« Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard »

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On behalf of NANOGENOTOX partners

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An European Joint Action

- approved in July 2009
- 6.2 millions of Euros , 46% funded by EC.
- Start in March 2010, for 3 years

Context :

Human exposure to manufactured nanomaterials (MNs) used in consumer products may occur during several phases of their life cycle.

The lack of scientific knowledge make regulation difficult. The JA general objectif is to support and add value to the Member States' policies and to contribute to increasing the safe use of MNs in the European Union.

Objectives :

* To obtain detailed physicochemical properties for each MN at the bulk powder and individual particle level
* To determine the influence of exposure media on MNs dispersability and to identify the optimum preparation protocols for the specific MNs
* To generate in vitro genotoxicity data on MNs
* To determine relevant doses and sampling time for biodistribution and in vivo genotoxicity studies, and to identify MN accumulation in organs for in vivo genotoxicity tests
* To perform a round robin test on in vitro genotoxicity testing of MNs
* To generate data from in vivo genotoxicity selected tests, and to assess the correlation between in vivo and in vitro results taking into account the kinetic results

Synergy with other activities
- **OCDE** sponsorship program
- **ISO TC229**
- Strong interaction with **all participants**

Partners

Main Partner: Afsset (**Fr**)

16 Associated Partners (11 countries):
ISS(**IT**), CLMC/IMB-BAS (**BULG**), FIOH (**Fin**), NRCWE(**DK**), BfR (**DE**), NIOM (**PL**), RIVM (**NL**), UAB (**ESP**), VAR/IPH(**BE**), INSA (**PT**), and AFSSA/IPL/INRS/CEA (**FR**)

12 collaborating partners:
7 ministries (**FR, IT, NL, DE, FI, ESP, BE**)
5 Institutes JRC (**CE**), HPA (**UK**), UCD (**IR**), LNE (**FR)**, AFSSAPS (**FR**)

Scientific Work Package:

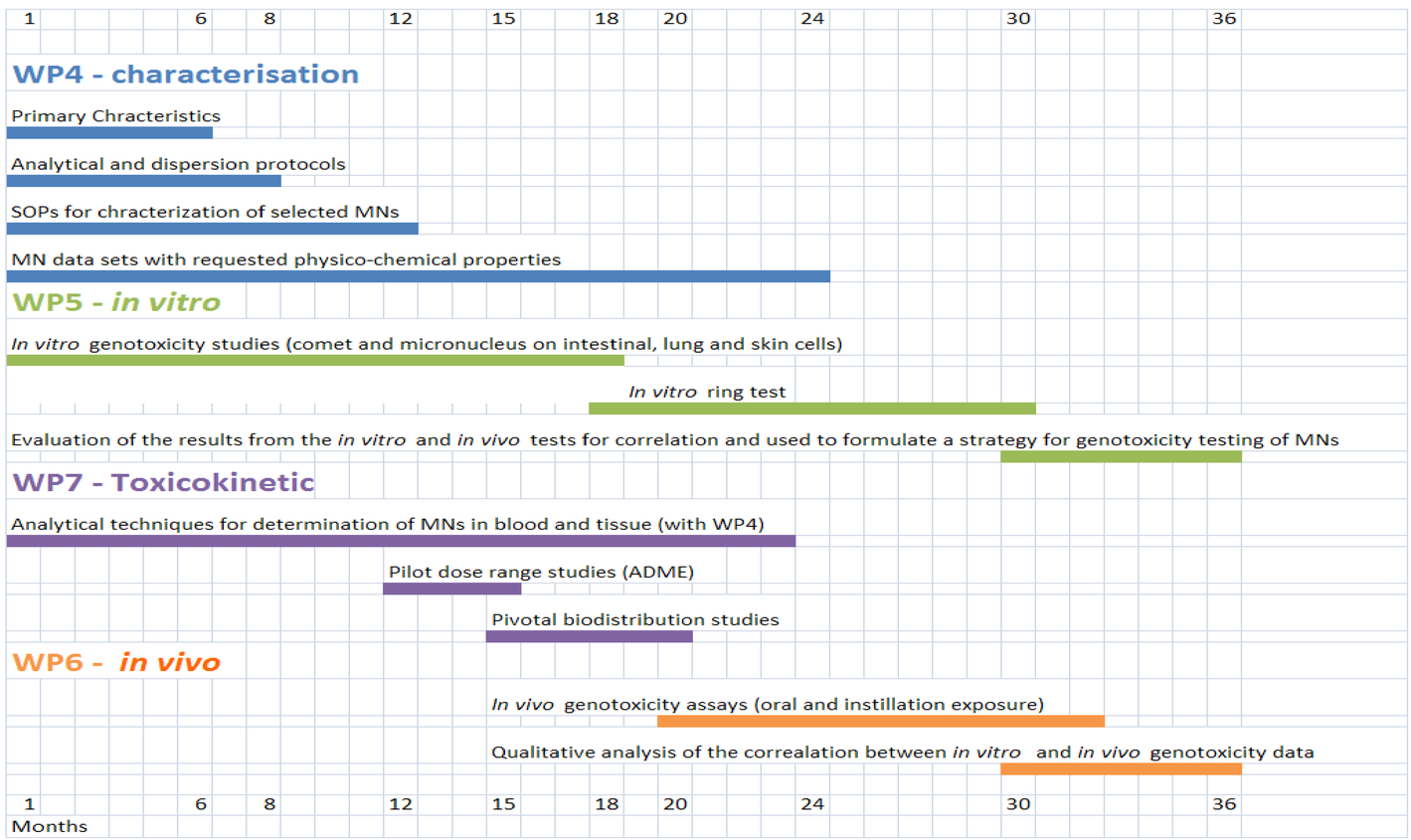
Tests will follow the available international guidance documents

Characterisation: NRCWE (DK)
* SOP for full characterisation of NMs including MN suspension in test media

***In vitro* genotoxicity:** FiOH (FI)
* Comet and micronucleus assays + specific tests (MLA and lymphocytes micronucleus assay)
* Different cell lines : pulmonary, intestinal for all MNs and human skin model for TiO_2
* A ring test with the most promising assays on selected MN s

***In vivo* genotoxicity:** ANSES (ex-Afssa) (Fr)
* On rat, 3 doses, 5 animals/dose,
* Gavage and instillation
* 5 target organs
* Correlation with in vitro tests and toxicokinetics

Toxicokinetics: RIVM (NL)
* Performed before *in vivo* genotoxicity testing
* Oral route and IV (TiO2 and SiO2), only IV (CNT)
* Dose range finding for genotoxicity tests: development of sample preparation and detection method.
* Determination of organ at risk for MN accumulation and genotoxicity tests



15 MNs commercially available will be tested
- **NT**C (7)
- **TiO_2** (4)
- **SiO_2** (4)

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