A standardized non-instrumental tool for characterizing workstations concerned with exposure to engineered nanomaterials

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Abstract. The French national epidemiological surveillance program EpiNano aims at surveying mid- and long-term health effects possibly related with occupational exposure to either carbon nanotubes or titanium dioxide nanoparticles (TiO_2). EpiNano is limited to workers potentially exposed to these nanomaterials including their aggregates and agglomerates. In order to identify those workers during the in-field industrial hygiene visits, a standardized non-instrumental method is necessary especially for epidemiologists and occupational physicians unfamiliar with nanoparticle and nanomaterial exposure metrology. A working group, Quintet ExpoNano, including national experts in nanomaterial metrology and occupational hygiene reviewed available methods, resources and their practice in order to develop a standardized tool for conducting company industrial hygiene visits and collecting necessary information. This tool, entitled "Onsite technical logbook", includes 3 parts: company, workplace, and workstation allowing a detailed description of each task, process and exposure surrounding conditions. This logbook is intended to be completed during the company industrial hygiene visit. Each visit is conducted jointly by an industrial hygienist and an epidemiologist of the program and lasts one or two days depending on the company size. When all collected information is computerized using friendly-using software, it is possible to classify workstations with respect to their potential direct and/or indirect exposure. Workers appointed to workstations classified as concerned with exposure are considered as eligible for EpiNano program and invited to participate. Since January 2014, the Onsite technical logbook has been used in ten company visits. The companies visited were mostly involved in research and development. A total of 53 workstations with potential exposure to nanomaterials were pre-selected and observed: 5 with TiO_2, 16 with single-walled carbon nanotubes, 27 multi-walled carbon nanotubes. Among the tasks observed there were: nanomaterial characterisation analysis (8), weighing (7), synthesis (6), functionalization (5), and transfer (5). The manipulated quantities were usually very small. After analysis of the data gathered in logbooks, 30 workstations have been classified as concerned with exposure to carbon nanotubes or TiO_2. Additional tool validity as well as inter-and intra-evaluator reproducibility studies are ongoing. The first results are promising.

1. Introduction

1.1. EpiNano, the French surveillance program for workers potentially exposed to engineered nanomaterials

The development of EpiNano surveillance program is conducted by the French Institute for Public Health Surveillance (*Institut de Veille Sanitaire, InVS*) at a joint request of the French Ministries of

Health and of Labour [1,2]. EpiNano aims at surveying mid- and long-term health effects possibly related with occupational exposure to either carbon nanotubes or titanium dioxide (TiO_2) nanoparticles, aggregates and agglomerates in workers employed in the nanotechnology-related industrial or research and development facilities in France. EpiNano consists of a registry of workers likely to be exposed to engineered nanomaterials and a prospective epidemiological cohort study [3]. The protocol of the EpiNano program received an approval from the French authority of privacy and individual rights protection (*Commission nationale de l'informatique et des libertés, CNIL*) for next 20 years of follow-up.

Carbon nanotubes and TiO_2 nanoparticles, aggregates and agglomerates were chosen as priority engineered nanomaterials based on the considerations as follow [2,3]:

- available toxicological data,
- quantities manufactured in France and projected for production development,
- the choice of France in the framework of the sponsorship program for the testing of engineered nanomaterials sponsored by the Organisation for Economic Co-operation and Development (OECD),
- social perception factors.

1.2. Identification of workers eligible for EpiNano program

Workers potentially exposed to carbon nanotubes or TiO_2 are identified using a 3-level approach [3]:

1. identification and selection of companies dealing with corresponding engineered nanomaterials (based on compulsory declaration and questionnaires [3,4]),
2. company in field visit and identification of the workstations concerned with exposure to engineered nanomaterials,
3. identification of workers involved in jobs and tasks performed in workstations identified as concerned with exposure to engineered nanomaterials and invited into the program.

2. Tool for characterizing workstations concerned with exposure to engineered nanomaterials

2.1. Aim and methodological development

To cope with high variability of companies in terms of size, activity, industrial process, work size as well as with operation and exposure conditions, a standardization of a second step of the worker identification method was extremely important. Moreover, additional criteria the EpiNano method should meet with were:

1. non-instrumental assessment based on the state-of-the-art methodology [5],
2. easiness of usage by EpiNano team members (i.e. epidemiologists and industrial hygienists non-specialized in engineered nanomaterial exposure),
3. inexpensiveness and friendly-using format,
4. extensiveness to all necessary information for workers' individual exposure assessment in upcoming epidemiological studies, and
5. potential usefulness for company occupational safety and health staff (managers and/or occupational physicians).

A working group *Quintet ExpoNano* was created including national experts from the leading French institutes (French institute for public health surveillance (InVS), the French institute for occupational health and safety (INRS), the Atomic energy commission (CEA), the French institute for industrial safety and environmental protection (INERIS), and the University of Bordeaux Segalen) specialized in nanoparticle metrology, industrial hygiene, occupational medicine, and epidemiology. The working group reviewed available methods and tools for in-filed observations and inspections, measurement technics and exposure measurement data, and compared their respective practices of in-field studies. The recommendations for characterizing potential emissions and exposure to aerosols released from nanomaterials in workplace operations published by INRS, INERIS and CEA [5] were respected. The

method integrated the first three stages of the general five-stage procedure, the fourth and fifth stages being dedicated to a measurement campaign [5].
At term of 6-months collaboration, a first version of the tool was proposed and tested in field. After a series of additional format improvements and rewordings, an agreement of the working group has been reach on a final version of the tool. This version was used on 10 workplaces during four months, before its final validation [6].

2.2. Tool description

The method consists of identifying within each company the workrooms and activities that work with engineered nanomaterials in order to identify the workstations possibly causing exposure to them and to assess this potential exposure semi-quantitatively. It is based on a technical inspection of the plant (in-field visit), interviews with workroom supervisors, and observation of the activity at each workstation. This inspection is based on the ***Onsite technical logbook*** [4,6]. This tool enables evaluators to standardize the in-field observation and data collection. Two versions of the Onsite technical logbook, in French and in English, are available [4,6].

The tool is structured in 3 parts:

1. Company: activity and process description;
2. Workrooms: type and dimensions, air flow, efficacy of the ventilation system, local maintenance, staff and workstations, potential sources of non-manufactured ultrafine particles emissions (background aerosols);
3. Workstations: instruments, techniques, equipment, process enclosure, details about incoming and outgoing products; presence of collective protection, personal protective equipment (PPE), tasks and operation performed in the workstation, quantity of product handled per operation, frequency and duration of operation.

A short questionnaire [3,4] sent to a company occupational safety and health manager prior to the onsite company visit allows to prepare the in-field visit, and to gather all potentially useful documents (the plant's blueprints, certificates of control and maintenance of the collective protective equipment, annual declaration reports and supplementary materials such as nanomaterial characterization data and results of the exposure measurement campaigns) to be consulted onsite during the in-field visit.

An in-field visit is generally organized over one or two days. It begins with an exchange of information with representatives of the company in a conference room, about the EpiNano project (objectives, procedures) and about the company (its activities and work processes). The discussion makes it possible to fill in the first part of the Onsite technical logbook on company's activities and processes implemented. The discussion is followed by a study of the plant's blueprints to locate the circulation of materials in the premises and thus identify the workrooms where nanomaterials are present.

The technical inspection, in the strict sense of the term, makes it possible to visit workrooms and to observe the workstations and real activity. This step enables to describe the use of nanomaterials in detail. During the inspection, the EpiNano team members (2 or 3 people, including at least one industrial hygienist and one epidemiologist) must be accompanied by the plant's director of hygiene and safety, the laboratory or department director, and the occupational physician. During the inspection, the items of the second and third parts of the Onsite technical logbook are completed, in order, so that the workstations possibly causing exposure can be identified and the potential exposure further assessed [6].

After the inspection, verification and data entry of the information in the logbook, a report of the inspection is sent to the company. This report includes the conclusions of the workstation evaluations and a list of the workstations that potentially cause exposure to nanomaterials, aggregates and agglomerates. A copy of the computerized data from the logbook is attached to the report.

2.3. Implementation of the method and first results

The method is designed for non-instrumental exposure assessment by non-specialized users. It was tested and further used for tracking workstations concerned with exposure to engineered nanomaterials and recruiting potentially exposed workers. Ten first companies which accepted to participate in EpiNano program were visited from January through May 2014 [6]. The visited workplaces had in average six workrooms (Min=1, Max=13) and 2 workstations per workroom (Min=1, Max=4). The mean number of workstations where carbon nanotubes or TiO_2 nanoparticles, their aggregates or agglomerates could be handled is around eight depending on company activity, with up to 27 workstations in a largest industrial workplace. In total, fifty three workstations were observed and resulted in completed Onsite technical logbooks. Among these workstations, there were twenty-five (47%) workstations in private companies and 28 (53%) in public workplaces, mostly academic research and development laboratories. Carbon nanotubes were most frequently handled material encountered in 43 of the observed workstations (single-wall carbon nanotubes in 16 (30%) and multi-wall carbon nanotubes in 27 (51%) workstations respectively), while TiO_2 was handled in 5 (9.4%) workstations. In 18 workstations (34%) multiple types of engineered nanomaterial were handled.

2*.3.1. In epidemiology and qualitative exposure assessment* In EpiNano system the identification of workstations with exposure concern is preformed regardless the use of personal protective equipment [2,6]. Workstations where a worker could experience a direct contact with engineered nanomaterial (including aggregates and agglomerates) that gives potential for inhalation or cutaneous contamination are classified as workstations concerned with exposure. The information about personal protective equipment, amount of engineered nanomaterial handled during an operation as well as frequency and duration of handling is gathered from workers' individual EpiNano inclusion questionnaire. This information will be accounted for in workers' individual exposure score for workers involved in workstations identified as concerned with exposure to engineered nanomaterials [2,3,6].

Overall, in ten workplaces visited till May 2014, 30 workstations (57%) were classified as concerned with exposure to either carbon nanotubes or TiO_2. Figure 1 presents the types of operations and tasks performed in the observed workstations and in workstations classified as concerned with exposure to engineered nanomaterial. Among the parameters assessed during the in-field visits, dustiness and humidity of the engineered nanomaterial seem to be the most important determinants of the possible exposure in a workstation [6].

2.3.2. In industrial hygiene and risk management. The data collected through the Onsite technical logbook are computerized and sent to the company. This data might be directly used by companies for risk management proposes, for instance by implementing control banding approach to assess and control exposure to engineered nanomaterials in different workstations. Several tools of control banding have been proposed specifically for engineered nanomaterials [7-9]. The Onsite technical logbook contains all essential parameters for implementing any of these tools for assessing exposure bands in workplaces. While there is no consensus on an appropriate exposure metric to be measured for assessing individual exposure to engineered nanomaterials in workers, International organization for standardization (ISO) recommends using control banding approach in workplaces dealing with engineered nanomaterials [9]. Consequently, our method may be straightforward and helpful for both exposure characterization and risk management which might be further improved with more accurate and quantitative exposure measurement data.

2.4. Method validation

A validation study is required in order to address the reliability of the proposed method and reproducibility of the exposure assessment results based on it in order to prevent bias in risk estimator in the epidemiological study [10]. The inter-method [11] and intra-method [12] comparisons of the exposure assessment were performed; the methods and results will be presented in the upcoming

publication (manuscript in preparation). According to the results of these comparisons, the proposed method presents a substantial agreement with a more precise expert exposure assessment (Cohen's Kappa=0.69) and a good agreement based on intra-method repeatability test.

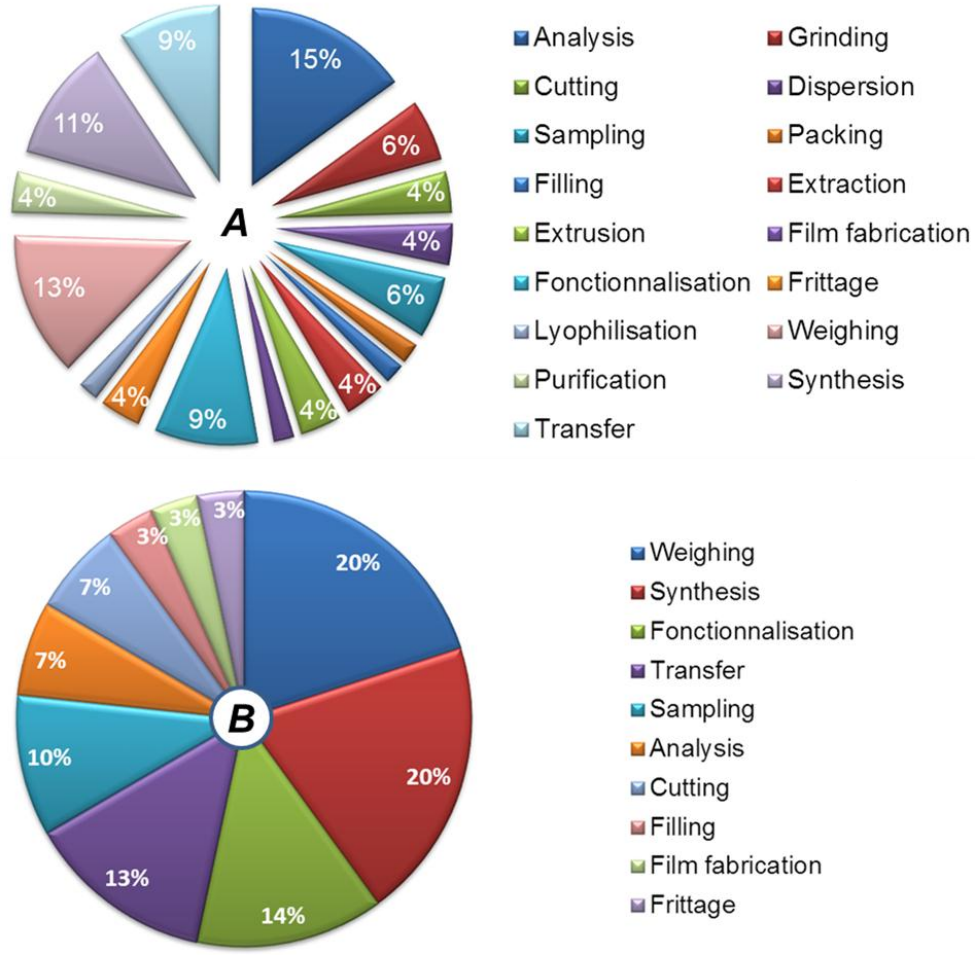

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Figure 1. Distribution of workstations according to the type of operation performed:
A-all workstations observed between January and May 2014 (n=53);
B-workstations classified as concerned with exposure to carbon nanotubes or TiO_2 nanoparticles, aggregates and agglomerates (n=30).

In conclusion, the method and the tool (the Onsite technical logbook) presented in this paper were developed by the French institute for public health surveillance (InVS), the French institute for occupational health and safety (INRS), the atomic energy commission (CEA), the French institute for industrial safety and environmental protection (INERIS), and the University of Bordeaux Segalen, as part of the partnership entitled ExpoNano Quintet. This tool makes it possible to collect all of the information necessary to identify and characterize workstations that might cause occupational exposure to carbon nanotubes or TiO_2 nanoparticles, aggregates, and agglomerates. It is part of a semi-

quantitative method to characterize the potential for exposure to intentionally produced nanomaterials in different workstations [2,3]. This practical method makes it possible to follow the recommended procedure for assessing potential emissions and characterizing occupational exposure during operations involving nanomaterials [5]. The results of validation studies are promising and will be provided in a forthcoming publication. This method, which is simple and does not require an instrument (no sampling, no aerosol measurements), is designed to be usable as part of the EpiNano program of epidemiologic surveillance of workers potentially exposed to nanomaterials in France [3,6]. Moreover, it can be useful for risk management purposes in companies, for instance in frame of implementation of the control banding approach to assign exposure bands to the different workstations concerned with exposure to carbon nanotubes or TiO_2 nanoparticles, aggregates and agglomerates.

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