

## Tour de Table - FRANCE

### **Format for the Tour de Table: Highlight of developments since the 14<sup>th</sup> meeting of the WPMN**

(In case of no information under a heading below, please put “None” or delete the heading itself)

**1. Any national developments on human health and environmental safety including recommendations, definitions, or discussions related to adapting or applying existing regulatory systems or the drafting of new laws/ regulations/amendments/ guidance materials;**

- For the third year, France has implemented the national mandatory declaration of substances at nanoscale produced, imported or distributed above 100 g on the French territory. A summary report with the identity and uses of those substances will be made available mid-November on the website of the French Ministry of Ecology (<http://www.developpement-durable.gouv.fr/-Nanomateriaux-.html>) and on the ‘r-nano’ website : <https://www.r-nano.fr/>. Until now, the collected data are in particular used by national designated institutes to target companies using those substances and to recruit workers for epidemiological studies or for assessing exposure and prevention practices at the work place. Data are also currently analysed by an expert working group to identify substances to assess in priority and to identify areas of improvement for the scheme.
- Following the commitments of the last national « Environmental Conference », the French Government has established a working group with all stakeholders (Industry, NGOs, scientists, Ministries...) to make propositions at the European level for :
  - a labelling strategy for consumer products containing nanomaterials. This approach appears complementary to the declaration obligation as it could provide more information to consumers ;
  - a restriction strategy for products in contact with skin, particularly products for children and pregnant women.

Works should be achieved by the end of 2015 and propositions from the French Government will be addressed to the European Commission and the other Member States.

**2. Have any new activities (e.g. regulatory changes, guidance, voluntary, etc.) been initiated to implement the OECD Council Recommendation<sup>1</sup>? If yes, please explain.**

**3. Developments related to voluntary or stewardship schemes;**

**4. Information on:**

- a. risk assessment decisions, including the type of: (a) nanomaterials assessed ; (b) testing recommended; and (c) outcomes of the assessment;**

The substance evaluation under REACH of TiO<sub>2</sub> by France should be included in the Community Rolling

<sup>1</sup>Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials

Action Plan depending on the outcome of the appeal on the compliance check procedure and its outcome.

**b. risk management approaches; and**

- A classification dossier (under the Classification Labelling and Packaging European Regulation) for TiO<sub>2</sub> carcinogenicity via inhalation is on the way to be submitted by France (ANSES) to the European Chemical Agency.
- Anses issued an internal request on 1<sup>st</sup> October 2010 in order to develop a pragmatic, qualitative risk assessment method to provide guidance for controlling risks to the general public. The proposed method applies to a commercial product initially containing one or more nanomaterials (nano-product) for a given use of the nano-product (scenario). Different results from the assessment model relate:
  - on the one hand to health risks for consumers and more widely to the general population,
  - on the other hand the ecotoxicological risks.

The proposed method leads to the expression of levels of individual health risks (interpreted by the combination of levels of exposure to danger) as well as an assessment of the ecotoxicological hazard levels. The results obtained by this method refer to the effects specifically attributable to nanomaterials (and not to other substances contained in the product) in the context of the use of nano-products. The method focuses on the implementation of the product and excludes the phases of production and nano-product end-of-life treatment (disposal/recycling).

A French version is already available on :

<https://www.anses.fr/fr/system/files/AP2010sa0262Ra.pdf>

An English version will be soon available on the Anses web site : <https://www.anses.fr/fr>

**c. any updates, including proposals, or modifications to previous regulatory decisions**

**d. new regulatory challenge(s) with respect to any action for nanomaterials**

- 5. Information on any developments related to good practice documents (e.g. standards, technical guidance, technical reports, notable articles in the popular and technical literature);**
  - 6. Information on any developments related to Integrated Testing Strategies and/or Alternative test methods (e.g. in-vitro and in-silico methods and high throughput methods)**
  - 7. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials; (e.g. government, national labs, academic, industry)**
- The French program for epidemiological surveillance of nanoworkers, EpiNano, was launched by Institut de Veille Sanitaire (InVS, future Public Health France) in 2014. In 2015 EpiNano pursued the recruitment of companies and workers handling nanoTiO<sub>2</sub> and carbon nanotubes at workstations potentially concerned with exposure to these NOAA. The identification of such

workstations and workers appointed to them is based on a standardized method which was described in original scientific publications, both in French and in English. Moreover, this method was validated by comparison with available exposure expertise and exposure measurement data. A manuscript of an original article describing validation results was recently submitted for publication.

By the end of 2015, twenty companies were visited within EpiNano program. About hundred questionnaires were sent to the eligible workers for inviting them into EpiNano cohort for prospective epidemiological follow-up. The workers' response ratio is currently around 56%. The recruitment of companies and workers into EpiNano should last three or four years more before the getting the first results from descriptive analyses of the data collected.

- A standardized non-instrumental tool for characterizing workstations concerned with exposure to engineered nanomaterials. Guseva Canu I, Ducros C, Ducamp S, Delabre L, Audignon-Durand S, Durand C, Iwatsubo Y, Jezewski-Serra D, Le Bihan O, Malard S, Radauceanu A, Reynier M, Ricaud M, and Witschger O. *Journal of Physics: Conference Series* 617 (2015) 012036 doi:10.1088/1742-6596/617/1/012036
  - Proposition d'une méthode d'identification et d'observation des postes de travail potentiellement exposant aux nanomatériaux. I. GusevaCanu, S. Ducamp, L. Delabre, S. Audignon-Durand, C. Ducros, C. Durand, Y. Iwatsubo, D. Jezewski-Serra, O. LeBihan, S. Malard, A. Radauceanu, M. Reynier, M. Ricaud, O. Witschger. *Références en Santé au Travail*, Septembre 2015; 143: 33-41.
  - Engineered nanomaterial exposure assessment within the French EpiNano program: A validation study. I; Guseva Canu, D. Jezewski-Serra, L. Delabre, S. Ducamp, Y. Iwatsubo, S. Audignon-Durand, C. Ducros, A. Radauceanu, O. Witschger, C. Durand, E. Flahaut. Submitted in *Scandinavian Journal of Work, Environment & Health*
- In 2015, the INRS (National Institute for Research and Security) conducts several toxicological studies, mainly on inhalation in animals. The main objectives of this work is to provide answers to questions about:
    - the defining properties of toxicity,
    - migration of nanomaterials in cells or body (transfer to the brain),
    - the genotoxic potential,
    - the development of test methods adapted to the specificities of nanomaterials.

**8. Information on any public/ stakeholder consultations;**

**9. Information on research or strategies on life cycle aspects of nanomaterials, as well as positive and negative impacts on environment and health of nano-enabled applications;**

**10. Information on any development related to exposure measurement and exposure mitigation.**

In 2015, the INRS (National Institute for Research and Security) conducts studies on :

- the monitoring of aerosol generation,
- the assessment of exposure measurements techniques applied to nanomaterials in aerosols and the development of protocols at the workplace,
- the development and harmonization of the exposure measurement strategy,
- the development of nanomaterials characterization methods,
- the characterization of exposure levels at the workplace (via several projects such as ExproPNano).

Studies on the collective and individual protection devices are also conducted with the aim to help companies in the choice of adapted equipment and to contribute to redefining the standard protocols used to test these devices. They aim in particular to highlight a possible specificity of nanomaterials towards existing prevention devices and quantify the effectiveness of these devices.

- 11. Information on past, current or future activities on nanotechnologies that are being done in your respective countries in co-operation on a multilateral basis, including with non-OECD countries. Including the nature of the collaboration, and the expected outcomes.**

*Additional Information*

- 12. Any consideration on the benefits of nanotechnologies;**
- 13. Consideration of ethical implications;**