

Good practices in running a JA: example of NANOGENOTOX

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Workshop on Joint Actions – 5 December, 2011

Presentation outline:

- Presentation of the JA NANOGENOTOX
- How to ensure the coordination
 - Consortium and management structures
 - Consortium Agreement
 - Management tools
- Dissemination of the JA
- Evaluation of the JA

NANOGENOTOX JA

- A European Joint Action on Safety evaluation of manufactured nanomaterials by characterisation of their potential genotoxic hazard
- Approved in July 2009
- Budget: 6.2 million Euros (46% funded by EC)
- Start in March 2010, for 3 years

NANOGENOTOX JA

- **Coordinator:** ANSES (FR), French Agency for Food, Environmental and Occupational Health & Safety
- **16 associated partners**
- **13 collaborating partners:** 7 ministries (FR, IT, NL, DE, FI, ESP, BE) and 6 Institutes JRC (EC), HPA (UK), UCD (IR), LNE (FR), AFSSAPS (FR), INERIS (FR)

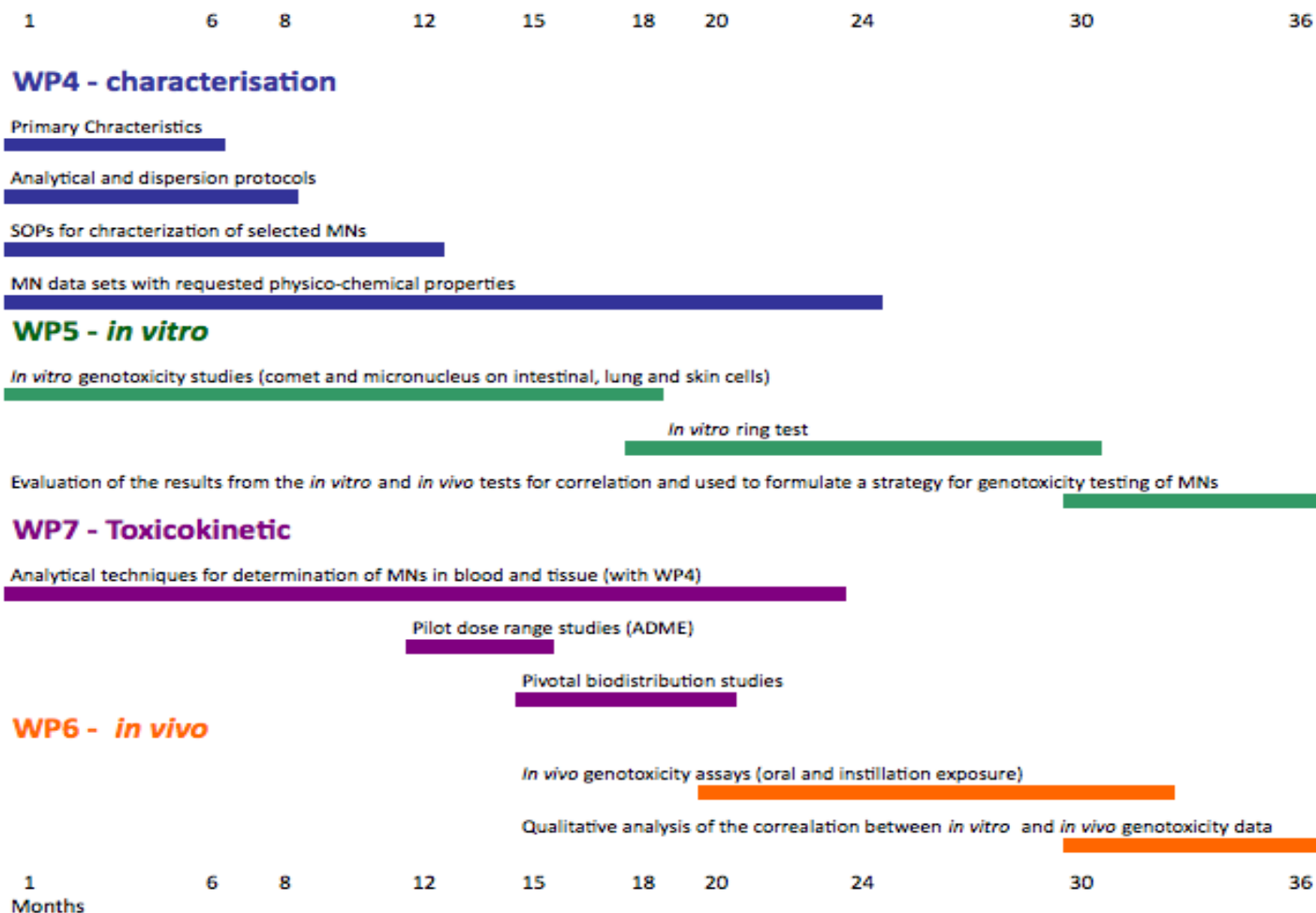
Associated Partners



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- Genotoxicity testing of 14 Manufactured Nanomaterials (TiO_2 , SiO_2 , CNTs)
- **Main objective:** to establish a robust (specific and sensitive) methodology to assess the potential genotoxicity of MNs
- 3 transversal Work Packages (WP)
 - Coordination
 - Dissemination
 - Evaluation

■ And 4 scientific WPs



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How to ensure the coordination of the JA ?

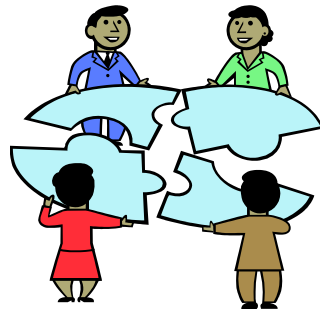
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Efficient coordination includes

- Stimulating effective exchange of information
- Following-up of the activities
- Managing the budget
- Providing guidance and interaction with the partners, stakeholders and the EAHC.
- Ensuring that the Consortium delivers the project outputs (deliverables) in due time and on budget.

Efficient coordination includes

- **A team**



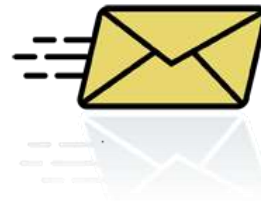
- **ANSES Coordination Team (CT)** is in charge of the contractual, financial and knowledge management, including reporting to the EAHC and budget consumption monitoring

Coordinator role

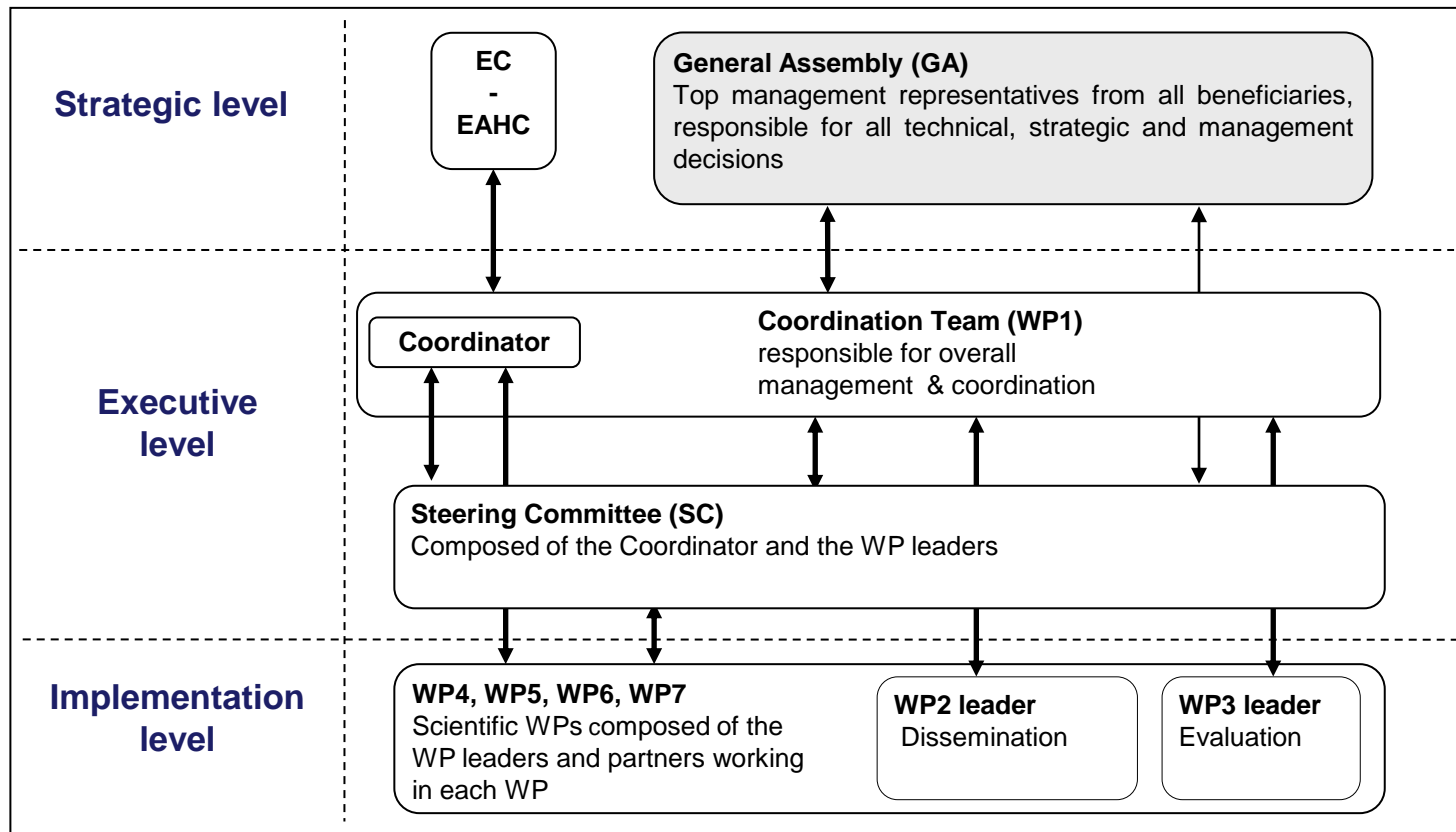
- Lead the partners network
 - Ensure that decision-making bodies are clearly indentified and effective
 - Bring people together, encourage communication between partners and with the EAHC
- Have a clear vision of the project in all its aspects
 - Scientific, financial, administrative, life-cycle of the JA
 - In details (“big picture” isn’t sufficient!)

Coordinator role

- Identify potential problems
 - look for warning signs
 - propose solutions to these problems
- Ensure that the funder approves changes (scientific, budget etc.)
- Follow the budget (per WP and per partner)
- *Be an expert in e-mails!*



Consortium and Management Structure



Consortium and Management Structure

- **General Assembly: ultimate decision body**
 - 2 meetings per year
 - 2 to 3 days with all the partners and the WP leaders
 - Strong involvement of the Coordination Team
 - Votes strategic decisions at 2/3 majority (except specific decisions requiring unanimous vote)

Consortium and Management Structure

- **Steering Committee: Executive level of the Consortium**
 - Meets at least every 3 months (10 meetings since the beginning of the JA, in person or by phone)
 - Supports the Coordinator in fulfilling the Grant Agreement obligations
 - Oversees the work progress of each WP

Consortium and Management Structure

■ Work Package Leaders

- ❑ Ensure day to day coordination of work progress
- ❑ Take corrective actions in case of discrepancies with project plan
- ❑ Provide WP reports (internal to the project) every 6 months
- ❑ Ensure the production of the Deliverables in due time

Consortium and Management Structure

■ Coordination Team

- ❑ Implemented by the Coordinator (ANSES)
- ❑ Single point of contact between EAHC and partners
- ❑ Composition: **8 members** involved in the various JA aspect: scientific, financial, managerial, communication tasks
- ❑ Meet every month

Control Tower of the JA



Consortium and Management Structure

- **Partners: Each party has a lead scientist**
 - ❑ Carries out its task & provides the Coordinator with the results
 - ❑ Promptly notifies the Coordinator of any modification, problem etc.
 - ❑ Provides all information requested for reporting to the EAHC
 - ❑ Keeps proper records of the work
 - ❑ Responsible for supervising its subcontractors (if any)

Agreements:

EAHC



ANSES

CMC-BAS

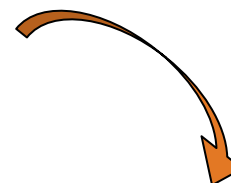
IMB-BAS

FIOH

NRCWE

BfR

NIOM



CODA-CERVA

CEA

INSA

RIVM

INRS

UAB



IPL

ISS

IPH

- **Consortium Agreement:** the only agreement signed by all the partners

Consortium agreement:

- Secures the partnership by contractualizing the cooperation
- Organizes the legal and operational framework of the Action
- Organizes the share of the competencies, the access rights and defines the rights and obligations of the partners in the Action



Not mandatory, but highly recommended !

Consortium agreement:

■ Six major parts:

- Part 1: Organization of the consortium and responsibilities of the parties (organizational bodies, rights and obligations of the beneficiaries)
- Part 2: Payment strategy
- Part 3: Confidentiality and dissemination
- Part 4: Use of the results (access rights, exploitation, ...)
- Part 5: Change in the consortium (accession, withdrawal or exclusion of a party and its consequences)
- Part 6: Dispute resolution

Consortium agreement

- Two rounds of negotiations (from March 2010 to June 2010)
- With the help of a sub-contractor
- Signed by all partners in Sept. 2010



NB: Collaborating partners signed a Confidentiality Agreement to participate to the JA activities

Tools provided to the partners

- Handbook of the Joint Action
 - Describes the “quality assurance” methodologies and management tools and communication rules (regularly updated, 3 versions since the start of the JA)
- Templates: Financial and technical reports, timesheet, agenda, minutes etc.
- Internal exchange platform (CIRCA), only for the partners of the project

Communication

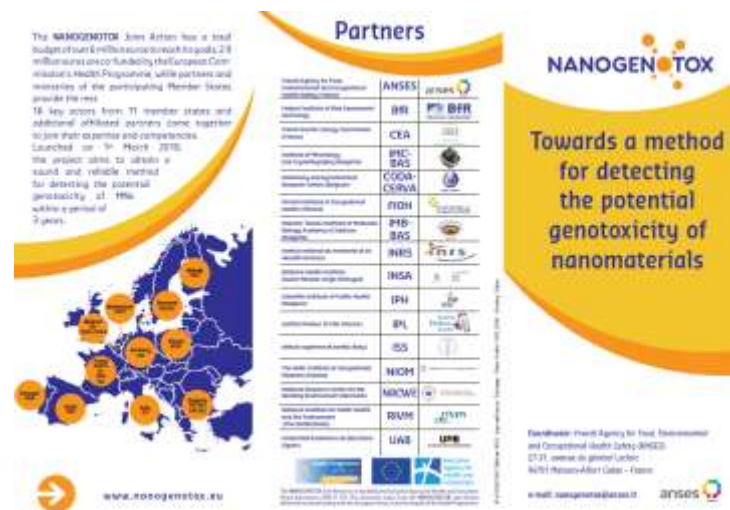
To ensure the visibility and publicity of the JA, and communication with the target groups

(WP leader B. Vergriette, ANSES)

- **Presentation of the communication tools**
 - Project identity and Logo
 - Leaflet
 - Dedicated website
 - Newsletters
- **Communication rules**
- **Stakeholders' consultation**

Project identity and leaflet

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- Graphic rules = project identity
- Dedicated mailbox : nanogenotox@anses.fr
- Leaflet
 - Sent to all partners for distribution in July 2010



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Website

- www.nanogenotox.eu
- Launched on 22-Sept-2010
- Around **2900 visits** from 62 different countries (EU, US, Asia, etc.)



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Website statistics

Since launch (Sept 2010 to Nov. 2011)

- 40% direct entries
- 40% came from search engines (Google, etc.)
- 20% came from websites mainly partners web sites, European agencies,
- Most consulted pages : First page, Project description, News, WPs, Newsletters and Publications.
- 500 documents were uploaded: 215 leaflets, 130 Newsletter n°1, 55 Newsletter n°2, 64 reports on stakeholders consultation etc.

Website improvement

- Actions were taken to increase the referencing of the website
- The publishable summaries (part of the 6-monthly reports) are regularly uploaded
- All the partners contribute to the site (i.e. pictures, news, related events etc.)
- All communications are uploaded (posters, abstracts, etc.)

Periodic Newsletter





- 1st newsletter issued in March 2011
- 2nd newsletter issued in September 2011
- 3rd newsletter planned for February 2012
- Format A4, same graphic rules as leaflet & web site
- Summarises research actions, scientific findings, other communications (events, meetings...)



- Contributions received from partners
- Sent by email to all partners, contacts identified through the web site, stakeholders etc.



Communication rules

- Logos (   ) on all documents
- **EAHC statement:** *This [e.g. publication] arises from the project NANOGENOTOX which has received funding from the European Union, in the framework of the Health Programme. This [publication] reflects only the authors' views and the EAHC is not liable for any use that may be made of the information contained therein.*
- **Art. 6.3 of the Consortium Agreement on Publication and Communication (notice given to all partners, 10 days to object or ask for modifications)**

Communications	OECD WPMN SG7	Jan. 2011, Paris	Nanogenotox Overview	NRCWE
	OECD WPMN TiO ₂ expert group	Jan. 2011, Paris	Nanogenotox Overview	ANSES
	First Portuguese Meeting on Nanotoxicology	Feb. 2011, Lisbon	Nanogenotox Overview	INSA
	First Meeting of the EFSA scientific network for risk assessment of nanotechnologies in food and feed	Feb. 2011, Parma	Nanogenotox Overview	ISS
	5th International Symposium on Nanotechnology, Occupational and Environmental Health (NanOEH)	Aug. 2011, Boston	Nanogenotox Overview	ANSES
Posters	3rd NanoImpactNet Conference	Feb. 2011, Lausanne	Nanogenotox Overview	ANSES
			Genotoxicity of zinc oxide nanoparticles in human bronchial epithelial cells and mesothelial cells <i>in vitro</i>	FIOH
	INRS Occupational Health Research Conference 2011	Apr. 2011, Nancy	Physicochemical characterization of manufactured nanomaterials (TiO ₂ , SiO ₂) used for genotoxicity testing	CEA
	TraceSpec 2011 (13th Workshop on Progress in Trace Metal Speciation for Environmental Analytical Chemistry)	May 2011, Pau	Exploring the potential of ICP-MS as analytical tool for detecting silica nanomaterials employed in the food sector	ISS
	4th International IUPAC Symposium for Trace Elements in Food (TEF-4)	June 2011, Aberdeen	Extending the potential of ICP-MS as analytical tool for evaluating the safety of food nanomaterials	ISS
	July 2011, Barcelona	Evaluation of the genotoxic and cytotoxic effects of titanium dioxide nanoparticles in human lymphocytes.	INSA	
Publication	Journal of Nanobiotechnology	May 2011	Determination of the volume-specific surface area by using transmission electron tomography for characterization and definition of nanomaterial	CODA CERVA

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First stakeholders' consultation

- identifying at an early stage some keys concerns regarding the aim and output of the project
- bringing the project to the attention of key concerned actors/stakeholders
- establishing contacts in order to facilitate further dissemination activities

First stakeholders' consultation

- Identification of stakeholders
 - EU risk assessors and policy makers
 - Scientific community
 - Professional federations representing companies
 - Non-governmental organisations (NGOs)
 - Trade unions
- First consultation: from October 2010 to January 2011
- Process
 - qualitative interviews *via* a questionnaire and
 - open discussion during the interview (by phone)

First stakeholders' consultation

- 19 persons consulted from 5 categories of stakeholders
- Report on first consultation issued in June 2011 (after feedback from the partners of the action)
- Report published on the web site

Stakeholders consultation results (1/2)

- Consultation process at the launch of the JA highly appreciated
- High interest and expectations about the aim of the JA
- Coordination with OECD WPMN seen as positive, no specific comments regarding selection of MNs
- Scientific and technical details should be made public as soon as they are available
- Translation of the results into policy orientations is of high concern

Stakeholders consultation results (2/2)

- Scientific validity and robustness of protocols and testing approaches to be used, under scrutiny
- Clarification might be needed about potential trade-off between the use of best knowledge available and the need for harmonisation of protocol
- Guidance for the use of the expected protocol and for data analysis is expected
- Strengthened coordination with other EU projects
- Dissemination of the results for policy making

Second stakeholders' consultation

- ½ day workshop during the 4th NANOGENOTOX GA meeting (3-May-2012, Brussels, BE)
- Presentation of the results and panel discussion
- Main objectives
 - Discussions between scientific partners of the JA and stakeholders
 - Knowledge transfer about preliminary results of the JA
 - Comments on preliminary outputs of the JA
 - Discussing and adjusting the dissemination activities
 - Future use of the final results of the JA
 - Preparation of the final conference

Evaluation

A systematic appraisal of the quality of the NANOGENOTOX JA (WP leader M. Götz, BfR)

Evaluation of the JA

- **Evaluation plan** and questionnaires are developed in cooperation with WP leaders and communicated to the partners
- **Cruise mode evaluation:** starting on month 6 and every 6 months (Apr. & Nov. 2011, Apr. & Oct. 2012) WP leaders complete reports reviewing JA data generation and knowledge sharing actions. The Internal Evaluation Team compiles the available information to be presented at the GA meetings.
- **Final evaluation** summarizes the evaluation procedures and provides an impact assessment of the JA.

Internal Evaluation Team

- Created during the first GA meeting (Oct. 2010)
- Voluntary commitments from participants of ANSES, INRS, BfR, JRC, IPL and IMB-BAS (1 representative per WP).
- **Aim:** The Evaluation Team monitors and analyses the quantitative (number of datasets) and qualitative (robustness, reliability of the tests) specific objective indicators, the JA's impact and its goal to improve health safety by improving knowledge on MN genotoxicity
- The Evaluation Team
 - Prepares the Evaluation Plan
 - Develops specific questionnaires for the WP evaluation
 - Prepares evaluation reports

External Academic Reviewer Panel

■ Aims

- to reflect on the soundness of the experiments performed and the suitability of the methods proposed for the hazard assessment of MNs,
- to discuss pitfalls and drawbacks of test systems,
- to provide questions or recommendations to the Consortium and
- to answer specific questions from the internal evaluation team
- Created at the third GA meeting (Oct. 2011), by vote of all partners after presentation of the pre-selected experts.
- Two to three representatives per WP, selected with regards to their field of expertise (peer-reviewed scientific journals in nano-analytics and nanogenotoxicology). Experts signed a Confidentiality Agreement
- Will receive Deliverables and other outputs of the JA and prepare their evaluation for the final meeting.

Final evaluation meeting (Berlin, Dec. 2012)

- To be attended by internal and external evaluators plus WP Leaders
- Will focus on topics as outlined in the evaluation plan
- Will gather opinions from external evaluators
- An evaluation report, to be drafted by the internal evaluators after the meeting, will summarize the outcome.
- The **final evaluation report** (March 2013)
 - Shall measure the JA's performance against its targets and its impact and added value on the European level
 - Will summarize the complete output and address the relevance and reliability of the methods developed
 - and discuss the outcome of the findings in light of the output indicators as defined in the Grant Agreement.

THANK YOU !



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