instituto sindical
de trabajo, ambiente y salud

Nanotechnology: European & Spanish Regulatory Framework
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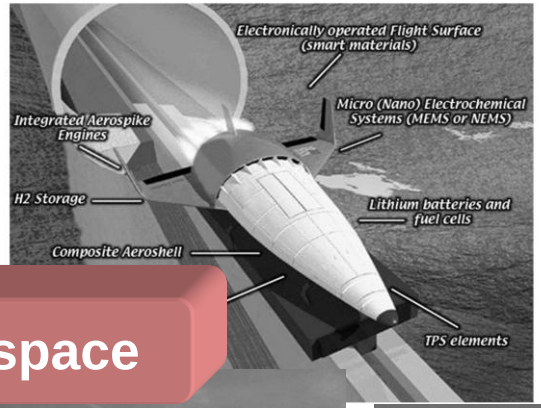
ISTAS-CCOO

Nanotechnology: Framework Regulatory

Presentation outline:

Introduction

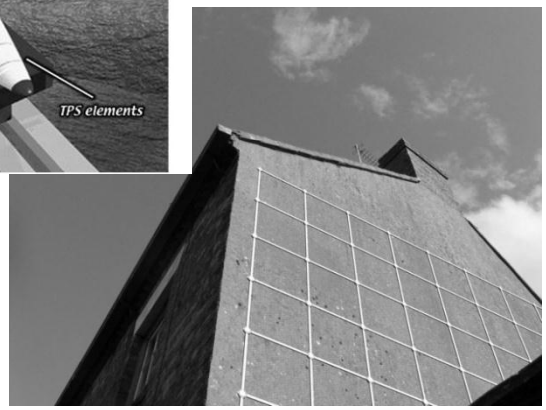
Activities…



Aerospace

Automotive

Construction



Energy saving

Renewable energies

Medicine/Pharmaceutical

Food & additives

etc……

Introducción

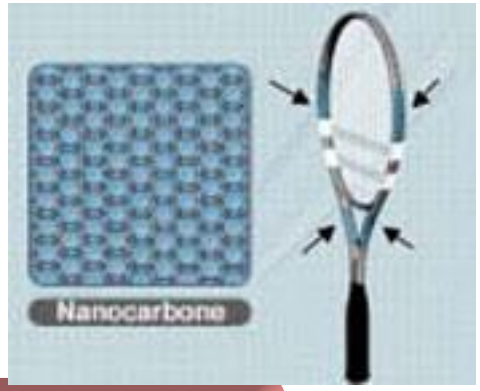
Some products…

Containers

Cosmetics

Fabrics/Clothing

Communications



Sports

Solar Panels

etc…..

http://www.nanotechproject.org/inventories/consumer/

Introduction: market

2009 Global market for nanomateriales

1. Coatings
2. Composites
3. Catalysts
4. Drug delivery
5. Energy storage
6. Sensors
7. Therapeutics
8. Display Screens
9. Memory chips
10. Solar Panels
11. Filters

Lux Research

Nanomaterials Market 2009: $1B

1. Ceramic nanoparticles
2. Carbon nanotubes (CNT)
3. Nanoporous materials
4. Graphene
5. Metal nanoparticles
6. Nano-encapsulation
7. Fullerenes
8. Dendrimers
9. Nanoestructured metas
10. Nanowires
11. Quantum dots

Nanointermediates Market 2009 $29B

Nano enabled products Market 2009 $224B

1. Cars
2. Construction
3. Electronics
4. Personal care products
5. Marine
6. Aerospace
7. Sports
8. Food , agriculture
9. Industrial equipment
10. Fabrics
11. Defense

Introduction: Potential hazards

INHALATION

- Translocation → increased possibility of crossing cell boundaries.
- If surface area is a driver for toxicity → increased toxic effects
- Reduction in size → Increased solubility, therefore increased bioavailability
- New and different properties (chemicals or physical) → different biological properties → different toxicity
- Comparison between high aspect ratio nanoparticles and asbestos, similar morphology than fibres → persistence and accumulation in lungs

DERMAL EXPOSURE

- Penetration through damaged skin

INGESTION

- Unlikely. Need to minimise exposure through this route

Nanotechnology: Regulatory Framework

Nanotechnologies: Regulatory Framework

Specific committees and working groups on Nanotechnology

ISO/TC 229 Nanotechnologies

- WG1 Terminology and nomenclature
- WG2 Measurement and characterisation
- WG3 Health, Safety & Environmental aspects of nanotechnologies
- WG 4 Material specifications

European Committee for standardisation CEN

- CEN/TC 352 “Nanotechnologies” European Committee for standardisation

IEC/TC 113

- Nanotechnology standardisation for electrical and electronic products and systems

OECD Grupo de trabajo de nanomateriales fabricados

- 8 steering group
- OCDE database containing databases with information about projects related to health, safety and environment

Mandate COM (2010) M/461 For standardization activities regarding nanotechnologies and nanomaterials

Nanotechnologies: Regulatory Framework

Specific committees and working groups on Nanotech ISO/TC 229

ISO/TS 27687:2008

- Nanotechnologies -- Terminology and definitions for nano-objects -- Nanoparticle, nanofibre and nanoplate

ISO/TR 12885

- Nanotechnologies -- Health and safety practices in occupational settings relevant to nanotechnologies

CEN ISO/TS 27628

- Workplace atmospheres -- Ultrafine, nanoparticle and nano-structured aerosols -- Inhalation exposure characterization and assessment

UNE- CEN ISO/TS 27687:2010

UNE-ISO/TR 12885

AENOR Asociación Española de Normalización y Certificación

nanotechnologies: Framework Regulatory

Regulation review (non- binding):

- COM (2004) 338: Towards a European Strategy for nanotechnology
- COM (2007) 505 final: Nanoscience and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007
- 2008 European activities in the field of ethical, legal and social aspects (ELSA) and governance of nanotechnology
- 2009 The Commission published the Second Implementation Report
- 2011 The Commission will issue a progress report on the implementation of existing regulations on nanomaterials
- Commission Recommendation: **Code of conduct** for responsible nanosciences and nanotechnologies research
- 2nd Action Plan2010-2015

Nanotechnologies: Regulatory Framework

REACH

- REACH: (CE) 1907/2006 Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals

CA/59/2008 (Competent Authorities REACH Steering Group) REACH in nanomaterials:

No specifically for nanomaterials, however…

- Nanomaterials are under the “substance” definition in REACH
- Substances manufactured or imported >1T require registration but if it is known to be of very high concern will have to be registered even below 1 T/y, authorisation and restriction processes will apply regardless
- When an existing chemical is introduced on the market in a nanomaterial form, the registration dossier will have to include specific properties of the nanoform (included tonnage)
- Competent Authorities may request further information (health, safety, physico-chemical properties, environment)

Nanotechnologies: Regulatory Framework

CA/90/2009 (Competent Authorities REACH Steering Group): REACH in nanomaterials:

Clasification, Labelling and Packaging of nanomaterials in REACH y CLP

Classification and labeling on a CASE by CASE basis

REACH Implementation Projects on Nanomaterials (RIPonN):

- RIP-oN1 Substance identity
  1. Case study CNT
  2. Case study Nanosilver
  3. Case study Nano TiO_2
  4. Case study Nano$CaCO_3$
- RIP-oN2 Information requirements and testing of nanomaterials
- RIP-oN3 Chemicals Safety Assessments

Nanotechnologies: Regulatory Framework

European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI)) NM (2010/C 184 E/18):

3. Does not agree with the Commission's conclusions that current legislation covers in principle the relevant risks relating to nanomaterials and it is effectively unable to address their risks due to lack of appropriate data and methods to assess the risks

4.The concept of the 'safe, responsible and integrated approach' to nanotechnologies advocated by the European Union is jeopardised by the lack of information on the use and on the safety of nanomaterials that are already on the market

5. Calls on the Commission to review all relevant legislation within two years (REACH)

June 2010: European Members of Parliament vote to ban Nanosilver and CNT in Electrical and electronic products (RoHD 2002/95/EC)

Nanotechnologies: Regulatory Framework

European Commission Public Consultation on a proposal for a definition of the term nanomaterial (2010)

1. Nanomaterial: means a material that meets at least one of the following criteria:

- *consists of particles, with one or more external dimensions in the size range 1 nm - 100 nm for more than 1 % of their number size distribution;*
- *has internal or surface structures in one or more dimensions in the size range 1 nm - 100 nm;*
- *has a specific surface area by volume greater than 60 m2/cm3, excluding materials consisting of particles with a size lower than 1 nm.*

2. Particle: means a minute piece of matter with defined physical boundaries (ISO 146446:2007).

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_cons_13_en.htm

Nanotechnologies: Regulatory Framework

01/March/2011

Public consultation (Scientific opinion) results:

SCENIHR
Scientific Committee for Emerging and Newly Identified Health Risks

- Size,
- Size distribution,
- Specific surface area,
- Surface modification,
- Other physical-chemical characteristics

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf

Nanotechnologies: Regulatory Framework

Commission Recommendation 18 Oct 2011

- "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.
- In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.
- By derogation from the previous point fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_cons_13_en.htm

Nanotechnologies: Regulatory Framework

Institute for Health and Consumer Protection

http://ihcp.jrc.ec.europa.eu/our_activities/nanotechnology/reference-nanomaterials

European Commission

- Nanomaterials Repository: representative nanomaterials
- Includes: titanium dioxide, silica, zinc oxide, cerium dioxide, nano-silver, nanoclays and carbon nanotubes
- Vials distributed to labs in France, Germany, United Kingdom, Belgium, Netherlands, Denmark, Spain, Poland, Italy, Austria, Slovakia, USA, Canada, Japan, Korea, China y Russia
- Nanohub: It is a comprehensive IT platform dedicated to the management of information on NM which are relevant for safety and risk assessment.

Nanotechnologies: Regulatory Framework

List of nanomaterials in the JRC Nanomaterials (NM) Repository (23 February 2011)1		
NM code	Type of nanomaterial2	Label name
NM-100	TiO2	Titanium Dioxide
NM-101	TiO2	Titanium Dioxide
NM-102	TiO2	Titanium Dioxide
NM-103	TiO2	Titanium Dioxide thermal, hydrophobic
NM-104	TiO2	Titanium Dioxide thermal, hydrophobic
NM-105	TiO2	Titanium Dioxide rutile-anatase
NM-110	ZnO uncoated	Zinc Oxide
NM-111	ZnO coated	Zinc Oxide coated triethoxycaprylsilane
NM-112	Zinc oxide	Zinc Oxide
NM-113	Zinc oxide	Zinc Oxide
NM-200	SiO2 precipitated	Synthetic Amorphous Silica
NM-201	SiO2 precipitated	Synthetic Amorphous Silica PR-B-01
NM-202	SiO2 thermal	Synthetic Amorphous Silica PY-AB-03
NM-203	SiO2 thermal	Synthetic Amorphous Silica PY-A-04
NM-204	SiO2 precipitated	Synthetic Amorphous Silica PR-A-05
NM-211	Cerium Dioxide	Cerium (IV) Oxide precipitated, uncoated
NM-212	Cerium Dioxide	Cerium (IV) Oxide precipitated, uncoated
NM-213	Cerium Dioxide	Cerium (IV) Oxide
NM-300	Silver	Silver <20 nm
NM-300K	Silver	Silver <20 nm
NM-300DIS	Silver	Ag - dispersant
NM-300K DIS	Silver	Ag – dispersant <20 nm
NM-400	MWCNT	Multi-walled carbon nanotubes
NM-401	MWCNT	Multi-walled carbon nanotubes
NM-402	MWCNT	Multi-walled carbon nanotubes
NM-403	MWCNT	Multi-walled carbon nanotubes
NM-600	Nanoclay	Bentonite

Nanotechnologies: Regulatory Framework

JRC EUROPEAN COMMISSION

Institute for Health and Consumer Protection

List of materials in the JRC Nanomaterials (NM) Repository

Last update: 27 October 2011

NM code	Type of material[1]	Label name	Mean particle size [nm]	Primary particle or crystal size [nm]	Specific surface area [m2/g]	Average Length[2] [micron]	Average Diameter[3] [nm]	Other information
NM-100	Titanium Dioxide	Titanium Dioxide	267	42 - 90	10			anatase
NM-101	Titanium Dioxide	Titanium Dioxide	38	6	320			anatase
NM-102	Titanium Dioxide	Titanium Dioxide, anatase	132	20	90			anatase
NM-103	Titanium Dioxide	Titanium Dioxide thermal, hydrophobic	186	20	60			rutile
NM-104	Titanium Dioxide	Titanium Dioxide thermal, hydrophilic	67	20	60			rutile
NM-105	Titanium Dioxide	Titanium Dioxide rutile-anatase	95	22	61			rutile-anatase
NM-110	Zinc Oxide, uncoated	Zinc Oxide	150	42	13			
NM-111	Zinc Oxide, coated	Zinc Oxide coated triethoxycaprylsilane	140	34	16			
NM-200	Silicon Dioxide	Synthetic Amorphous Silica PR-A-02	47	20	230			precipitated
NM-201	Silicon Dioxide	Synthetic Amorphous Silica PR-B-01	62	8-15	160			precipitated
NM-202	Silicon Dioxide	Synthetic Amorphous Silica PY-AB-03	108	8-15	200			thermal
NM-203	Silicon Dioxide	Synthetic Amorphous Silica PY-A-04	137	8-20	226			thermal
NM-204	Silicon Dioxide	Synthetic Amorphous Silica PR-A-05	75	8-15	144			precipitated

[1] Nanomaterials, even of the same chemical composition, can come in various sizes and/or shapes, which may influence their chemical and physical properties.

[2,3] Applicable only to NM-40x series, CNT.

Nanotechnologies: Regulatory Framework

- REACH-Regulation 1907/2006 on Registration, Evaluation [illegible]d Restriction of Chemicals
- Regulation (CE) nº 1272/2008 on classificación, labelin[illegible] substances and mixtures

ONLY 3 REGISTRATIONS

Health and Safety Legislation

Framework Directive 89/391/EEC Health & Safety at Work	Ley 31/95 Prevención Riesgos Laborales
Directive 2004/37/EC Carcinogens and Mutagens	R.D 665/1997 Cancerígenos y mutágenos
Directive 98/24/EC Chemical agents	R.D 374/2001 Agentes químicos
Directive 89/655/EEC Work Equipment	R.D 1215/1997 Equipos de Trabajo
Directive 89/656/EEC Personal Protective Equipment	R.D 773/1997 Equipos de Protección Individual
Directive 99/92 Explosive atmospheres	R.D 681/2003 Atmósferas explosivas

Nanotechnologies: Regulatory Framework

Example of global production of some nanomaterials (T/a):

TiO2	Ag	ZnO	CNT	Fullerenes
679	4	18	140	0.15
3000	5	20	278	5
5000	434	528	295	10
60926	563	1800	426	
		9845	473	
			500	

Source EMPA: Swiss Federal Laboratories for Materials Testing and Research

Titanium dioxide applications: Cosmetics, filters, cleaning agents, electronics, plastics, paints, ceramics and glass, light bulbs, metals, batteries, dying agents

Nanotechnologies: Regulatory Framework

European Initiatives

Belgium

Political agenda with a strong proposal for national authorities to hold discussions on coordinating national strategies and bringing forward concrete measures on risk management, information and monitoring of nanomaterials.

France

Grenelle II Act: It requires the public and consumers to be informed about the quantities and uses of manufactured, imported or marketed nanoform substances; the materials that might release such nano-substances; and the presence of nanomaterials in articles

Italy

Ministry of Health is drafting regulations on a national nanomaterials database with stakeholder participation

Netherlands

15% of the 125M euro innovation subsidy has been allocated to risk-related research for a 5 year period and the National Programme on Nanotechnology

Nanotechnology: Regulatory Framework

Spain: Current situation

MINISTERIO DE CIENCIA E INNOVACIÓN

DIRECCIÓN DE COMUNICACIÓN

GABINETE DE PRENSA

Nota de prensa

España y Japón suscriben un Acuerdo para fortalecer la cooperación científica e impulsar la innovación empresarial

- El nuevo marco, que consolida y amplia las relaciones promovidas por el Ministerio de Ciencia e Innovación desde 2008, incrementará el intercambio científico y multiplicará el desarrollo de proyectos de desarrollo tecnológico conjunto entre empresas españolas y japonesas.
- La biotecnología y la nanotecnología destacan como prioridades de la colaboración por la existencia en ambos países de grupos de investigación y empresas con oportunidades de liderazgo a nivel internacional.
- El Ministro de Educación, Cultura, Deportes, Ciencia y Tecnología japonés ha comunicado a la Ministra Garmendia la visita inminente a España de una misión científica japonesa de alto nivel para explorar nuevas áreas de cooperación.

Spain: Current situation

- NanoSpain: Spanish network of nanotechnology
- 308 Working groups(41 companies)
- 2000 Researchers
- Databases for nanotechnology information (http://www.nhecd-fp7.eu/index.php?id=523)

  NHECD

  Creation of a critical and commented database on the health, safety and environmental impact of nanoparticles

  NHECD is supported by the European Commission's 7th RTD Framework Programme

  Project Number: NMP4-SA-2008-218639

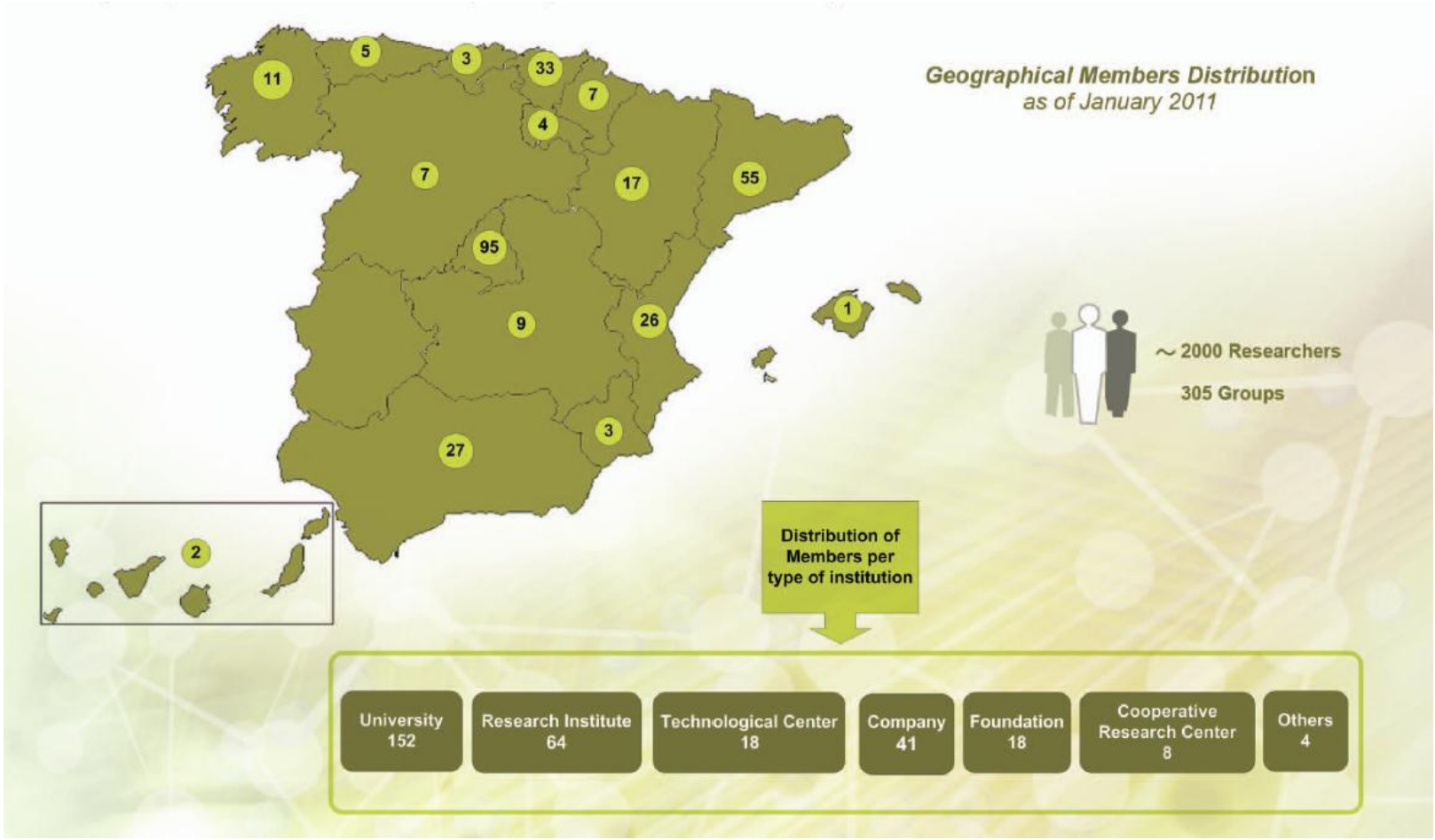
  Project Start: December 1st, 2008

  Project Duration: 48 months (2008-2012)
- NanoJOBS – (from nanowerk)
- Nanoenergía: Red de nanotecnologías para energía de la región iberoamericana

red NANOENERGIA

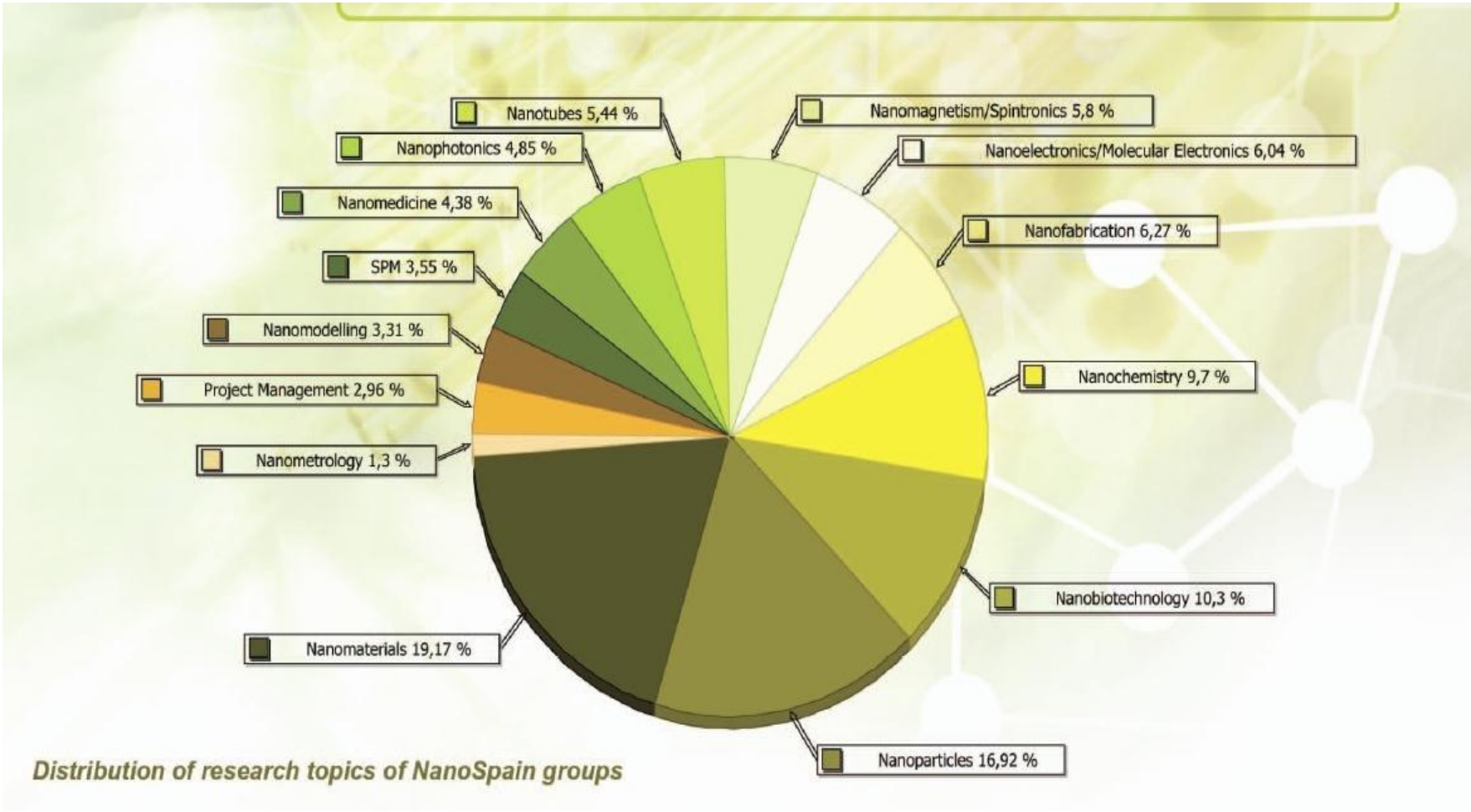
Red de Nanotecnologías para energía de la región Iberoamericana

Spain: Current situation



Fuente: Fundación Phantoms

Situación española

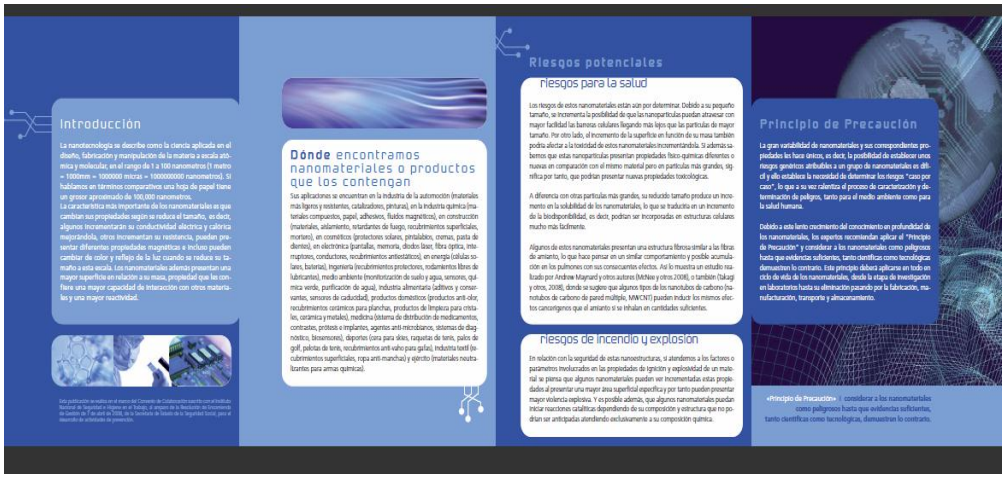


Source: Phantoms

ISTAS-CCOO Activities

Awareness leaflets for workers and health and safety reps:

1. Introduction to nanotechnology
2. Health and safety management measures for nanomaterials



ISTAS-CCOO: Activities

Courses

- Universidad Complutense (Madrid)

Articles

- Daphnia magazine: Dossier

Books

- “Nanomundos, multiconflictos”
- “Bioética y nanotecnología” 2010

- AENOR GET 15: Nanotechnology Technical Committee:

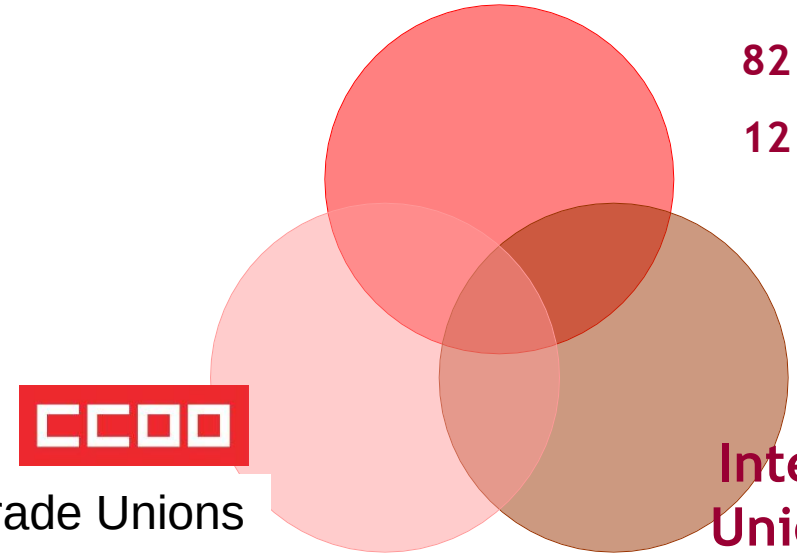
ISTAS-CCOO: Activities

European Trade Union Confederation
ETUC

60M Workers

82 National Trade Unions

12 European Federations



National Trade Unions

International Trade Union Confederation
ITUC

176M Workers

151 Countries

301National Organisations

ISTAS-CCOO: Activities

ETUC 1st and 2nd Resolution

1. **Inclusion of the societal dimension of nanotechnologies**

   Environment, sustainability, social rights

2. **Implementation of the Precautionary Principle**

   Risk assessments, risk management measures, health surveillance, registry of exposures

3. **The applicability and revision of existing regulations**

   Current legislative framework should be updated: REACH, biocides, food, worker protection, water quality, air quality and waste.

   Transparent Regulation on protection against potential risks related to nanomaterials

ETUC 1st and 2nd Resolution

4. REACH and its use of the term nanomaterial

"No data no market" principle

All engineered substances in the "nanoform" be considered as new substances and be registered regardless of the volume

5. Transparency and traceability of nanomaterials

Development of harmonised mandatory registers of articles containing nanomaterials, including a life cycle assessment of the article

Standardisation is NOT a substitute for regulation.

6. Occupational Health and Safety issues

Set up a register of workers´ exposures to nanoparticles in association with health surveillance programmes

Workers participation and involvement, information and training

Worker participation

Anyone involved or who could be affected by the activities related to nanomaterials should be involved in the Risk Assessment and management process, otherwise, any control measured identified is unlikely to be fully effective

- Name of substances/NM and potential risks
- Relevant OELs
- Information on SDS available (Safety Data sheets)
- Significant findings of the risk assessment
- Precautions that should be taken
- Results of any monitoring exposure
- Personal Protective Equipment
- Health Surveillance

Nanotechnology: Regulatory Framework

Lack of information

1. There is not specific legislation for nanomaterials
2. Evidence of toxicological effects
3. Important: to collect all information related to chemical and physical properties
4. **Precautionary principle**: to be considered as hazardous
5. Development of H&S management strategies
6. Information, instruction and training

Thank you !!!

¿Questions?

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