Haut Conseil de la santé publique (High Council for Public Health)

STATEMENT

on management measures to be implemented towards workers in sites where titanium dioxide nanoparticles (TiO_2 NPs) are manufactured and handled, and towards populations in the vicinity of these sites.

29th April 2018

Through a formal request dated 4th July 2017, the French General Directorate for Health (*Direction générale de la santé* - DGS), the French Directorate-General for Risk Prevention (*Direction générale de la prévention des risques* - DGPR), and the French General Directorate for Labour (*Direction générale du travail* - DGT) requested the opinion of the French High Council for Public Health (*Haut Conseil de la Santé Publique* - HCSP) on management measures designed to protect workers in sites that manufacture and handle titanium dioxide nanoparticles (TiO_2 NPs) with dimensions inferior to 100nm, and populations in the vicinity of such sites.

More specifically, the HCSP was asked to:

1. propose preventive and curative measures pertaining to this management: providing guidance on best practices, containment conditions, aeration and sanitation measures;
2. make proposals on the training and information for those concerned : workers and neighbouring populations;
3. recommend criteria justifying the implementation of health monitoring and screening procedures;
4. produce proposals on threshold limit values pending the opinion of ANSES (on the development of toxicological reference values (TRVs) for nanoscale TiO_2.

The HCSP has taken the following into consideration:

- analysis of the R-Nano database (DGPR, 2017) indicated that a number of sites in France handle nanoscale TiO_2, which may be the source of worker exposure and emissions outside of handling sites, resulting in the potential exposure of neighbouring populations;
- the 2006 classification by the International Agency for Research on Cancer (IARC) of TiO_2 in the form of aerosol particulate as possibly carcinogenic when inhaled (Class 2B) (IARC, 2006);

- the request made by the French Agency for Food, Environmental and Occupational Health and Safety (*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail* - ANSES) in 2015 to the European Chemicals Agency (ECHA) to classify TiO_2 by inhalation in the 1B category (substances presumed to have carcinogenic potential for humans) within the framework of the European CLP Regulation on Classification, Labelling and Packaging of substances and mixtures (ANSES, 2018);
- the response from the Committee for Risk Assessment (RAC) to ECHA, who proposed Category 2 classification for the substance (substances suspected to be carcinogenic to humans) pending a decision from the European Commission;
- ECHA's proposal to include TiO_2 in its CoRAP (Community Rolling Action Plan) for 2018-2020 for evaluation purposes by EU Member States as being a CMR substance (carcinogenic, mutagenic and/or reprotoxic);
- recent publications on the ability of TiO_2 NPs to cross alveolar-capillary, intestinal, blood-brain and placental barriers, obtained from experimental results in laboratory animals, raising the question of the future of these particles;
- recent studies on the accumulation of TiO_2 NPs in laboratory animals after crossing biological barriers, which show that certain organs (liver, spleen, kidneys, brain and reproductive organs) are targets, with accumulation persistent over time;
- recent studies on the environmental behaviour of TiO_2 NPs which highlight their persistence in water and soil, as well as their accumulation in plants;
- the opinion of the National Institute of Occupational Safety and Health, in the United States (NIOSH) on recommendations for maximum occupational exposure limits for fine and ultrafine TiO_2 (NIOSH, 2011);
- recommendations from the French National Institute for Research and Safety (*Institut National de Recherche et de Sécurité* - INRS) on the identification and prevention of occupational exposure to TiO_2 NPs (INRS, 2013) as well as on the definition of maximum occupational exposure limits for fine and ultrafine TiO_2 (INRS, 2017);
- general recommendations provided by ANSES on preventing exposure to nanomaterials (ANSES, 2014);
- the study by the French National Institute for Industrial Environment and Risks (*Institut national de l'environnement industriel et des risques* - INERIS) aimed at developing a benchmark for exposure to TiO_2 nanoparticles amongst populations in the vicinity of TiO_2 handling sites (INERIS, 2016);
- consultation with actors on the ground and interviews carried out with researchers implicated in terms of industrial production, metrology, epidemiology, occupational medicine, occupational and environmental risk prevention, and environmental protection associations.

The HCSP made the following recommendations, structured in three parts:

- to protect workers and provide them with medical supervision as well as guidance on best practices in the workplace. Recommendations concern the production, handling, storage, packaging, transport and incorporation of TiO_2 NPs in finished products;
- to protect residents and the environment in the vicinity of sites that manufacture, handle and store TiO_2 NPs;
- metrology and monitoring of exposure with focus placed on the introduction of maximum exposure limits specific to TiO_2 NPs in the workplace and environment, in relation to current practices and recommendations (notably from INRS, INERIS and NIOSH) pending values which may be proposed on the basis of toxicological reference values (TRVs) developed by ANSES.

1. Recommendations concerning the protection of workers potentially exposed to TiO_2 NPs

Provisions aimed at controlling health risks associated with exposure to different categories of workers handling TiO_2 NPs are prioritised by the HCSP. The HCSP recalls that work regulations concerning the handling of powdered substances must apply to TiO_2 NPs (INERIS 2004). As such, respecting these regulations in sites producing and handling TiO_2 NPs is a primary objective. However, TiO_2 NPs pose specific risks which must lead to specific provisions, concerning:

Safety Data Sheets

Safety Data Sheets must include information on the presence of TiO_2 NPs and their associated risks.

Information on the risks associated with TiO_2 NPs must be regularly updated in line with developments in knowledge and consideration by official bodies (INRS, ANSES, INERIS, etc.).

They must be distributed to all actors in the supply chain (production, storage, transport, incorporation, implementation and recycling).

Traceability of TiO_2 NPs

Manufacturers and suppliers are responsible for informing their customers on the presence of TiO_2 NPs. Traceability must be correctly ensured by all actors in the supply chain (production, storage, transport, incorporation, implementation and recycling). In particular, it must respect existing regulations intended for final consumers[1] of foodstuffs (INCO) and cosmetics (EC 1223/2009).

In line with this, end consumer information on all products containing nanoparticles must be improved.

[1] By definition, a consumer is not a manufacturer

Risk analysis concerning the entire life cycle, including occupational exposure scenarios (incorporating end-of-life and waste treatment), is recommended for these products.

Training for handlers

Training is essential in order to raise awareness of the risks associated with nanomaterials and constitutes an essential factor in prevention methods. All workers associated with the production, storage, transport, end use and end-of-life of TiO_2 NPs should undergo training. Training must include three components:

- knowledge of the hazards posed by nanomaterials to health and the environment;
- exposure in line with their use,
- and prevention methods.

Women of childbearing age and women who are pregnant or nursing must be given specific information in order to avoid exposure to nanomaterials (see '*Recommandations : La médecine et les services de santé au Travail* - Recommendations: occupational medicine and health services').

Prevention methods

Prevention measures must respect the following factors:

i. The first measure should concern eliminating the source of exposure. In order to do this, methods must be researched and applied if production, storage, transport, integration and recycling processes give rise to exposure by inhalation (see guide written by the DGPR, French Ministry for the Ecological and Inclusive Transition on the substitution of hazardous chemicals);

ii. Apply collective and organisational protection measures.

General prevention measures relating to nanomaterials, proposed by the INRS (2011 and 2012), must be rigorously implemented in order to avoid occupational and environmental contamination, considering the high capacity of nanoparticles for dispersion. Amongst these measures, it is important to recall specific preventive factors for workplaces where nanoparticles are present (see VII.1.1.3):

- local, adapted ventilation system which enables low levels of nanoparticles in the air to be maintained in the workplace;
- filtering air before discharging it into the atmosphere outside of buildings, using high efficiency particulate air (HEPA) filters;
- implementation of pollution abatement at the source using fume hoods, glove boxes or laminar flow devices;
- identification and definition of the work area, which must only be accessed by operators indicated by adapted pictograms;
- application of workplace hygiene rules such as no drinking or eating, with the exception of areas dedicated to this effect.

A **pictogram** recognised at national level as a minimum requirement, which indicates the level of risk posed by nanoparticles in all operations and in all

handling, transport and storage areas. It is advisable for the measure to be recognised at European-level.

iii. Recommendations in place regarding **personal protective equipment for workers (PPE)** which state that equipment should only be used as a last resort and for a limited duration (INRS, 2011 and 2012). Recommendations must be applied according to exposure conditions; this requires prior assessment of work stations:

- respiratory apparatus, adapted according to occupational risk assessments carried out, whilst maintaining the highest possible comfort levels for workers: they may be required to wear a mask or a half-mask equipped with anti-dust filters, self-contained respiratory apparatus in the form of a full face mask, hood, or suits equipped with powered respirators supplying compressed air. However, some PPE may present difficulties when worn by people presenting major obstructive pulmonary risks;
- protective clothing which should provide protection against Type 5 chemical risks, airtight, made from high density polyethylene (HDPE) between 0.5 and 10µm thick, gloves that are both waterproof and disposable (made from nitrile or vinyl), and shoe covers. Specific areas within changing rooms equipped with showers must be presented in order to avoid contaminating other areas where nanomaterials are not handled and to avoid mixing work clothing with casual clothing;
- safety glasses equipped with side shields.

Storage, handling and packaging of TiO_2 NPs

The entire life-cycle of nanomaterials is composed of a number of storage phases which last for variable durations and concern vastly wide-ranging quantities.

Particular attention should be paid to the following points:

- displaying hazard pictograms in the event of substance storage;
- specialised training given to all internal and external workers in storage areas;
- specialised training given to workers in internal and external relief emergency response and environmental protection teams;
- periodic checking of signage;
- information concerning the presence and type of nanomaterials.

Transporting TiO_2 NPs

The multiplicity of uses of TiO_2 NPs has resulted in high demand for transport from industrial production and importation sites. As such, risk management associated with production and importation sites means that it is necessary to incorporate sites linked to the resulting transport, which requires:

- incorporating the risks posed by nanomaterials into transport regulations (land, sea and air);
- displaying hazard pictograms in the event of substance transfer;

- reporting on the frequency in which signage is checked;
- information concerning the presence and type of nanomaterials;
- giving specialist training to internal and external workers in transport sectors;
- giving specialist training to internal and external workers in emergency response and environmental protection teams;

Ensuring that the safety data sheet is imperatively distributed throughout the entire supply chain.

Occupational medicine and health services

Medical records must facilitate traceability of worker exposure and to this end, it is necessary to enhance training and information given to multidisciplinary teams, particularly occupational physicians.

All members of prevention teams (occupational physicians, occupational health nurses, hygienists, ergonomists) should receive specialist training in nanomaterial risks. Training should cover production, transport, recycling, and user sectors.

A list of jobs with the highest levels of exposure must be established in order to promote measures within the roles identified (user mapping). It is important to note that beyond manufactured TiO_2 NPs, there may be situations where exposure to TiO_2 NPs is unintentional (fumes, machining, additive manufacturing, etc.)

In the particular case of the construction and recycling industry, further research on the emissivity of street furniture must be carried out since the latter contains TiO_2 NPs (street paving, concrete, self-cleaning glass); research results must be distributed amongst occupational health services.

At this stage, exposure and effect markers typically able to measure inhaled air, which would enable specific responses from workers exposed to the TiO_2 NPs to be identified, do not exist. Therefore, primary prevention in the workplace, according to previously described methods, must be strengthened. As a precaution, occupational physicians should take into account the ability of workers to wear PPE, notably for workers suffering from major obstructive respiratory disorders.

Taking into account results currently available from studies focused on the crossing of placental barriers (however, yet to be consolidated), the possibility of IARC issuing a carcinogenic classification (2B by inhalation), and ongoing discussions at ECHA regarding the 2B category proposal, the HCSP recommends that pregnant or nursing women should benefit from the same protection measures in place for “agents that are dangerous for reproductive and developmental health”, which means that employers must propose a temporary transfer as soon as they are made aware of these circumstances.

Women of childbearing age must be notified of the risks associated with TiO_2 NPs when they take up employment, so that they can protect themselves, particularly when they are planning a pregnancy.

Risks posed by nanomaterials should form part of risk management plans (RMP). In this case, it is no longer an issue for occupational physicians alone, but also for facility managers.

It is crucial that all stakeholders (site managers, user site managers, occupational health services, etc.) ensure that the risk management plan (RMP) relating to external business

intervention specifically identifies the presence of nanomaterials and the associated risks.

Epidemiological monitoring of a cohort of workers

It is important to pursue the epidemiological study (EpiNano) carried out by the French Public Health Agency (*Santé Publique France)*. The focus of the cohort put in place is placed on long-term monitoring of the impacts of occupational exposure to nanomaterials. To do this, it is important to further encourage business leaders and workers to participate in this cohort.

A line of questioning on the impact of occupational exposure on fertility and pregnancy should be introduced.

Generally speaking, the HCSP recommends:

- making amendments to Decree No. 2017-765 on the provision of data in order to widen accessibility to the R-Nano database, CARSAT (*Caisse d'Assurance Retraite et de la Santé au Travail* - Employment Health Insurance Fund) and CRAM (Caisses régionales d'assurance maladie - State Regional Health Insurance Offices) which are certified, as well as agencies which provide advice on the risks posed by nanomaterials. The HCSP did not have access to the database as part of this formal request;
- developing the R-Nano database so that it provides all data required in order to carry out nanomaterial risk assessments. In this respect, amendment to the Order of 6th August 2012 on the content and submission conditions of annual declarations of nanoscale substances is necessary, regarding the minimal proportion of particles with one or more external dimensions in the size range of 1 nm-100 nm, currently set at 50% of the number size distribution referred to in article R. 523-12 of the French Environmental Code. For products containing a mixture of nanoscale substances, this proportion should be lowered to 10% of the number for all substances, and to 1% of the number in specific cases. This recommendation is made in accordance with Decree No. 2012-232 of 17th February 2012 on the annual declaration of nanoscale substances implementing article L. 523-4 of the French Environmental Code which states “This minimum proportion may be reduced in specific cases where this is justified for reasons pertaining to protection of the environment, public health, safety or competitiveness. It is detailed by a joint order issued by Ministries of the environment, agriculture, health, labour, and industry.”;
- strengthening of human and financial roles and resources allocated within the field of nanomaterials in prevention agencies in terms of occupational health, particularly the INRS, the French Public Health Agency, INERIS and ANSES;
- the use of devices to measure individual exposure levels in the workplace;
- encouraging partnerships between bodies working on the subject (CNRS, CEA, INSERM, INRS, INERIS, INRA, ANSES, ADEME, IRSN, ANSM, CSTB, OPPBTP, etc.), and facilitating coordination of a sustainable research, expertise and regulatory community based on this;
- supporting research on the toxicity and ecotoxicity of nanomaterials including TiO_2 NPs, focusing particularly on the development of assessment tests which are

better adapted to the characterisation of their dangers, and which focus on controlling risk by developing Safer by Design / Safer by Process approaches;
- particularly supporting research on mutagenesis, carcinogenesis and the reprotoxicity of TiO_2 NPs given recent discoveries on their ability to cross biological barriers and accumulate in certain organs;
- that the competent authority for REACH Regulation in France, ANSES, requests for manufacturers/importers of TiO_2 NPs to include studies on their reprotoxic potential in applications submitted to REACH experts;
- in terms of measurement campaigns, the NECID (Nano Exposure Contextual Information Database) is highly relevant and should be supplied with more data, whilst avoiding data duplication, and promoting synergies. In this way, the SCOLA database could be supplemented by incorporating elements relevant to the 'nanoparticles' component;
- guidance on best practices is in place for inspectors and investigators of the DREAL (French Directorate of the Environment, Planning and Housing); one French guide exists (DGPR, 2017), in addition to other guides, including a European one (EU, 2014); it would benefit from being made available depending on the target group and business sector;
- implementing best practices for nanomaterial risk management based on STOP principles (AFSSET, 2008).

2. Recommendations for the protection of residents in the vicinity of sites that manufacture, store, handle and recycle TiO_2 NPs

It is important to avoid environmental contamination throughout the manufacture, transport and handling of TiO_2 NPs by putting appropriate methods in place:

- The guide on best techniques for environmental protection in nanoparticle production and handling sites, written by experts at the INERIS at the request of the Ministry of the Ecological and Inclusive Transition, published in 2017, provides a set of relevant recommendations which should enable businesses concerned to manage environmental risks appropriately if recommendations are implemented by actors in the field. This document was subject to consultation before being published, notably by industrial federations. It aims to provide the best available techniques to limit environmental emissions and protect residents.

- Regular monitoring of contamination levels should be carried out in the vicinity of industrial sites that emit TiO_2 NPs into the environment. In order to do this, we recommend:

    - taking indirect measurements in the air using filters and gauges to collect wet and dry discharge followed by atomic emission spectrometry (ICP-MS);
    - carrying out chemical analysis in water and soil, following sampling of the plant and surrounding areas at effluent levels, prioritising areas located under prevailing winds. These measurements must take into account environmental background noise in the area of interest.

Information on the risks posed by nanomaterials must be given to residents in order to:

- promote discussion spaces within which scenarios can be described, problems set out and solutions shared;
- structure site monitoring commissions composed of a wide range of actors and resident associations in order to develop informational material for local residents, in which results and discussions will be widely reported, particularly by the local press;
- offer relevant and appropriate information found on official ministry websites.

3. Recommendations concerning metrology, monitoring of TiO_2 NP exposure and exposure limits

These limits play a key role in the implementation of the management procedures detailed previously. The report provides an update on limits implemented in various countries, including France. Focus is largely placed on occupational limits and very rarely on environment limits. Occupational limits vary greatly from one country to another, and not all of them are specific to TiO_2, whether nanoscale or not. With respect to current toxicological data, we recommend establishing a limit (or limits depending on the nanoscale) as well as measurement methodology.

In terms of the environment, only the French body (INERIS) and the Canadian State of Ontario have made proposals, but both vary to such an extent that it is necessary to review these assessments; a task to be carried out by ANSES. The following recommendations are made regarding occupational exposure pending completion of this report:

NIOSH proposed the following limits, revised in 2011: 2.4mg/m^3 and 0.3mg/m^3 for fine TiO_2 and ultrafine TiO_2 respectively, for an increased risk of lung cancer of 1/1,000 (NIOSH, 2011). Based on NIOSH's revised limits, the BAuA proposed the following limits: 0.11mg/m^3 and 0.19mg/m^3 for an increased risk of lung cancer of 1/5,000 and 1/2,000 respectively.

The HCSP advises a lower limit for ultrafine TiO_2 and nano TiO_2 than for fine TiO_2, and retains limits proposed by the INRS which, based on the opinion produced by NIOSH in 2011, converted to an additional risk of 1/10,000 classically considered in France[2], are 70µg/m^3 for ultrafine/nano TiO_2, and 500µg/m^3 for fine TiO_2. NIOSH has not proposed different limits between crystalline rutile or anatase structures.

With respect to environmental limits in the vicinity of sites handling TiO_2, due to the lack of data and the heterogeneity of the small number of limits currently proposed at international level, the HCSP recommends awaiting the outcome of the work entrusted to the ANSES on occupational exposure limits, in order to propose exposure limits for neighbouring populations, as well as threshold limits on this basis, beyond which management measures would be initiated.

[2] The risk considered by NIOSH was 1/1,000, deemed too high by the HCSP.

These recommendations, developed based on knowledge currently available at the date of publication of this opinion, may change in line with new knowledge and epidemiological data.

The CSRE (Commission spécialisée sur les Risques liés à l'Environnement - Environmental Risks Expert Committee) voted electronically on 29th April 2018. All 18 qualified members participated in the vote. The text was unanimously approved by voters. Members of the CSRE completed a public declaration of interest to which the HCSP found no conflict of interest.

Acronyms and abbreviations

ANSES: *Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail (*French National Agency for Food, Environmental and Occupational Health & Safety)

IARC: International Agency for Research on Cancer

CMR: Carcinogenic, mutagenic and/or reprotoxic

CLP: European Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures

DGPR: *Direction générale de la prévention des risques (*Directorate-General for Risk Prevention)

DREAL: *Directions régionales de l'environnement, de l'aménagement et du logement* (French Regional Directorate of the Environment, Planning and Housing)

ECHA: European Chemicals Agency

PPR: Personal Protective Equipment

SDS: Safety Data Sheets

INERIS: *Institut National de l'Environnement Industriel et des Risques* (National Institute for Industrial Environment and Risks)

INRS: *Institut National de Recherche et de Sécurité* (The French Institute for Research and Security)

NIOSH: National Institute for Occupational Safety and Health

REACH: EU Regulation (EC) No. 1907/2006 (Registration, Evaluation, Authorisation of Chemicals)

EU: European Union composed of the twenty-eight Member States

OEL: Occupational Exposure Limits

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Members of the working group have completed a public declaration of interest to which the HCSP found no conflict of interest.

Statement produced by the CSRE (*Commission spécialisée sur les Risques à l'Environnement* - Environmental Risks Expert Committee) on 29th April 2018

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