Grant agreement number 2009 21 01

Nanogenotox

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ANSES
French Agency for Food, Environmental and Occupational Health & Safety (France)

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- A European Joint Action on

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

- Work Plan for 2009 of the Second Programme of Community Action in the Field of Health (2008 to 2013)
- Budget: 6.2 million Euros (46% funded by EAHC)
- Approved in July 2009
- Started in March 2010, for 3 years

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JA Partners

- **Coordinator: ANSES** (FR)
- **16 associated partners**
- **15 collaborating partners:**
  - **7** ministries: **FR, IT, NL, DE, FI, ESP, BE**
  - **8** Institutes: JRC (**EC**), HPA (**UK**), UCD (**IR**), LNE (**FR**), ANSM (**FR**), INERIS (**FR**), Université de Rennes 1 (**FR**), Duke University (**USA**)

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Associated Partners

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- **3 horizontal Work Packages**
  - Coordination (WP1)
  - Dissemination (WP2)
  - Evaluation (WP3)
- **And 4 scientific Work Packages**
  - Characterisation (WP4)
  - *In vitro* genotoxicity (WP5)
  - *In vivo* genotoxicity (WP6)
  - Toxicokinetics (WP7)

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Coordination

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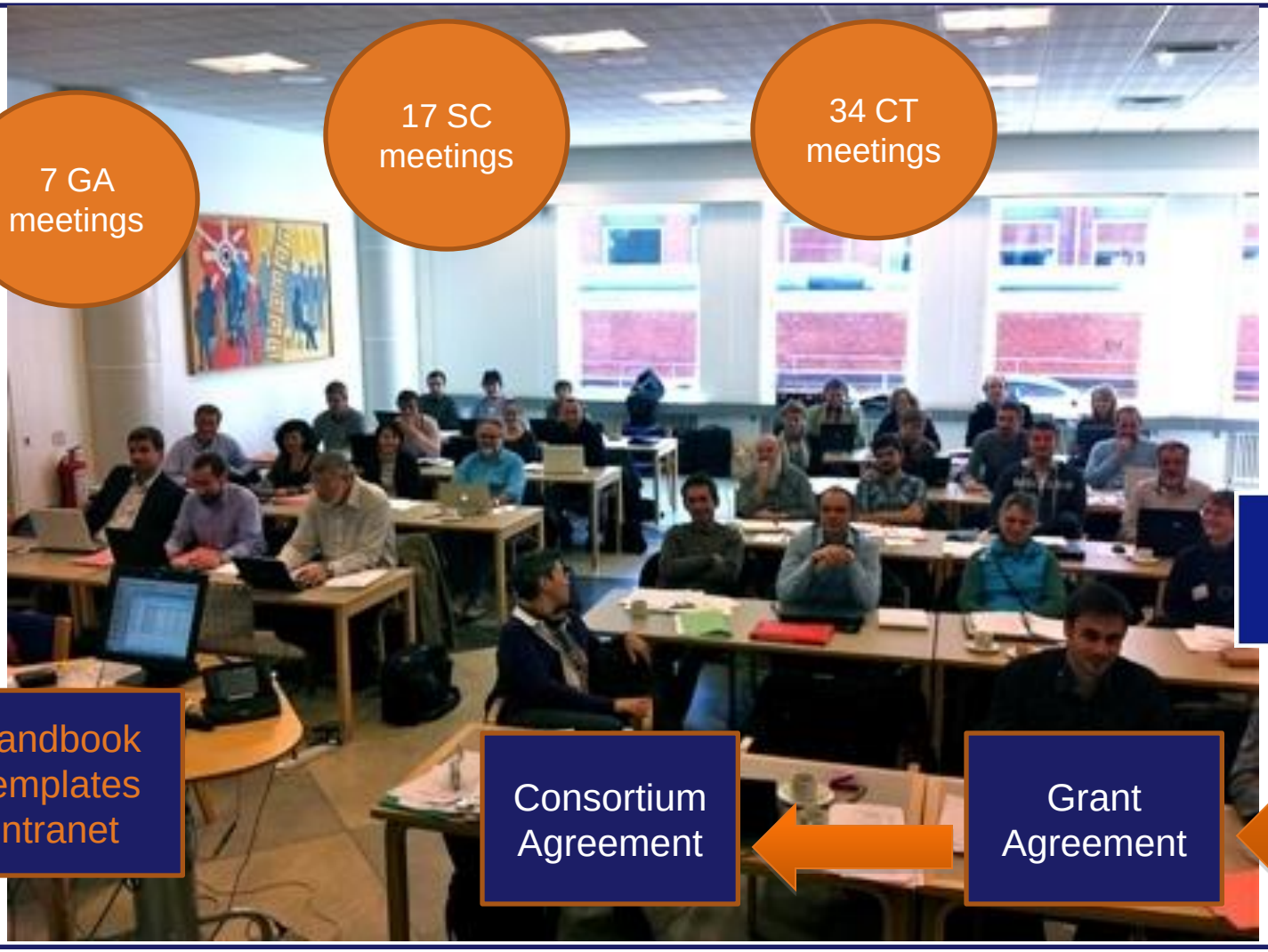

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NANOGENOTOX

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Dissemination

Project leaflet

7000 visits

2000 documents uploaded

4 News letters

21 commu-nications

2 Stakeholder consultations

2 reports

4 Publications accepted

18 Publications planned

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Evaluation

Evaluation plan

Cruise mode evaluation

Final evaluation

Confidential Evaluation reports

Internal evaluation Team

External Academic reviewer panel

Evaluation meeting Nov. 2012

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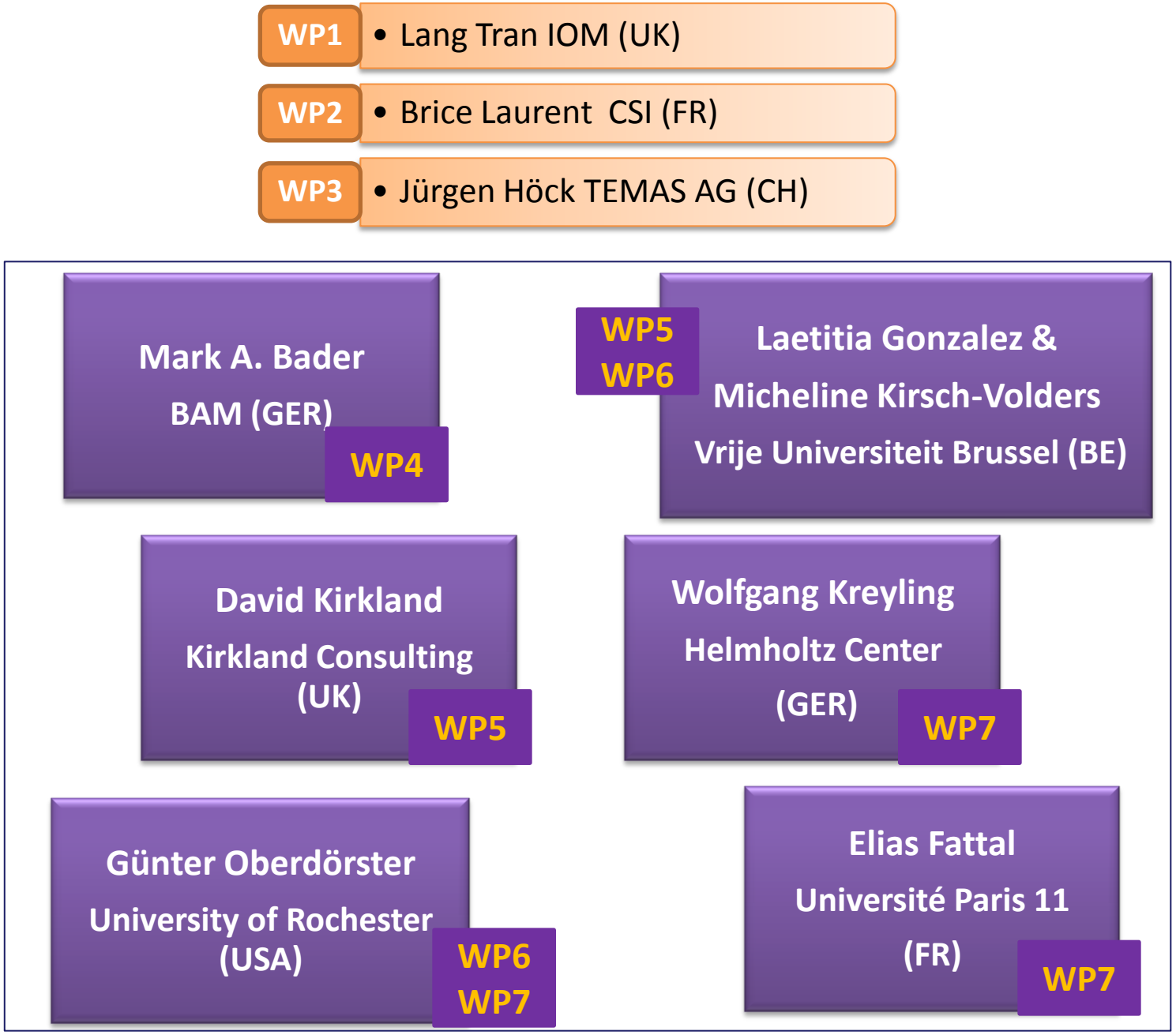
WP1
• Lang Tran IOM (UK)
WP2
• Brice Laurent CSI (FR)
WP3
• Jürgen Höck TEMAS AG (CH)
Mark A. Bader
BAM (GER)
WP4
WP5
WP6
Laetitia Gonzalez &
Micheline Kirsch-Volders
Vrije Universiteit Brussel (BE)
David Kirkland
Kirkland Consulting
(UK)
WP5
Wolfgang Kreyling
Helmholtz Center
(GER)
WP7
Günter Oberdörster
University of Rochester
(USA)
WP6
WP7
Elias Fattal
Université Paris 11
(FR)
WP7

Hazard identification of MNs – Status in 2009

- No full characterisation of MNs (primary particle size, surface area...) → clear need of data
- Case by case study according the MNs
- Many *in vitro* and few *in vivo* studies with no correlation
- Mainly focused on inhalation
- No standard operating procedures (SOP)
- OECD guidelines need to be adapted: sample preparation, dosimetry and dose range

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- **Main objective**:

For Safety evaluation of manufactured nanomaterials by characterisation of potential genotoxic hazard

To build a robust methodology (sensitive and specific) with alternative test for risk assessment of MNs by using a ring tests

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Methodology:

- *In vitro* testing set for predicting needs of further *in vivo* testing
- Not specific to a MN
- Test easy to do
- Simple method of identification
- To use the data sets generated as reference

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Main Issues :

- To use the existing knowledge on hazard assessment (testing methods, cell lines...) on genotoxicity
- To elaborate a unique dispersion protocol, and common protocols for in vivo and in vitro tests
- To manage the follow up the identification of the tested MNs
- Full characterization or raw and dispersed MNs

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Main Issues :

- To identify a dose range and target organ(s)
- To provide datasets and SOPs
- To do a comparison between *in vivo* and *in vitro* studies
- To consolidate the methodology by a ring test

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- Genotoxicity testing on 14 MNs
  - CNT (6)
  - TiO_2 (4)
  - SiO_2 (4)
- Commercially available
- Widespread exposure for workers and consumers

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SiO_2

NM-series number	process	Main Use	Primary particle size (nm)
NM-200	Pre.	Food	5-35
NM-201	Pre.	Rubber	10-15
NM-202	Pyr.	Both	No data
NM-203	Pyr.	Food	approx. 12

Not in WP 7

Not in WP7

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TiO_2

NM-series number	Size (nm)	Crystalline form	Main use
NM-100	200-220	Anatase	Multiple uses, pigment
NM-101	7-10	Anatase	Photocatalytic effects
NM-102	**15-25**, spherical	Anatase	Photocatalytic effects, Denox
NM-103	**20**, spherical	Rutile	Cosmetics
NM-104	**20**, spherical	Rutile	Cosmetics
NM-105	**22**, spherical,	85% anatase, 15% rutile	Photocatalytic effects

WP 7

WP4

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CNTs

NM-series number	Type	Use	
NM-400	MWCNT	structural composites and energy applications	
NM-401	MWCNT	Not specified, longest	
NM-402	MWCNT	structural composites and energy applications	
NM-403	MWCNT	structural composites and energy applications	Not in WP 7
NRCWE-006	MWCNT	energy/ Lithium/ion battery	
NRCWE-007	MWCNT	Not specified	Not in WP 7

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- Synergy with other activities
  - OECD WPMN and in particular the sponsorship program
  - ISO TC229
  - Strong interdisciplinary interaction within the project
  - Interaction with existing FP7s Project : ENPRA, Nanodevice, etc.

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THANK YOU !

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