x exposure

- Risk assessment is a process which entails some or all of the following elements:
  - hazard identification,
  - hazard characterization,
  - exposure assessment and
  - risk characterization.

- It should be also remembered that both a hazardous nature of the studied material and exposure to the material are needed for causing a health risk.

2.2 Risk assessment and management scheme used in the SUNPAP project

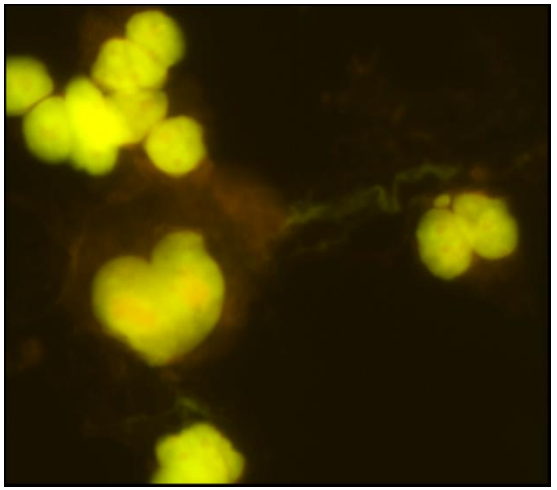


3.1 Hazard results used in Risk Assessment

- Short summary of the results presented earlier:

In vitro tests:

  - No cytotoxic effects were seen from the NFC samples tested.
  - Slight immunotoxic effects were seen.
  - Slight genotoxic effects were seen in comet assay, but this is likely related to the general response of the test method to small particulate material, rather than to any genotoxicity of NFC. In micronucleus tests no genotoxic effects were seen.



Micrograph of human bronchial epithelial Beas 2B cells exposed to NFC-VTT (250 µg/ml). NFC can be seen as light green material on top of the micronucleated cell. Source: FIOH Kati Hannukainen and Hilkka Järventaus

3.2 Hazard results used in Risk Assessment

- *In vivo* tests:
  - In the nematode model no effects were seen in viability, mobility or reproduction abilities. No neurotoxic effects were seen.
  - In the pharyngeal aspiration tests on mice NFC caused inflammatory response. Based on this test it cannot be concluded weather the response was due to the NFC, the bacterial contamination present in the tested material or the combination of both → further evaluation recomended.

Illustration of the nematodes used in the *in vivo* tests. Source: Professor Garry Wong, University of Eastern Finland, The A.I. Virtanen Institute

4. Suitability of Hazard assessment methodology

- The used methods are a suitable first step in Hazard assessment of NFC.
- In *In vitro* tests NFC was not toxic or marginally toxic – results were clearly weaker than the used positive controls.
- The nematode model indicated that NFC does not have systemic effects.
- The pharyngeal aspiration studies with mice indicated the effects of inhalation of NFC, which is the most likely route of occupational exposure.

5.1 Exposure results

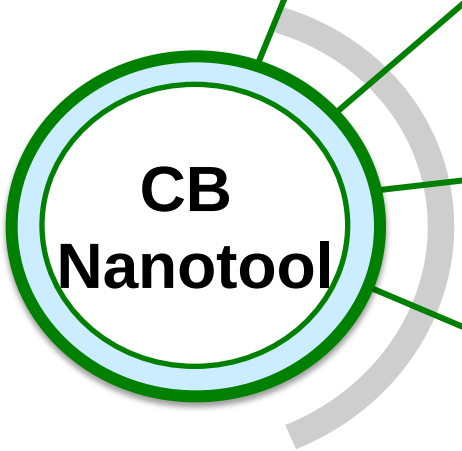
- Occupational exposure was assessed with 4 scenarios used in CB Nanotool and 7 different scenarios used in Stoffenmanager Nano
- The scenarios included two different types of NFC manufacturing in lab/pilot scale and various steps in manufacturing two different NFC applications
- The information used in the scenarios included information from the lab and pilot scale plants, expert opinions and modeled information for production plants for applications.

5.2 Exposure results

- **Exposure was assessed to be low in all the scenarios used.**

- This was mainly due to the facts that:
  - the amount of workers in each scenario is low
  - NFC is used in the processes in wet stage
  - production systems in some scenarios are partly closed
  - fume hoods and mechanical ventilation are used
  - regular maintenance and cleaning were assumed

6.1 Risk assessment results from CB Nanotool



- **Focuses more on the hazard assessment taking into account some toxicological data and physico-chemical properties.**
- **CB Nanotool is sensitive to fiber's size. This might be an issue in products like NFC which might not be very homogenous.**
- **CB Nanotool is sensitive to description of surface reactivity which it is dependent on the expert's judgement.**
- **The hazard data from toxicological studies obtained in SUNPAP are not sufficient for CB Nanotool. If "unknown" is used as an input for toxicity in hazard evaluation, severity was estimated as "high"**

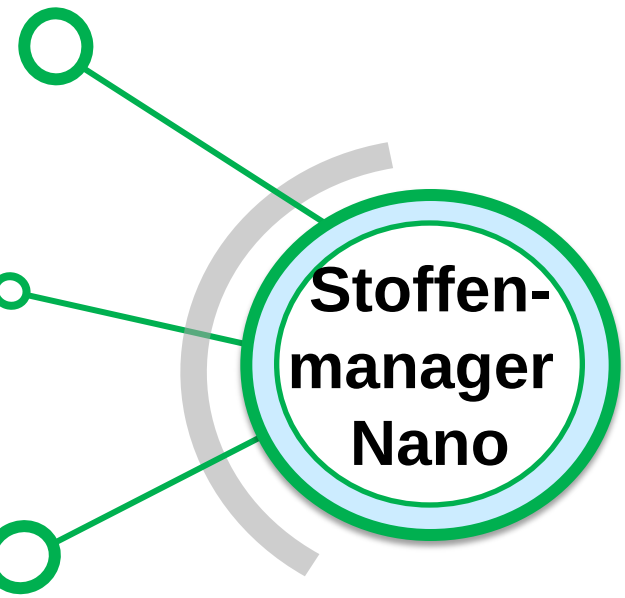
All the assessed scenarios resulted in to RL3: Containment/Enclose the process

7.1 Risk assessment results from Stoffenmanager Nano

Stoffemanager Nano focuses on occupational inhalatory exposure. It takes into account source of emission, transmission and immission. It also takes into account more bands than CB Nanotool.

The tool offers very limited possibilities to take into account hazard characterisation results, especially in the case when fibres or fibre-like particles are assessed.

In addition, any nanofibres assessed are automatically located to the highest hazard band (Duuren-Stuurman et al., 2011). Any control measures taken do not affect this result. Thus Stoffenmanager Nano 1.0 may not be the most suitable tool for assessing the risk related to NFC.



All the scenarios had lowest exposure band and the highest hazard band.

8. Risk Assessment results

Exposure

It's likely that the possible **exposure to NFCs is low** in all the scenarios studied.

Hazard

The results suggests that **NFC is not very hazardous material**, even that it had slight toxic effects *in vitro* and inflammatory response from the *in vivo* tests.

Risk

The overall risk related to the assessed scenarios and materials is thus assessed to be low. However, since there were some inflammatory responses in *in vivo* tests, precautionary control measures should be used in occupational settings to decrease the possible exposure.

9. Conclusions

NFC has no worrying toxic effects noticed in the *in vivo* tests. Exposure through inhalation might induce inflammatory reactions. This calls for exposure control especially in the occupational environment.

This assessment is applicable only for the scenarios studied. The information about the levels of exposure are limited to qualitative information. In addition consumer exposure was not assessed during this project.

Acknowledgement

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