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# Nanoparticle risk management and cost evaluation: a general framework

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**Abstract.** Industrial production of nano-objects has been growing fast during the last decade and a wide range of products containing nanoparticles (NPs) is proposed to the public in various markets (automotive, electronics, textiles...). The issues encountered in monitoring the presence of nano-objects in any media cause a major difficulty for controlling the risk associated to the production stage. It is therefore very difficult to assess the efficiency of prevention and mitigation solutions, which potentially leads to overestimate the level of the protection barriers that are recommended. The extra costs in adding nano-objects to the process, especially that of nanosafety, must be estimated and optimized to ensure the competitiveness of the future production lines and associated products. The risk management and cost evaluation methods presented herein have been designed for application in a pilot production line of injection-moulded nanocomposites.

## 1. Introduction

Nanotechnology is the name given to a wide range of new technologies which were mostly developed in the last decade and which, according to ISO nomenclature standard [1], explore nanoscale phenomena and structures. Most of today's technology explores the use of nano-objects, especially manufactured engineered nanomaterials. This new class of anthropogenic products can lead to better performances of existing materials and composites, improving mechanical resistance, thermal or electrical conductivity or optical properties, to name just a few. However, as nano-objects appear to show properties which differ from their bulk parent material, there is an uncertainty on how to evaluate the risk associated with handling them. Indeed, there is an ongoing debate about the potentially increased toxicity of nanoscale materials in comparison with conventional ones, which even led to the creation of a new field, called nanotoxicology [2,3].

One of the proposed answers to deal with the risk evaluation and management of nanomanufacturing is to use the precautionary principle, and instead of using threshold limit values

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(which are undefined for nanomaterials), through an ALARA (as low as reasonably achieved) approach, prevent workers exposure to nano-objects [4].

The plastics industry is considered to be one of the main field in which the new nanotechnologies can play a key role. For many decades now, common polymeric materials have been reinforced with suitable additives to prepare reinforced plastics and polymer composites. The main examples are fibre-reinforced materials and laminate composites, in which embedded components (glass or carbon fibres, metallic panels) impart mechanical strength and polymeric components (epoxies, thermoplastics) provide flexibility, lightweight and/or isolation properties. The possibility to incorporate engineered nanomaterials, tailored to a specific end, can represent a major breakthrough.

The present work was developed inside the European Project “SAPHIR – Safe, integrated and controlled production of high-tech multifunctional materials and their recycling”. It consists in developing a framework to analyse the risk associated with nanomanufacturing of polymer nanocomposites and evaluating the potential cost increase due to prevention and mitigation barriers to be put in place. CRP’s pilot production line [5], which is used for producing innovative prototype series of automotive lighting devices, served as a model for the study.

## **2. Risk assessment according to European directives**

For the health and safety domains, the term risk refers to the possibility of negative consequences [6]. In risk assessment, risk is a combination of the probability that a harm occurs by the severity of this harm. The source of risk is a hazard or a hazardous situation, while its consequence (harm) can be a physical injury, damage to the health of people or damage to property or to the environment. Through risk analysis, a chain of interdependence (event sequence) can be established linking hazards to harms.

In industrial safety, the risk can be classified either as chronic or accidental. Chronic risk is linked to the expected impacts on human health and on the environment of pollution and releases resulting from the facility operations in normal conditions. The Chronic risks can cause long-term impacts, then, the cumulative and time factors are of importance. On the other hand, accidental risk is the possibility of an undesirable (and sometimes unexpected) event on a site using substances or processes which can cause a hazard, resulting in an immediate harm. Principal accidental risks cause explosions, fire or emissions of toxic substances. Concerning nanomaterials, and more specifically nano-objects, both chronic and accidental risks are relevant and should be estimated

A literature review of risk assessment methodologies reveals a number of methods and procedures, such as ATEX<sup>4</sup> [7] for explosion risks, SEVESO II [8] for general chemical hazard, or IPPC [9] for chronic health and environmental risks. The generally adopted framework of risk estimation in these methods (“classical risk assessment approach”) comprises several successive steps, starting with (i) define the scope of risk assessment, (ii) identify the hazards, (iii) set the links between hazards and harm severity, (iv) through exposure scenarios estimate exposure doses, and (v) perform a quantitative estimation of the considered risk. This quantitative “substance-based” approach is hardly, if at all, applicable to engineered nanomaterials. Anthropogenic nano-objects exist with a wide range of properties, ranging from simple chemical composition, to different particle size, surface treatment, particle shape and state of aggregation. In other words, the existing methodologies are not compatible with the present uncertainty of the harm associated to nanomaterials.

## **3. Basis of proposed risk assessment**

The methodology proposed (Figure 1) is based on a broad qualitative analysis and tries to cover effects on human beings (on site and off site), environment (pollution of air, water, soil) and to converge towards a unique method to assess both chronic and accidental effects. In line with the objectives of the SAPHIR project, this method uses concepts already developed and used in standard industries or developed in the scope of regulations and European directives. In this way, the “SAPHIR

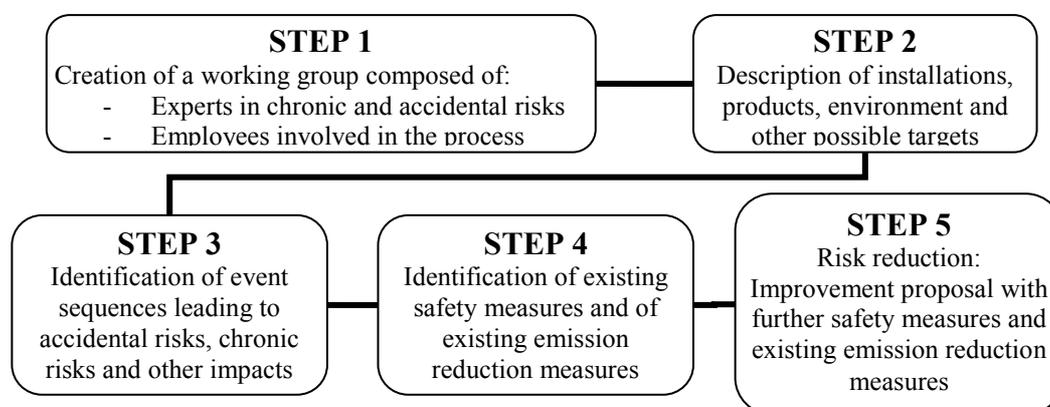
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<sup>4</sup> ATEX is the name commonly given to the framework for controlling explosive atmospheres and the standards of equipment and protective systems used in them.

methodology” is based on well-known techniques already used by industries to identify and reduce risks. Unlike existing procedures, however, each step has to assume a new focus to deal with the uncertainty associated to nanomaterial-related risk, and the lack of usual toxicity (MSDS, dose-response) or emission data.

### 3.1. Step 1: creation of a working group

With the help of a group of stakeholder [6], experts will carry out the risk assessment of the pilot lines. The working group must be composed at least of (i) a person in charge of the process: his knowledge, especially on the properties and characteristics of nanomaterials and the nanomanufacturing process is vital for the completion of the risk assessment, (ii) a person responsible for the maintenance of the plant/unit, (iii) a person in charge of HSE prevention: his knowledge of the existing situation will allow to evaluate the need for improvements of the safety measures, (iv) a person that will lead the risk assessment, and (v) experts having an extensive knowledge in risk assessment.



**Figure 1.** Main steps of SAPHIR risks assessment methodology.

### 3.2. Step 2: Description of installations, products, environment and other possible targets

The working group, to identify each of its elements, should process an inventory of the studied installation. The analysis will be carried out for each part of it. The list of the workplaces, threatened persons and objects, should be made during this step, in order to be able to estimate consequences for workers, people and environment.

The perimeter of the process investigation is established at this stage, especially regarding the possible on-site further processing steps of the nanomaterial produced (for instance, incorporation of manufactured nanoparticles (NPs) or nano-objects into another material).

### 3.3. Step 3: Identification of event sequences leading to accidental and chronic risks

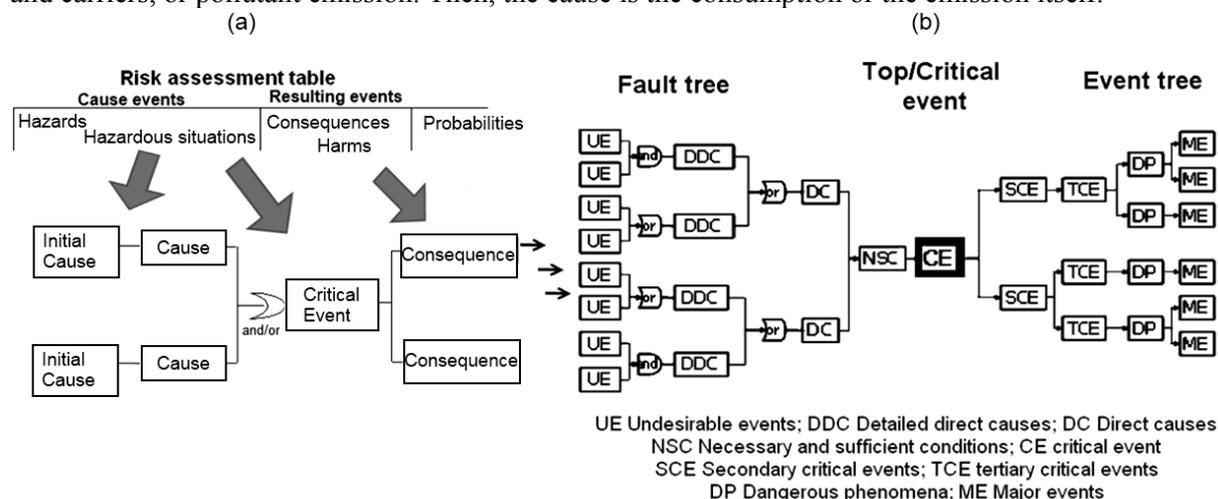
The objective of this step is to provide a single framework to identify the accident event sequence from a cause to a consequence expressed in terms of a damage and to inventory all consumption (energy, water,...) and chronic pollutants (including but not limited to nanomaterials) released in the environment.

This is a critical part of the risk evaluation, where the knowledge of both the process and the risk analysis is required. To limit the risk of communication problems between process experts and risk analysts, some tools are presented in the next sessions, which can be of help in structuring the analysis.

*3.3.1. The use of a table.* The sequence of event will be studied through a risk assessment table used both for accidental risk and for chronic risk (Figure 2a). This table is frequently compiled in an exchange session where hazards and harms are listed and interconnected. Another important step of the risk analysis is the estimation of a probability (or occurrence frequency) for a given event [6], allowing a suitable risk management by the definition of priorities [10,11].

3.3.2. *The cause tree and the “bow-tie” diagram.* Through the analysis of hazards and hazardous situations listed on the table, and the critical events they lead to, it is possible to identify event chains. Through a cascade of other events (indirect and direct causes), these chains go from an initial cause, to the critical events that result in consequences, and possibly dangerous phenomena. The multiple chains of events that result in the top one (critical event) are called the fault tree, while the different consequences of a given top event are grouped in an “event tree” (Figure 2b).

Causes can be either internal, for example the cause explaining a high / low pressure in a capacity, or external: work nearby the installation, flooding, etc. For accidental risks, the method will also include assessing any deviation of parameters like pressure, temperature, level, flow, contamination. The search for internal causes will rely on a HAZOP-based approach [13] (only the safety aspects of the HAZOP are considered). For chronic risks, the initial causes are identified by screening throughout the process all the steps that cause externally provided utilities, including water and energy sources and carriers, or pollutant emission. Then, the cause is the consumption or the emission itself.



**Figure 2.** Risk analysis through table (a), and cause/event trees in the form of a bow-tie diagram (b)

3.3.3. *The critical events and their foreseen consequences.* Generally, two types of events can be identified during the risk analysis: events that may lead to accidental consequences (as defined in the SEVESO II directive [8]), or events that lead to a chronic disease or pollution (in the meaning of the IPPC directive [9]).

A loss of containment can cause a release of NPs in the workplace or outside the plant and lead to chronic or accidental consequences with short or long term effects, for instance: disease for workers or for population, and pollution of the environment. Accumulation of NPs during the process can lead to fire or explosion events. In such cases, foreseen consequences can be thermal and / or overpressure effects. In case of the presence of an ATEX, what is feared is the production of an explosion with thermal and overpressure effects.

#### 3.4. Step 4: Identification of existing or recommended safety and emission reduction measures

Safety and emission reduction measures are identified during risk assessment of NPs processes. For existing processes, only existing measures are listed; for processes still on project phase, only recommended measures are identified. Measures related to nanotechnologies that can be identified are defined in the following sections of this article.

#### 3.5. Step 5: Risk estimation, risk reduction and risk control

A hazardous critical event or a chronic exposure, as explained in previous steps of this method, results from the get-together of a hazard and a target (human or environment). After the identification of the hazardous, risk estimation assigns values to the probability and the consequences of each risk. In

classical methods of accidental risks assessment, this step of risk severity estimation and risk probability estimation, aims at prioritising risks and setting up reduction measures.

The probability for an accidental event is linked to the frequency to which an event is likely to occur while for a chronic risk, it is embedded in the dose-response function [6]. A chronic event is such if it is certain and is occurring continuously. Indeed, exposure takes into account the lasting time of the event which occurrence probability is 1. The accidental risk probability is the dangerous event probability (NP release) modulated by the probability to have an exposure. Estimating the probability for an accidental event to occur requires considering safety barriers or measures.

Concerning severity estimation, two parameters are highlighted by the classical methods: severity of the event or of the exposure, and vulnerability of the target. According to the probability and the severity of the event sequence, an acceptability matrix is designed to identify and set priorities to the risks that need to be reduced through further safety measures or environmental control measures.

In the scope of developing a unique method for both accidental and chronic risks, adapting this system with probability and severity classes is tricky for nanotechnologies as dose-response and effects are mostly unknown.

#### **4. Existing measures and control options for preventing and mitigating consequences**

NP manufacturing is in its infancy and mainly focuses on production problems. Therefore it is not surprising that current Environmental and Health Safety (EHS) practices – including selection of engineering controls, Personal Protective Equipment (PPE), cleanup methods, and waste management – do not significantly depart from practices for handling conventional chemicals.

Additionally, the intrinsic problems in monitoring NPs/nano-objects in any media cause a major difficulty for controlling the associated risks. That makes very difficult to assess experimentally the efficiency of prevention and mitigation systems.

##### **4.1. Combating risks at source – Process design and containment**

Process design is generally the most cost-effective way to prevent risks and should foresee the inclusion safety and chronic risk evaluation still at the design phase whenever possible. Process design options such as enclosure, isolation, and closed circuits can reduce workplace exposure and risks in general.

Recently, Morose synthesised the basic principles of safe process design applied to nanotechnologies [12] through the “SAFER” acronym: Size/Surface/Structure, Alternative materials, Functionalisation, Encapsulation, Reduce quantity. This approach can be considered an application of the “Eliminate, Substitute, Isolate” steps in the common ALARA methodology [4].

Most of NPs and nanomaterials processes involve already some degree of containment, be it for the need of controlled atmosphere or high temperatures involved. This has of course also a beneficial effect of minimising the release of NPs into the workplace during production, but if there are any leaks in the system then NPs may pass through and disperse into the workplace. With time, the NPs may form agglomerates that are not easily dispersed into the air. However, inhalation exposure to these agglomerates is still a hazard.

To a certain extent, laminar flow booths or clean rooms are an alternative containment solution for powders, already used (but not for NPs) in the pharmaceutical industry. The common system configuration is designed to extract powders downwards away from the operators and to air intakes, and then direct the flow to a filtering system. The main filters can be bag-sealed on removal from the system to prevent the release of powders. Laminar flow booths can also be used in addition to conventional containment as an additional safety measure to prevent emissions.

Finally, using dispersions, pastes and compounds (commercially sold as *premixes*, *concentrates* or *masterbatches* – the “masterbatch approach”) instead of neat powders as far as possible can reduce workplace exposure, but this option may however bring the need to reconsider process design, and can lead to a higher material cost.

The storage of NPs may also involve specific conditions to conserve the products. On the one hand, NPs tend to agglomerate and aggregate, and therefore lose their nanoscale structure and unique properties. On the other hand, the small size of the particles provides a very large surface area in contact with the surrounding air, thereby facilitating chemical reactivity. Possible solutions include storage in inert gas or in anhydrous conditions. It may also be possible to embed the NPs in a protective layer of salts or polymers (as in the *masterbatch* approach). These layers can be either discarded before using the product or, if possible, incorporated into it.

#### 4.2. Process control and “good housekeeping”

The preferred control option is “no control option”, in the sense that preventing or avoiding exposure is better than to have to control exposure. A possible solution in this respect is to avoid human intervention with automation, which can reduce or suppress exposure of workers. If such a solution is not possible, working period in contaminated areas should be reduced to a minimum.

The regular cleaning of working areas should take place at the end of each work shift or more often. It avoids returning the deposited particles into suspension, and so further exposure. Dry nanomaterials should be wetted with soapy solutions or cleaning oils to prevent release, as wet instead of dry sweeping favours agglomeration). Absorbent traps should be used to isolate spills. The use of commercially available wet or electrostatic microfiber cleaning cloths may also be effective in removing particles through adsorption without release to the air.

Uncontrolled cleaning will not always reduce emissions of nanomaterials to the environment but rather shift the contamination from air to water. Adapted procedures must be put in place to ensure that waste material is removed from the system as soon as the cleaning operation is complete, and placed in suitable storage containers waiting for controlled disposal. A list of other good practices includes (i) preventing the storage or consumption of food or beverages in places where nanomaterials are handled, (ii) providing hand-washing facilities and encouraging workers to use them before eating, smoking, or leaving the worksite, (iii) providing facilities for showering and changing clothes to prevent the inadvertent contamination of other areas (including take-home) caused by the transfer of NPs on clothes and skin, and (iv) training personnel in the safe handling and understanding of powders. It is also important to ensure that Material Safety Data Sheets, if existing, are readily available for the emergency services and should be located with fire evacuation documents.

#### 4.3. Prevention of nanoparticles emission

In addition to process containment, other measures can be taken to prevent NPs emissions in the workplace. One of the main prevention barriers is the use of local exhaust ventilation (LEV) systems. LEV enclosures and fume hoods are commonly used to control emissions from materials handling processes such as bagging, mixing and weighing. For NPs in well-dispersed, suspended aerosol form, the specification and quality of these systems should be similar to that used for vapours. Heaviest NPs or agglomerated ones can deposit and stick to surfaces, not being captured in an air flow, contaminating the workspace or even the workers. For this, it is essential that the LEV entry hood is always positioned correctly and adequate capture velocity is maintained.

Maintenance and cleaning of the systems may pose the highest risk of exposure. There is frequent documentation of significant exposure levels in carbon black production, because this equipment is not designed or maintained adequately [14]. The evacuated air could have to go through several filtration stages and possibly capture in wet scrubbers or electrostatic precipitators in the final stage, to avoid significant release of NPs in ambient air and possible recirculation.

LEV systems equipped with flexible ducts or telescopic arms should be positioned closely above or adjacent to the NPs source. The emission source should also be as enclosed as possible.

*4.3.1. LEV-like systems.* Fume hoods, glove boxes and clean rooms can be considered LEV-like systems, but they exhibit distinctly different efficiencies and applications. Fume hoods are a classical

equipment of chemical laboratories but not much information is available on their effectiveness against NPs aerosols.

At times some chemical or materials companies use glove boxes, primarily to protect the integrity of the material sample rather than out of concern for worker exposure. The main advantage of using glove boxes for nanoparticle production is that all the work can be carried in an inert gas. Glove boxes are also assimilated to containment protection, and thus the pertinent doubt about the outcome of containment loss in the glove box. Potentially explosive material, or substances sensitive to normal atmosphere should not be stored inside a glove box if loss of containment risk exists. For long shifts, glove boxes can be difficult to work with, resulting in supplementary operator fatigue. Glove bags are a smaller cheaper version of glove boxes, but provide a much less reliable protection, only assimilated to containment.

Clean rooms are isolated compartments in which a laminar flow is generated, like in laminar flow booths, the main difference being that the clean room provides better containment through physical isolation from the outside. Accordingly, clean room installation and running leads to high costs, both fixed and variable, noteworthy from the electrical power to run air pumps and the HVAC systems.

*4.3.2. Is filtration efficient for nanoparticles?* A frequent question related to nanosafety and safe nanomanufacturing is the filtration efficiency for nanoparticles. For large particles, impaction and interception forces dominate filtration mechanisms, but as particle size decreases, efficiency drops off to a minimum at roughly 200 nm, size limit at which the diffusion forces start to become significant. For a given filtration medium, there is a minimum efficiency at a particle size known as the most penetrating particle size (MPPS), and most filter efficiency tests are carried out using aerosols with mass median diameters equal to the MPPS [15]. So, it is expected that correctly specified fibrous filters will be good collectors of NPs. Problems may occur however if the filter material has pinhole leaks or if the filter housing has poor seals, because NPs with behaviour close to gases will penetrate these with ease. It has been recently suggested that filter efficiency drops again for very small particle size (under 2-5 nm) because of the “thermal rebound effect” [16]. Work needs to be carried out to investigate this suggestion. This is particularly relevant for cleaning systems in materials handling areas and filters installed into collection systems that circulate the air back into the workplace. Alternative systems may include modified axial-flow cyclones, which can attain a particle diameter cut-off of 20 nm [17], or magnetic filter systems, especially useful for magnetic nanoparticles.

When designing a filtration system at the workplace, there is a need to take into account the impact of change of ventilation methods on the aerosol size distributions at different locations: close to the source, in the vicinity of the worker, and in the exhaust duct.

#### 4.4. Mitigation of nanoparticles emission

*4.4.1. Personal protective equipment for inhalation exposure.* Respirators for control of exposure to airborne dust use low-pressure drop filters with a range of efficiencies dependent upon the particle size distribution of the airborne dust and the specific hazard that it poses. For nanoparticles, P3 or FFP3 filters are the most relevant [15]. At this level, half-face mask will provide a protection factor of 20; better protection will be gained from full-face masks (PF = 40) and more comfort using powered air-fed masks. The same problems previously discussed for filter efficiency apply to respirators. For respirators, however, the problem of seal leakage is more severe around the face [18].

Intermediate protection is assured by using a powered air-purifying respirator (PAPR), which includes high-efficiency filtration and a pump supplying a full-face mask. The air current generated on the wearer's face increases the level of protection while maintaining positive pressure inside the mask. This results in greater comfort for the worker and minimizes exposure when the mask seal is imperfect. In cases where high-efficiency dust filters are insufficient, airline respirators or self-contained breathing apparatus are necessary. Wearing a full-face mask with high-performance filters or with a powered air purifying respirator system provides the highest protection level.

*4.4.2. Personal protective equipment for dermal exposure.* From now, less emphasis has been placed on dermal exposure as a route of exposure. One consequence is that the effectiveness of control measures to prevent dermal exposures is poorly understood. The facility with which NPs get airborne is such that there is a strong probability of cutaneous exposure. The product recovery and packaging stages, and general maintenance, all provide opportunities for skin contact. Evidence has been emerging that nano-objects can penetrate through the skin [19]. As an example, it has been shown that fluorescent CdSe nanoparticles (5-8 nm) can penetrate not only into the *stratum corneum* of pigskin, but can also migrate into the hair follicles, from where it is possible to diffuse into the body [20]. Moreover, chemical constituents of NPs could penetrate the skin by dissolution, and the effect of nanoparticles on damaged skin or during physical activity is still unknown.

Given the context, it would be desirable to use disposable clothing made of nonwoven impermeable materials. For example, the use of hooded coveralls, aprons and shoe covers should provide good skin protection; the same principle applies to gloves. However, there is currently no guideline for selecting protective suit materials based on nanoparticle penetration. Schneider *et al* proved that there are many factors that contribute to the inefficiency of skin protection equipment [21]. The main factors include, notably: (i) direct penetration of solid material or permeation of a liquid through the clothing, and (ii) the transfer of substances through direct contact between the equipment surfaces and the skin. Work should be carried to determine the real effectiveness of skin protection equipment with particular attention to weak points such as the hands, cuffs and opening areas.

Dermal exposure is also correlated to the risk of nanoparticles ingestion. Exposure by ingestion is likely to arise where dermal exposure to the hands is present, linked to hand to mouth contact. Consideration of exposures in relation to ingestion is at a very early stage. As with dermal exposure, it is unlikely that current preventive methods for exposure by ingestion will be more effective for NPs than for larger particles.

## **5. Framework for cost analysis of new nanomanufacturing processes**

Analysing only the materials cost, the added-value character of nanometric fillers (such as carbon nanotubes) makes them not competitive with conventional materials from the economic-only point-of-view. Nanotechnology devices are economically competitive if they present a remarkable technical advantage, such as a performance unmatched by conventional materials (also as a much lower filler loading) or a multifunctional performance (replacing multiple conventional materials).

In the present example, polymer nanocomposites can have a whole new set of properties if compared to conventional polymers, such as thermal and electrical conductivity. On the other hand, if compared to more traditional materials, such as ceramics or metals, they excel in lightweight and ease of moulding and assembling. From the industrial point of view, thermoplastic nanocomposites parts can be of interest both due to their performance and their ability to replace both plastics and metals.

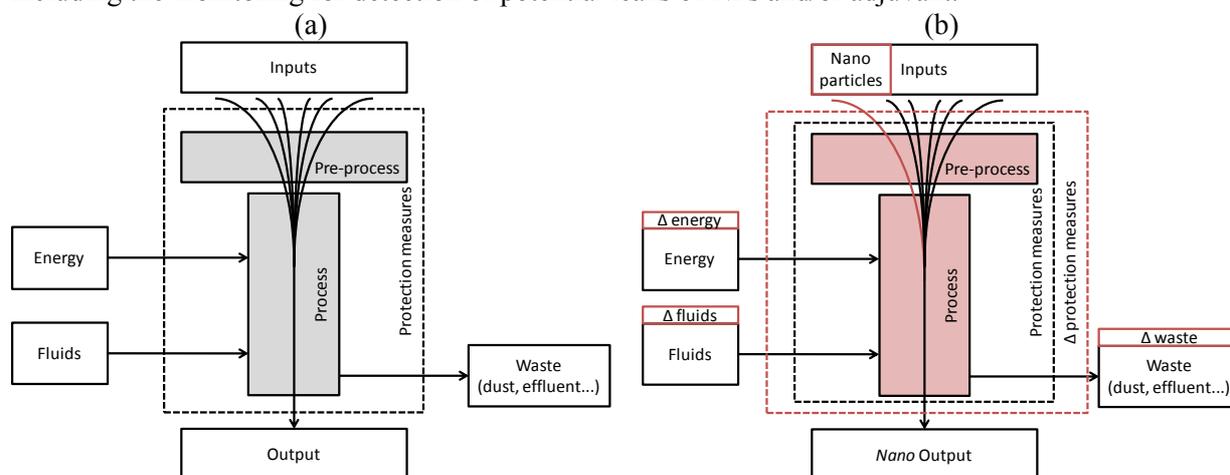
### **5.1. Additional costs due to nanomanufacturing**

A first order approach to evaluate the economic implications of the inclusion of nano-objects in an industrial process consists in analysing how the manufacturing process is altered to include NPs as substitutes for a certain number of inputs.

First of all, the pre-process might be altered to include some adjuvants, activators or surfactants. Secondly, the process itself might be modified, and energy and fluids consumption might be impacted. Accordingly, existing protection measures might have to be reinforced and extended, and new measures may also need to be implemented. Finally, the waste generated by the process might evolve: NP dust generation or presence in effluents and waste (figure 3).

The cost of the control of additional risk generated by including NPs in the process can then be estimated by combining different costs, from that due to additional protection or mitigation measures required, including all the consumables (energy, fluids, filters...) and the manpower needed to implement them (management, training, monitoring, maintenance...), to the costs generated by the

waste treatment due to the presence of NPs (or the adjuvant used) in the different waste flows, including the monitoring for detection of potential leaks of NPs and/or adjuvant.



**Figure 3.** Alteration of an industrial process by the inclusion of nanoparticles

### 5.2. Effluent treatment and end-of-life issues

Brar and colleagues analysed the scientific publications on nanoparticles [22]. The majority of papers published on the subject deals with the synthesis of NPs (79%). Other two major subjects are the behaviour of these particles in the air (15%) and their toxicity (5%). Very few publications are focusing on the issue of NPs in wastewaters or environmental remediation. Some publications already indicate that it is possible to filtrate and flocculate NPs and nanotubes during their production [23] or in wastewater [24]. There is however no indication of industrial applications and very few researches focus on the behaviour of NPs in water or on the techniques of filtration to concentrate these particles by filtration. The added cost of effluent treatment depends largely if the current systems can be used for nano-effluents and should still be considered in the cost calculation.

The end-of-life issues related to nanostructured materials, or materials which contain engineered nano-objects, are still recent and yet to be solved [25-27]. Most of the difficulties related to nanomaterial end-of-life and waste management relates to the multiplicity of matrices and NPs to deal with, each combination displaying different physico-chemical properties. It is mandatory for European car producers to take into account end-of-life aspects in their production costs [28], and they should be considered within the development of every nanoproducts since a release may occur during machining, maintenance or recycling. The task is not easy because only limited information is available about this aspect. Higher costs due to additional treatments should be expected, but can only be evaluated on a very specific level. The authors are involved in an ongoing study on the end-of-life possibilities (recycle, thermal valorisation) of automotive nanocomposites.

### 5.3. Beyond the industrial aspects

A thorough economic analysis should include more aspects than the industrial part only. It would not be limited to comparing the production costs of nano and non-nano products, but should follow a life cycle approach, evaluating risks, costs and benefits from “cradle to grave”. Societal considerations should thus be taken into account, such as final users’ potential risks and real benefits, potential damages to the environment (accidental releases of nanoparticles, explosion...) as well as potential irreversibility. These aspects were not part of SAPHIR scope but are to be developed further by the authors.

## 6. Conclusion

The framework presented here is not based on specific nanomaterial properties or toxicity, and thus can be applied to different systems. This work gives a general framework methodology for assessing

the nanomaterials-associated risks in the context of the European directives and describes a new methodology adapted to the nanoparticles. The difficulties that arise in trying to identify the link between physicochemical properties of nanoparticles and the associated risks are also discussed, as well as a synthetic view of cost analysis strategy, which is also presented. Because of the lack of data, it is difficult to set a method for risk estimation and also risk criteria for risk evaluation. Interviews of existing nanotechnology industries will allow to identify keys parameters for risk estimation and key risk criteria for risk evaluation. This whole methodology is being exploited for the particular case of the pilot production line of *Centro Ricerche Plast-optica* (CRP), which will be the target of a forthcoming communication.

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