4a Conferenza Nazionale del Programma N.I.C.”

Milano, 2 Dicembre

Hard e Soft Regulation per le Nanotecnologie

Elvio Mantovani

THE 2020 EUROPEAN AGENDA FOR DEVELOPMENT

SUSTAINABLE GROWTH

Respecting Economic, Social and Ecological Objectives

(Regulation: ELSA, HSE)

SMART GROWTH

Basing on Knowledge and Innovation

INCLUSIVE GROWTH

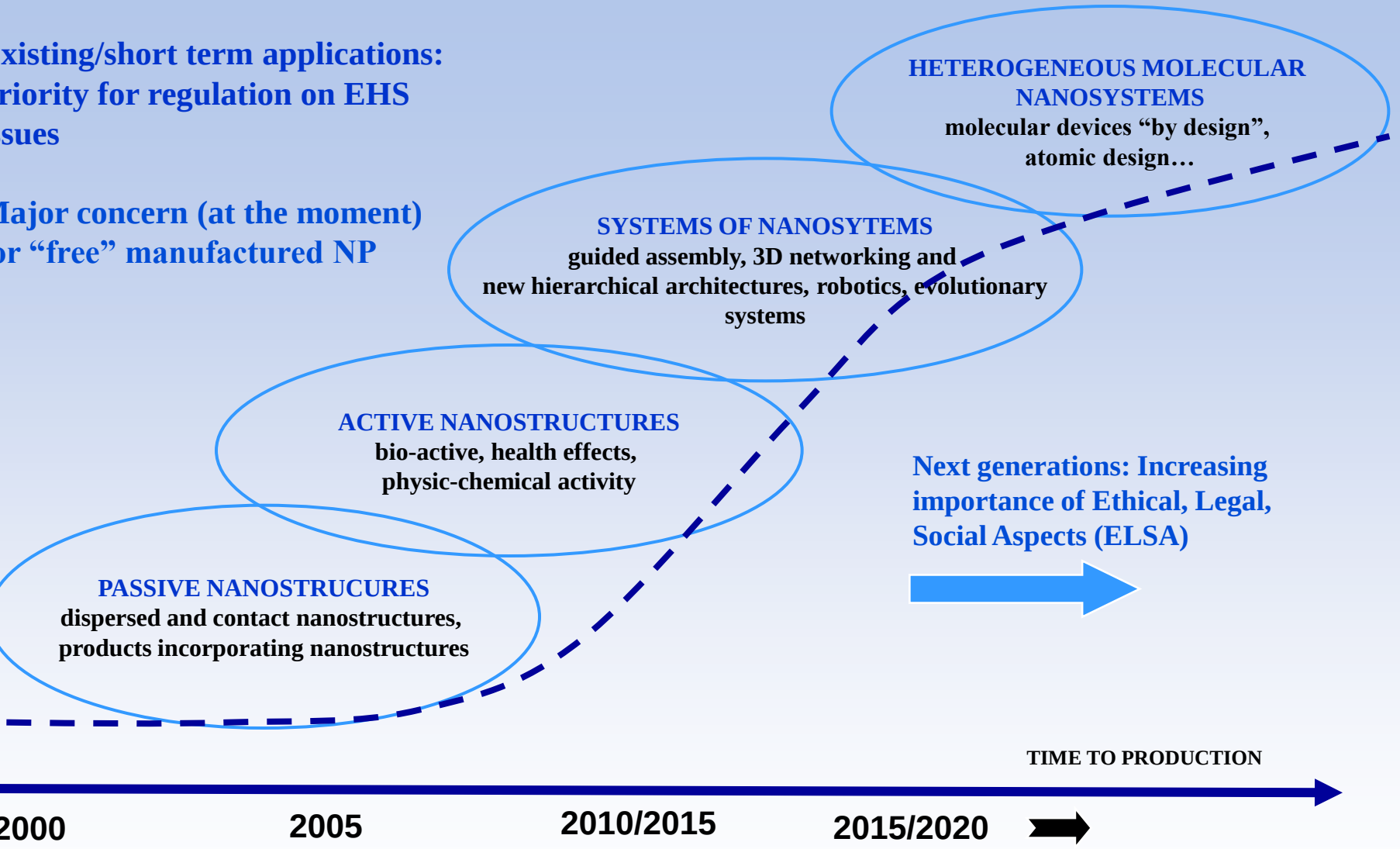
Delivering Social and Territorial Cohesion

Source: Communication From The Commission : EUROPE 2020 Agenda - Brussels, 3.3.2010

The “S” curve of nanotechnology…

Existing/short term applications: priority for regulation on EHS issues

Major concern (at the moment) for “free” manufactured NP



AIRI/Nanotec IT on data from M.C. Roco (NSF) and IRGC

Challenges in regulating nanotechnologies

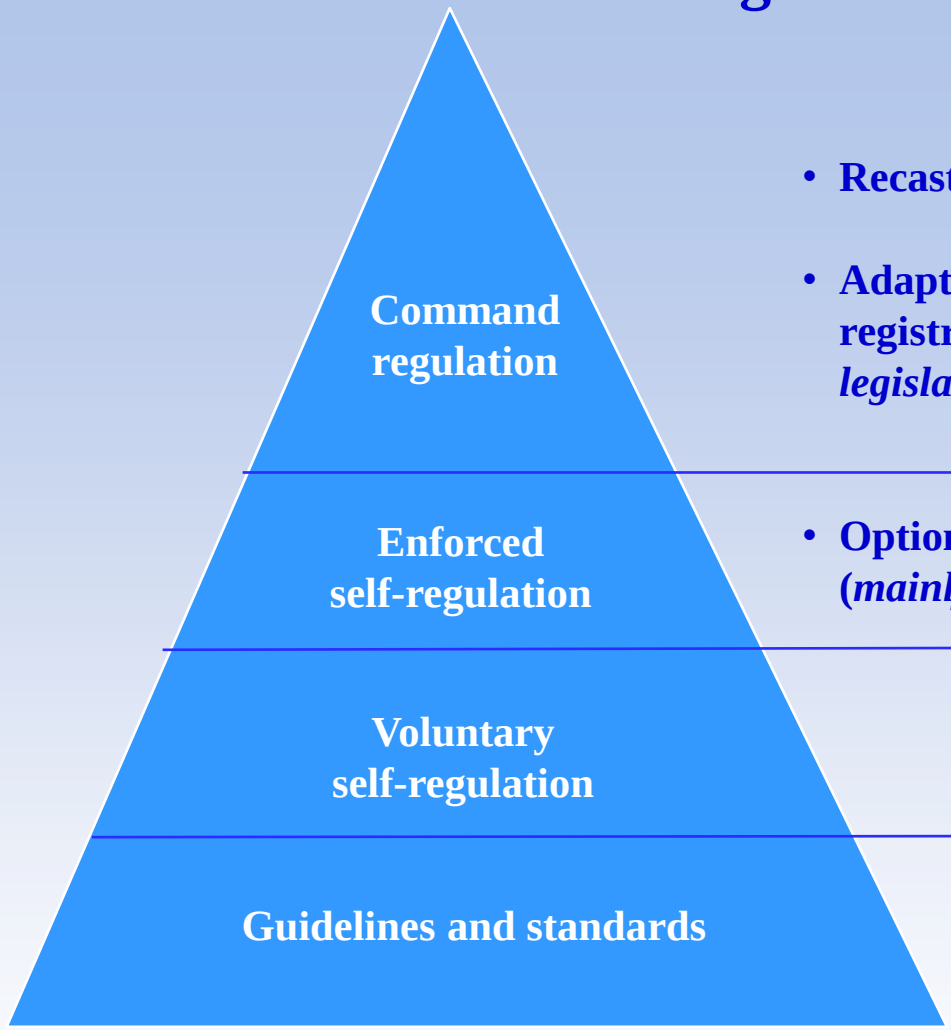
- **Diversity of materials and applications**
- **Limited data and methods for characterization and risk assessment**
- **Proprietary nature of information** (access to relevant information)
- **Lack of harmonised standards and guidance**
  (for risks management and to support implementation of regulation)
- **Potential inadequacy of statutory authorities**

Stakeholders position about the way to regulate N&N

Position/opinion	Policy makers	Business	Researchers	CSOs
The existing regulatory situation is adequate. Nanomaterials are not new materials. In the case that scientific evidence indicates the need for modification, the regulatory framework will be adapted.	+	+		
Specific guidance and standards must be developed to support existing regulations when dealing with N&N	++	++	++	
Regulation should be amended (on a case by case basis) for specific N&N. When a high potential risk is identified a precautionary approach is recommended.	++	+	++	+
The existing regulatory situation is not adequate at all. Nanomaterials are new materials. They should be subject to mandatory, nano-specific regulation.				++

Source: AIRI/Nanotec IT & FramingNano project – www.framingnano.eu

Nanoregulation: the regulatory pyramid*



- **Recast of cosmetics and food regulation**
- **Adapt/strengthen premarket notification and registration procedures (*mainly for chemical legislation)***
- **Options for mandatory reporting schemes (*mainly for chemical legislation)***
- **Codes of conduct/practice, risk management systems**
- **Technical guidelines for specific NM & products (mainly for OSH)**
- **ISO/OECD activities on N&N**

***AIRI/Nanotec IT elaboration from Linkov and Satterstrom and IRGC (2008)**

Command (hard) regulation:
The case of EU regulation on Cosmetics

Update of the European Regulation on Cosmetic Products approved in 2009 (will come into force in 2013) and includes:

- **Definition of (insoluble or biopersistant) manufactured nanomaterials**
- **Premarket notification of any new cosmetic product containing NM (info on NM: chemical name, physical and chemical properties, quantity, toxicological profile, safety data and exposure conditions)**
- **Labeling of ingredients in the form of NM (name + "nano in brackets")**
- **Reporting: catalogue of nanomaterials used in cosmetic products made by publicly available by the EC *(starting from 2017)***

REACH and nanomaterials

Potential limits	REACH Implementation Projects (RIP) *
No clear definition	**RIP-N1:** Substance Identification of Nanomaterials
Mass metrics: **1tonn threshold** (other metrics, based on surface, size could be instead used)	**RIP-N2- NanoInfo:** information requirements on intrinsic properties of nanomaterials
Lack of characterization and exposure models	**RIP-N3-NanoHazEx:** exposure assessments, hazard and risk characterization for nanomaterials within the REACH context

- **Funded by the Institute for Health and Consumer Protection of the European Commission's Directorate General Joint Research Centre (JRC) to give answers and guidance on REACH by 2011-2012**

Voluntary Self-Regulation

CODES OF CONDUCT

- **CoC of EC for Responsible Research, German NanoKommission (DE)**
- **Responsible Nanocode (UK, International), IG-DHS Code of Conduct (CH)**

INDUSTRY CODES OF PRACTICE/RISK MANAGEMENT SYSTEMS

- **Responsible Care Global Charter , ICCA (International Council of Chemical Associations)**
- **BASF, Code of Conduct on Nanotechnology,**
- **Bayer, Code of Good Practice on the Production and on-site-use of Nanomaterials**
- **DuPont, Nano Risk Framework**
- **DSM Risk Management Program**

ACCREDITATION/CERTIFICATION SYSTEMS

- **AssuredNano (UK), Cenarios (CH), Stoffenmanager Nano (NL)**

REPORTING SCHEMES

- **Canada, France, USA, UK and Australia**

+ ISO 26000: Guidance on Social Responsibility (including labour practices) – October 2010

The Code of Conduct for Responsible N&N Research (EC, Feb 2008) – VERSIONE SOLO Con PRINCIPI

General principles

- **Meaning** (comprehensible to public and designed for public benefit)
- **Sustainability** (safe, ethical, and sustainable)
- **Precaution** (conducted in accordance with the precautionary principle)
- **Inclusiveness** (guided by openness and access to information, contributions from all stakeholders)
- **Excellence** (must meet highest standards, share best practice)
- **Innovation** (governance should encourage creativity and growth)
- **Accountability** (researchers and organisations should be accountable for their actions)

NanoCode project to support CoC implementation (www.nanocode.eu)

The Code of Conduct for Responsible N&N Research (EC, Feb 2008)

Principles

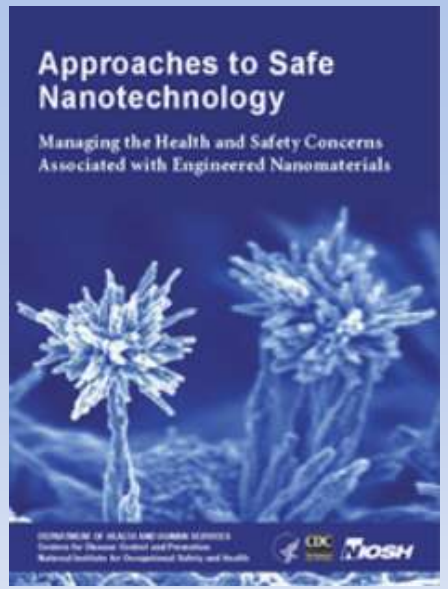
- ❑ meaning
- ❑ sustainability
- ❑ precaution
- ❑ inclusiveness
- ❑ excellence
- ❑ innovation
- ❑ accountability

Actions to be taken

- ❑ priority to safety and protection
- ❑ good practices
- ❑ reduction of uncertainty
- ❑ balanced assessment
- ❑ stakeholder awareness
- ❑ respect of fundamental rights and principles
- ❑…

NanoCode project to support CoC implementation (www.nanocode.eu)

Guidances and standards: OHS and risk management



USA

FR

CH

CANADA

DE

EU

Precautionary matrix (CH) *ITALIAN VERSION at:*
http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=it

AIRI/Nanotec IT, 2010

Guidances and standards: ISO & OECD

1) **ISO - International Standards Organization**
   (Technical Committee TC 229 on Nanotechnologies)
   WGs: Terminology & Nomenclature; Measurement & Characterisation; HSE; Material Specifications

2) **OECD**
   WPMN (Working Party on Manufactured Nanomaterials),
   WPN (Working Party on Nanotechnology)

Liaison ISO TC 229 - OECD WPMN on common work items

ISO : Published Standards

WG1: TERMINOLOGY & NOMENCLATURE

- **ISO/DTS 80004-1 Nanotechnologies -- Vocabulary -- Part 1: Core terms**
- **ISO/TS 27687 : (will become 80004-2): Terminology and definitions for nano- objects – Nanoparticles, nanofibres and nanoplates**
- **ISO/TS 80004-3: Nanotechnologies -- Vocabulary -- Part 3: Carbon nano-objects**
- **ISO/TR 12802: Nanotechnologies -- Model taxonomic framework for use in developing vocabularies -- Core concepts**
- **ISO/ TR 11360: Nanotechnologies -- Methodology for the classification and categorization of nanomaterials**

WG2 (MEASUREMENT & CHARACTERIZATION) & WG3 (HSE)

- **ISO 10867: Nanotechnologies -- Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy**
- **ISO TS 11251: 2010: Nanotechnologies -- Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry**
- **ISO/TR 12885: Health and safety practices in occupational settings relevant to nanotechnologies**
- **ISO 29701: 2010: Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amebocyte lysate (LAL) test**

OECD: Highlights

OECD – Working Party on Manufacture Nanomaterials:

- **Project on safety Testing of a Representative Set of Manufactured Nanomaterials (OECD Sponsorship Programme on the Testing on MN)***

- **OECD Database on Research into Safety of Manufactured Nanomaterials (launched April 2009, 732 records)**

*** priority list of 14 MNs (based on materials which are in or close to commerce) and 60+ list of endpoints to be tested through an international effort.**

ISO TC 229 working definition

ISO/TS 80004-1 – Core Terms: Nanotech-Vocabulary- Core terms with definitions for nanotechnology, nanomaterial, nano-object, nanostructure, nanostructured materials, etc..

Nanotechnology :

"the application of scientific knowledge to manipulate and control matter in the nanoscale to make use of size- and structure-dependent properties and phenomena distinct from those associated with individual atoms or molecules or with bulk materials "

"The nanoscale is the size range from approximately 1 nm to 100 nm.2

Reference Activities on Nanoregulation in Italy

- **UNI:** U22 Technical Commission on Nanotechnologies
- **INAIL :** WG "emerging risks in the occupational setting of N&N"N
- **ISPESL *:** WG "Nanomaterials " (White Book On Occupational Exposure To Engineered Nanomaterials)
- **ISS:** Research activities within Environment and Primary Prevention and Technology and Health Dep
- **Federchimica:** WG "Nano Product Stewardship "on responsible development of Nanotechnologies"
- **Several public research organisations active in the field (such as ECSIN, Società Italiana di Nanotossicologia-SIN….)**

• ISPESL's functions have been transferred to INAIL according to DD.Lgs 78/2010.L

• INAIL: The Italian Workers Compensation Authority ; ISPESL: National Institute of Occupational Prevention and Safety; UNI: Italian National Organization of Unification ; ISS: National Institute of Health

Follow as at:

•NanoCode (www.nanocode.eu)
(2010 – 2011, AIRI/ Nanotec IT coordinator):
Multistakeholder dialogue on the Code of Conduct of N&N research of the European Commission

• ObservatoryNANO (www.observatorynano.eu)
(2008 – 2012, AIRI/Nanotec IT partner):
The European Observatory on Nanotecnologies

THANK YOU FOR YOUR ATTENTION!

Elvio Mantovani
Andrea Porcari

AIRI/Nanotec IT

info@nanotec.it