

# *Regulation of nanotechnologies*

Guillermo Foladori

Autonomous University of Zacatecas,  
Mexico

Latin American Nanotechnology and Society  
Network –ReLANS-

[www.relans.org](http://www.relans.org)

NANOFORUM Colombia 2015  
Cartagena 4-6 agosto 2015

# **Reasons for regulating**

- **Risks to health & environment**
- **Commercial homogenization**
- Economic disruption (employment / social division of work) and/or areas to incentivize
- Individual freedom, ethical issues (transparency, producer responsibility, military applications, etc.)

# **Contents**

## **I. Context**

- 1.** Nanotechnologies: general purpose technologies
- 2.** Chemicals: world pandemic
- 3.** Risks of nanomaterials
- 4.** Commercial context

## **II. Regulation**

- 1.** Generalities
- 2.** World level
- 3.** Latin America

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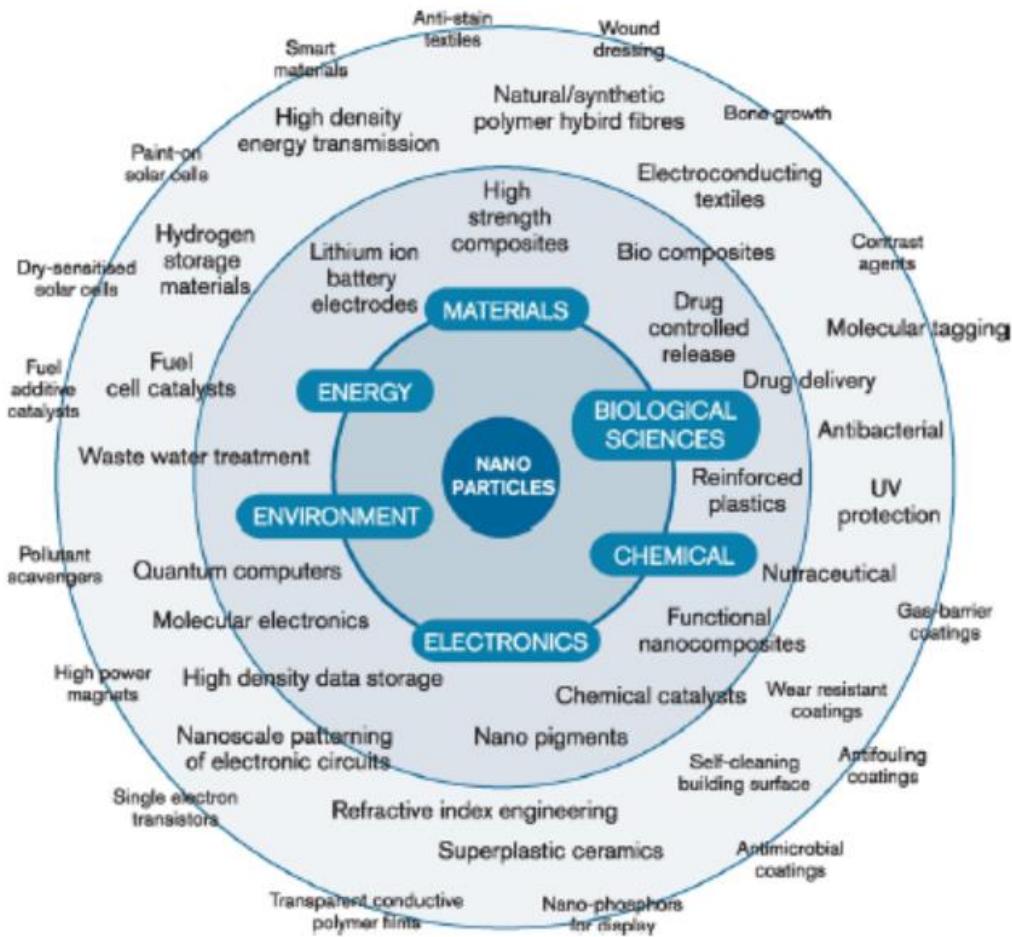
## **I. Context**

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# Nanotechnologies: general purpose technologies



Not all sectors have equal capacity on occupational safety, neither consumers

Tsuzuki, T. (2009). Commercial scale production of inorganic nanoparticles. *International Journal of Nanotechnology*, 6(5), 567–578. doi:10.1504/IJNT.2009.024647

# Nanomaterials enter marketplace without regulation

Consumer Products Inventory



The Project on Emerging Nanotechnologies

— [CPI HOME](#) / [PRODUCTS](#) —

## All Products

Products 1-25 of 1814

WWICS. (2015). *A nanotechnology consumer products inventory project on emerging nanotechnologies*. Washington DC:WWICS (Woodrow Wilson International Centre for Scholars). Retrieved from

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

Search: 07/02/2015

# Great variety of nano raw material



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## Nanomaterials Database

The unique Nanowerk *Nanomaterial Database*™ is a powerful, free tool for the nanotechnology community to research nanomaterials such as carbon nanotubes, nanoparticles, graphene or quantum dots from more than 200 suppliers worldwide. Currently, our database contains over 3,000 nanomaterials.



# Main nano raw materials (OCDE)

- Fullerenes (C<sub>60</sub>)
- Single-walled carbon nanotubes (SWCNTs)
- Multi-walled carbon nanotubes (MWCNTs)
- Silver nanoparticles
- Iron nanoparticles
- Titanium dioxide
- Aluminium oxide
- Cerium oxide
- Zinc oxide
- Silicon dioxide
- Dendrimers
- Nanoclays
- Gold nanoparticles

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# Chemicals: World pandemic OMS 2004

- 2004: almost 5 million death (8.3% of world total). 86 million sick / disability
- 248 000 chemical substances in the market. 700 new chemicals enter the USA market per year.
- 181 tested by public entities for health & environmental effects
- Only 7% out of 3000 chemicals produced in high quantities with data claimed by OCDE

UNEP (2012) *Global Chemicals Outlook. Synthesis Report for Decision-Makers, 2012*, [www.unep.org/pdf/gco\\_Synthesis%20Report\\_cbdtie\\_unep\\_September5\\_2012.pdf](http://www.unep.org/pdf/gco_Synthesis%20Report_cbdtie_unep_September5_2012.pdf).

De los 5.7 millones de toneladas métricas de contaminantes liberados o desechados en Norteamérica durante 2006, 1.8 millones de toneladas métricas eran sustancias químicas persistentes, bioacumulativas o tóxicas, 970.000 toneladas métricas eran sustancias cancerígenas conocidas o sospechosas de serlo y 857.000 toneladas métricas eran sustancias químicas tóxicas para la reproducción y el desarrollo.

PNUMA. (2012). Global Chemicals Outlook. Pnuma. Retrieved from  
<http://www.unep.org/chemicalsandwaste/Portals/9/Mainstreaming/GCO/Rapp%20Synthese%20Espanol.pdf>

# Ex. of toxic chemicals in articles

| Químico   | Producto  | Toxicidad   |
|---|---|---|
| Perfluorinated compounds (PFCs)<br>1950-2000 (US EU)<br>then China...                     | <b>Water repellent and non wrinkle Textiles</b><br>(fire-fighting foams, hydraulic fluids, photo images, semiconductors for personal computers, carpet spot removers, mining and oil well surfactants, and other specialized chemical formulations. They are also used as water, oil, soil and grease repellents on carpets, fabric, upholstery, and food packaging, among other) | Persistent & bio-cumulative. Cancer   |
| Lead  | <b>Toys and jewelry</b><br>(radiation and sound shields, batteries, wheel weights, fishing sinkers, ammunition, and other products. Lead and lead compounds are also used in making paints and pigments, and heat stabilizers for polyvinyl chloride (PVC) plastics)  | Neurotoxic. Kidney damage, blood pressure and reproductive effects. Cancerígeno |
| Nonylphenol ethoxylates   | Textiles (surfactants)  | Persistent & toxic for aquatic org. + endocrine disruptor                       |
| Lead, cadmio, mercury, berilio antimonio, fire retardants of bromo, organo fluorates, PVC | Computers and electronics   | Several toxicities  |
| Asbesto, fire retardants  | Construction  | Several toxicities  |

# Voluntary agreements on chemical substances

| Año  | Nombre            | Tema  | Nota sobre Nanomateriales                           |
|------|-------------------|---|---|
| 1987 | Montreal Protocol | Ozone layer   |   |
| 1989 | Basel             | Transboundary movement of hazard waste                  | Incipient study of nanomaterials in waste           |
| 1998 | Rotterdam         | Previous notification to export of hazardous substances |   |
| 2001 | Stockholm         | POPs Persistent organic pollutants                      | Most of nanomaterials are not organic               |
| 2012 | SAICM/ICCM        | nanomaterials   | Only agreement with recommendation on nanomaterials |
| 2013 | Miramata          | Mercury   |   |

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# Risks of nanomaterials

- They develop different physic and chemical and toxicological properties than in bulk
- Living organisms do not have the historical experience of centuries of evolution to be immune
- They enter the marketplace with no specific toxicological analyze
- There is evidence of toxicity on several nanomaterials. Hundreds of scientific articles on this (6000 in the *Virtual Journal of Nanotechnology, Environment, Health and Safety*)

# **Why nanomaterials enter the market without regulation?**

- **Chemical regulation is new (70s).** By that time thousands of chemicals already in the market. (Reach existent chemicals vs. New chemicals).
- **Toxicological analysis expensive and slow.**
- **Workers pay social costs, consumers; and society through taxes.**
- **Chemical industry.** Lobby and litigation to delay and block regulation

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# Nanotech context is different from ICTs and Biotech. 1980s & 1990s vs. 2000

- Greater corporative wealth concentration
- Greater corporative control of value chains
- Greater requirements for initial investment
- Greater difficulty for Small & Medium enterprises to survive (“Strategic investor” & patents bum)

# Nano-raw material. Huge corporative concentration

10 companies produce more than 80% of CNT

- Cnano Technologies
- Showa Denko
- Nanocyl
- Yunnan Great Group
- Nano Carbon Tech
- Hyperion Catalysis
- Frontier Carbon Corp
- Arkema
- Shenzhen Nano-Tech
- Iljin Nanotech

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  1. Tendency to private litigation & private regulation
  2. 2 confronting forces
2. World level
3. Latin America

# Tendency to private litigation and regulation

- A) Standard (vocabulary and definitions, toxicity, safe protocols, etc.)
- B) Litigation: international and national

# A) Standard

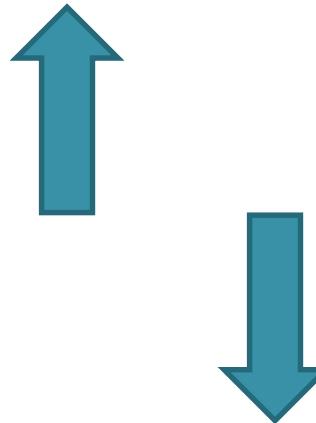
Regulated by private international agreements  
**Ex: ISO standard**

WTO requires countries to base their regulation on international standard. ISO is the only recognized by the WTO

International Organization for Standardization (ISO). **Technical Committee on Nanotechnology (ISO/TC 229)**

## B) Litigation: Trade treaties need to homogenize regulation

- Level up
- Level down



Home > Sustainable Dev. > News > NGOs fear TTIP clauses will affect EU chemicals regulation

NGOs fear TTIP clauses will affect EU chemicals regulation



## RESEARCH REPORTS

# Securing the Promise of Nanotechnologies Towards Transatlantic Regulatory Cooperation

**Authors:** Linda Breggin, Robert Falkner, Nico Jaspers, John Pendergrass and Read Porter

**Date Released:** September 2009



Securing the Promise  
of Nanotechnologies

Towards Transatlantic  
Regulatory Cooperation

Linda Breggin, Robert Falkner, Nico Jaspers,  
John Pendergrass and Read Porter

September 2009



“In no area has this been a greater problem than in chemicals. In this sector, the U.S. and EU have fundamentally different regulations on issues such as genetically modified organisms (GMOs), hormones, and the registration and restriction of chemical substances”

Ahearn, R. J. (2009). Transatlantic Regulatory Cooperation: Background and Analysis. Retrieved September 7, 2014, from  
[http://www.europarl.europa.eu/meetdocs/2009\\_2014/documents/d-us/dv/d-us\\_transatlantic\\_regulatory/d-us\\_transatlantic\\_regulatory\\_4.pdf](http://www.europarl.europa.eu/meetdocs/2009_2014/documents/d-us/dv/d-us_transatlantic_regulatory/d-us_transatlantic_regulatory_4.pdf)

## B) Litigation: Investor-State Dispute Settlement (ISDS)

Guarantee foreign investors private arbitration when litigation with States.  
States internal law does not run for foreign investors.

# The Investor-State Dispute Settlement (ISDS)

**OECD: 57 ISDS cases filed against governments in 2013**

| Year | Country   | Corp.                | Topic                        |
|------|-----------|----------------------|------------------------------|
| 2012 | Canada    | Lone Pine            | Quebec ban on fracking       |
| 2012 | Indonesia | Churchill Mining     | Revoked concession           |
| 2012 | Ecuador   | Occidental Petroleum | Violation of contract 1.8 bn |
| 2012 | Uganda    | Tullow Oil           | VAT on goods                 |
| 2012 | Egypt     | Veolia group         | Salary increment             |
| 2012 | Germany   | Vattenfall           | Ban on nuclear plants        |
| 2011 | Australia | Philip Morris        | Plain packaging              |
| 2010 | Uruguay   | Philip Morris        | Graphic health warning       |
| 2010 | Ecuador   | Burlington Resources | Indigenous revolt            |
| 2009 | Germany   | Vattenfall           | Ban on fire coal plants      |

# Ottawa sued over Quebec fracking ban

Company's suit based on NAFTA provisions

The Canadian Press Posted: Nov 23, 2012 11:05 AM ET | Last Updated: Nov 23, 2012 12:23 PM ET



Hydraulic fracturing has come into widespread use in North America. (Associated Press )

13 shares



An American company intends to sue the Canadian government for more than \$250 million over Quebec's controversial moratorium on hydraulic fracturing or fracking.

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# ISDS

- Favors private arbitration over State regulation.  
(Implicit: National courts do not offer justice for investors). Different conflict resolution for national and international investors
- Property rights over human rights (e.g. labor rights)
- UNCTAD. In 2012 514 ISDS. 70% won by transnational corporations
- 64% of ISDS initiated by investors from EEUU and EU.
- The highest compensation from a ISDS: 1770 US\$ to Occidental (Oil) over Ecuador
- In 2011, 3 law firms run 130 ISDS
- Medium costs for arbitration 8 million US\$

# Patents

## OMPI

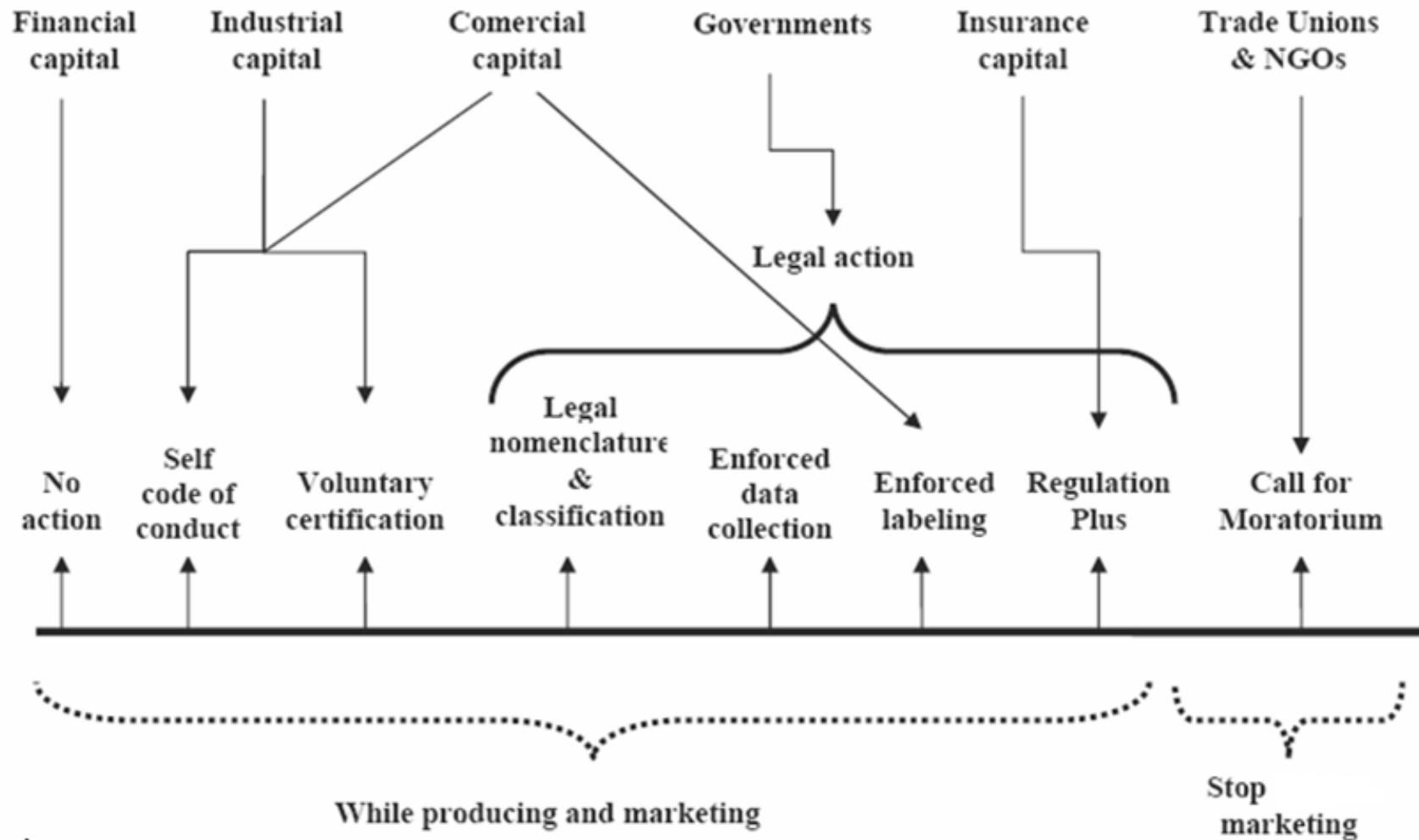
- 1990: 20 000
- 2000: 90 000
- 2006: 140 000

American Intellectual Property Law Association: The cost of litigate a patent is around 2.6 million U\$\$S (increased of 70% from 2001).

# Confronting forces

- **Two parallel movements**
  - ❖ Ministries of Commerce, Economy etc.
  - ❖ Ministries of Health, Environment, Labor etc.

# Who is interested in regulating nanotechnologies?



# Questions & difficulties for regulating nanotechnologies

- Is regulation needed?
- Regulate only new or also existent nanomaterials?
- % of nanoparticles?
- Definition by size, size & new function, other?
- 100 nm is the limit size?
- Regulate by size, mass, shape?
- One criteria for different nanomaterials?
- Only intentional or also incidental & natural nanoparticles?

- Existential toxicological protocols or new and specific?
- Should products without toxicological data enter the market?
- How to regulate active nanomaterials?
- 1 ton/ year; 100 gr / year ?
- What to do with products that are simultaneously biocides, pesticides, food package? (e.g. silver nanoparticles)

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# Landmark in nano regulation

| Year | EU & Europe | USA                  |
|------|-------------|----------------------|
| 2004 |             | US Patent Class 977  |
| 2008 |             | EPA SNURs            |
| 2009 | Cosmetics   |                      |
| 2011 |             | Canada & USA Council |
| 2011 |             | EPA SNURs MWCNT      |
| 2011 |             | Memo Dept Commerce   |
| 2011 | Food        |                      |
| 2012 | Biocidals   |                      |
| 2013 | France      |                      |
| 2013 | Norway      |                      |
| 2014 | Belgium     |                      |
| 2014 | Denmark     |                      |
| 2015 | Sweden      |                      |
| 2015 | Canada      |                      |

# Main positions on the regulation of nanomaterials

| Topic                   | USA                                     | EU                         |
|-------------------------|---|----------------------------|
| Precautionary principle | No. Politic of Known Risks              | Accepted                   |
| Hazard vs. risk         | Manage risk                             | Address hazard before risk |
| Manage risk             | Economic benefit > risk;<br>End of Pipe | Includes ESLI              |
| Producer responsibility | Presumption of safe                     | No data no market          |
| Property rights         | Priority. No registration, no labelling | Basic civil rights first   |

# Current EU regulation

| Year                         | Item                                  | Evaluation & Authorization | Registration                         | Labelling                         |
|------------------------------|---------------------------------------|----------------------------|--------------------------------------|-----------------------------------|
| 2011<br>(EU) No<br>1169/2011 | Food additives & materials in contact | Required                   |                                      | Labelling                         |
| 2012                         | Biocidal                              | Required                   |                                      | Hazard classification & labelling |
| 2009<br>(EC) No<br>1223/2009 | Cosmetics                             |                            | Required ingredients and safety data | Labelling                         |
|                              | Chemicals                             |                            | Required for new substances          | Hazard classification & labelling |

# France

## Mandatory registration of industries working with nanotechnology

- 2013 on -

República Francesa (2012 feb., 18). Chapitre III : Prévention des risques pour la santé et l'environnement résultant de l'exposition aux substances à l'état nanoparticulaire. [Code de l'environnement](#) Article L523-1, 2, 3, 4, 5.

[http://www.legifrance.gouv.fr/affichCode.do;jsessionid=4BA24E14E56D824D6E9FB410958E690E.tpdjol4v\\_3?idSectionTA=LEGISCTA000022494883&cidTexte=LEGITEXT000006074220&dateTexte=20120220](http://www.legifrance.gouv.fr/affichCode.do;jsessionid=4BA24E14E56D824D6E9FB410958E690E.tpdjol4v_3?idSectionTA=LEGISCTA000022494883&cidTexte=LEGITEXT000006074220&dateTexte=20120220)



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### Norwegian Government Agency makes Submission of Information on Nanoscale Substances mandatory

Posted on 09 Jan 2013

The Norwegian Climate and Pollution Agency (Klif) has changed the information requirements for chemicals registered with the Norwegian Product Register. It states that 'information about substances in nano form must be given'. This news comes as the agency sends out letters requesting registrants to do their annual update of chemical information.

The register this year contains a NANO box, which 'should be marked if the chemical contains nanomaterials'. Respondents will also need to 'identify which constituent [it is] that is in the nanoform'. Furthermore during the course of 2013 registrants 'will have to update the composition for all your mandatorily declared chemicals that contain substances in nanoform'.

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**NIA** Voice of Nanotech 13 Jul ▲

# Denmark



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## Nanoproduktregister

Danske virksomheder kan her indberette  
informationer om nanoprodukter som de er  
forpligtet til at registrere jf. Bekendtgørelse nr.  
644 af 13. juni 2014.

# Belgium



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Voir ce communiqué en [NL](#) [FR](#)

## La Belgique met en place un registre des nanomatériaux

Par Sarah Delafortrie, Christophe Springael

Publié le 07/02/2014

Appartient au [Conseil des ministres du 7 février 2014](#)

Sur proposition de la ministre des Affaires sociales et de la Santé publique Laurette Onkelinx, le Conseil des ministres a marqué son accord sur l'arrêté royal relatif à la mise sur le marché des substances manufacturées à l'état nanoparticulaire.

# France, Denmark, Belgium

| Criteria     | EU<br>(Reach) | France 2013    | Denmark 2014                         | Belgium 2016 /17                           |
|--------------|---------------|----------------|--------------------------------------|--|
| Reg.         |               | Ex post market | Ex post market                       | Ex ante market                             |
| Nanomat.     |               | Intentionally  | Intentionally + Natural + Incidental | Intentionally                              |
| Prod /import |               | Yes            | If for B2C (no B2B)                  | Yes (except when in articles)              |
| Threshold    | 1 Ton         | 100 gr/year    | No                                   | 100 gr/year                                |
| Penalty      |               | Fine           | To determine                         | Fine & prison                              |
| Exception    |               | Defense        |                                      |  |
| Other        |               |                |                                      | Inf. to Health & Safety worker's committee |

Based on: Squirepattonboggs.com. (15 Feb). Growing issues in a miniature world: nanomaterials registers in the European Union. Retrieved from <http://www.squirepattonboggs.com/news>; Bochon, A. (2015, March 16). Do you need to register your nanomaterials in the European Union? *My Chemical Monitoring*. Retrieved from [http://www.mychemicalmonitoring.eu/news/73403e63-3194-4295-96a0-740c8b9bbe8/Do\\_you\\_need\\_to\\_register\\_your\\_nanomaterials\\_in\\_the\\_European\\_Union](http://www.mychemicalmonitoring.eu/news/73403e63-3194-4295-96a0-740c8b9bbe8/Do_you_need_to_register_your_nanomaterials_in_the_European_Union) and personal review of docs.



# Sweden

## Sweden to develop a Nanomaterial Registry

Posted on 22 May 2015

The [Swedish Chemicals Agency \(KEMI\)](#) has been tasked with the designing of a national nanomaterial register in Sweden. Upon the [request of the Swedish Ministry of the Environment \(Miljödepartementet\)](#) [in Swedish], KEMI is drafting a proposal for a register and conducting an impact assessment. Consultations will be run with Agencies and stakeholders. KEMI intends to finalise this process by 1 December 2015.

In 2013, the Swedish authorities had already advocated the creation of register in its [\*National Action Plan for the safe use and handling of Nanomaterials\*](#).

# Germany, on the way ...



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NEWS

Print Version

## German minister backs register for nano-products

ENDS Europe

Thursday 3 February 2011

An advisory body to the German government has issued preliminary guidelines for assessing nano-products' risks and benefits. It is divided on the need for a register of such products but Norbert Roettgen backed the idea.

The environment minister was referring to the need for a registry at EU level, an idea championed by [Belgium](#) during its presidency of the union in the second half of 2010. Germany-based Oeko Institute welcomed Mr Roettgen's support for an EU register.

### Related Content

[German retailers oppose tax on drinks packaging](#) 10 Feb 2011

[Access to biomaterials still an issue – CEFIC](#) 10 Feb 2011

[EU states to adopt ecolabel criteria for detergents](#) 8 Feb 2011

[EU chemicals agency facing challenges ahead](#) 7 Feb 2011

[EU advised to keep limit for cadmium in food](#) 4 Feb 2011

### Environment ministers meet in Luxembourg



The ministers discussed the draft EU ship recycling regulation on 25 October



Canada

# Canada Gazette

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### Part I: Notices and Proposed Regulations

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ARCHIVED — Vol. 146 (2012)

ARCHIVED — Vol. 145 (2011)

ARCHIVED — Vol. 144 (2010)

### Part I: Quarterly Index

Vol. 149 (2015)

ARCHIVED — Vol. 148 (2014)

ARCHIVED — Vol. 147 (2013)

ARCHIVED — Vol. 146 (2012)



Vol. 149, No. 30 — July 25, 2015

## GOVERNMENT NOTICES

### DEPARTMENT OF THE ENVIRONMENT

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

*Notice with respect to certain nanomaterials in Canadian commerce*

Pursuant to paragraph 71(1)(b) of the *Canadian Environmental Protection Act, 1999*, notice is hereby given that the Minister of the Environment requires, for the purpose of assessing whether the substances described in Schedule 1 to this notice are toxic or are capable of becoming toxic, or for the purpose of

# New Zealand

## **Labelling on cosmetics mandatory from 2015**

Environmental Protection Authority Application to Amend the Cosmetic Products Group Standard 2006., ERMA200782 (2012). Retrieved from  
[http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/ERMA200782\\_ERMA200782%20Decision%20\(28.06.2012\).pdf](http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/ERMA200782_ERMA200782%20Decision%20(28.06.2012).pdf)

# USA

- **EPA.** Two laws:
  - **TSCA** Toxic Substance Control Act
    - Nano should be “New substance”
    - SNUR Significant new use rules. 90 d/pre-market reg.
    - More than 10 tons/year
  - **FIFRA** Federal Insecticide Fungicide and Rodenticide Act. Pre-market registration
- **FDA.** Guides for industry.
- **Secretary of Commerce**

# **Sec. Commerce / White House**

*Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials.*

–No vinculante–

<http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf>

***Policy Principles for the U.S. Decision-Making  
Concerning Regulation and Oversight of  
Applications of Nanotechnology and  
Nanomaterials***

- *Not to generalize. Each case is a case*
- *Not to block commerce*
- *Favor risk analyze over hazard substitution*
- *Known risks policy*
- *Favor industry confidentiality over transparency to public*

# China. New regulation 2010

- No minimum weight for production /import.  
All nanomaterials included
- Industries should inform

Legislation more strict than in US, But China is the first producer of chemicals!!!

<http://www.chemsec.org/news/news-2010/october-december/649-new-chemicals-regulation-in-china>

# **ICCM-SAICM 2012**

- To easier data exchange, including risks
- Recommend International Regulatory Guides
- Call for public dialogue, including risks and benefits over the whole lifespan
- Invite International Organizations to capacitate countries
- Call industries to public dialogue
- Invite experts on hazard chemical transportation to consider nano within the GHS (Globally Harmonized System of Classification and Labeling of Chemicals)

# **SAICM América Latina**

## **2 Workshops: Kingston (2010) y Panamá (2011)**

- Enfoque precautorio;
- Etiquetado;
- Registro público nacional;
- Responsabilidad ampliada del productor, etc.

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# Brasil

| Fecha   | Proyecto       | Autor         | Tópicos  | Resultado   |
|---------|----------------|---------------|--|---|
| 04/2005 | No. 5.076/2005 | Edson Duarte  | <ul style="list-style-type: none"> <li>• Criterio: Principio de Precaución</li> <li>• Reglamentar y orientar investigaciones</li> <li>• Etiquetado</li> <li>• Registro de investigaciones</li> <li>• Estudio de impacto ambiental/salud</li> </ul> | <p>Rechazo en 10/2008. Argumentos:</p> <ul style="list-style-type: none"> <li>• Inhibe inversiones</li> <li>• Normas existentes suficientes</li> <li>• Incrementaría precios por burocracia</li> </ul>  |
| 05/2010 | PLS 131/2010   | Tião Viana    | <ul style="list-style-type: none"> <li>• Etiquetar alimentos, medicamentos, cosméticos</li> </ul>  | <p>Rechazo en 08/2013. Argumentos:</p> <ul style="list-style-type: none"> <li>• No hay evidencia científica q/ justifique protección</li> <li>• Son muchas técnicas no se puede generalizar</li> <li>• Etiquetado induce a percepción diferente</li> <li>• Puede reducir inversiones</li> <li>• Incrementaría precios por burocracia</li> </ul> |
| 03/2013 | No. 5.133/2013 | Sarne y Filho | <ul style="list-style-type: none"> <li>• Etiquetado para todos los productos</li> <li>• En cosméticos, alimentos y fármacos además del etiquetado la nanomateria prima utilizada</li> </ul>  | <p>En comisión</p> <p>11/2013. Realización de audiencia pública</p>   |
| 11/2013 | PL 6741/2013   | Sarne y Filho | <ul style="list-style-type: none"> <li>• Política nacional de nanotecnología</li> <li>• Control de riesgos por el poder público</li> </ul>   | <p>En comisión: análise conclusiva das comissões de Meio Ambiente e Desenvolvimento Sustentável; de Seguridade Social e Família; de Ciência e Tecnologia, Comunicação e Informática; e de Constituição e Justiça e de Cidadania.</p>  |

# Brasil

- 2011 (Agosto). Primera reunión para normas y reglamentación. *Forum de Competividade de Nanotecnologia.* [www.desenvolvimento.gov.br/sitio/interna/noticia.php?area=3&noticia=10869](http://www.desenvolvimento.gov.br/sitio/interna/noticia.php?area=3&noticia=10869)
- Propuestas de ley **divorciadas** del trabajo del *Comité Interministerial de Nanotec.*

# México

| Año  | Institución               | Propuesta  | Fuente |
|------|---------------------------|--|--------|
| 2005 | Comisión de C&T<br>Senado | Declaración a favor de<br>Plan Emergencial de NT | 1      |
| 2013 | Comisión de C&T<br>Senado | Formación de un<br>Programa de I&D en NT         | 2      |

- I. Comisión de Ciencia y Tecnología. Senado de la República. Dictamen de la Comisión de Ciencia y Tecnología a la propuesta con punto de acuerdo por el que el Senado de la República ... 145 *Gaceta Parlamentaria* (2005). [www.senado.gob.mx/sgsp/gaceta/index.php?sesion=2005/12/15/1&documento=1012](http://www.senado.gob.mx/sgsp/gaceta/index.php?sesion=2005/12/15/1&documento=1012).
2. Robles-Montoya, A. (2013). Proposición al Senado de la República relativo al diseño de un programa de investigación y desarrollo de la nano ciencia y la nanotecnología. Senado de la República. LXI Legislatura del Congreso de la Unión.

# México

**2010:** Calderon & Obama. Se forma el **High Level Regulatory Cooperation Council US-Mex (HLRCC)**. En el marco de los tratados comerciales. En torno a 6 sectores:

- 1. Alimentos
- 2. Transporte
- 3. **Nanotecnología**
- 4. Electronic Health Certification
- 5. Oil & gas offshore standards
- 6. Reconocimiento mutuo de certificaciones y laboratorios

# México

- 2012. “*Lineamientos para regulaciones sobre nanotecnologías para impulsar la competitividad y proteger al medio ambiente, la salud y la seguridad de los consumidores*”
  - *Documento NO-vinculante. Elaborado por Comisión Ad Hoc coordinada por el CENAM-Sec. Economía*

*<reproduce sin mayor diferencia el documento de USA>*

# México: normas ISO 2014

- NMX-R-10867-SCFI-2014 Caracterización de **nanotubos de carbono de una capa** mediante espectroscopia de fotoluminiscencia en el infrarrojo cercano
- NMX-R-10929-SCFI-2014 Caracterización de muestras de **nanotubos de carbono de múltiples capas**
- NMX-R-27687-SCFI-2014 Terminología y **definiciones** para nano-objetos- nanopartícula, nanofibra y nanoplaca
- NMX-R-80004-1-SCFI-2014 Nanotecnologías; **Vocabulario**-Parte 1: Conceptos básicos
- NMX-R-80004-3-SCFI-2014, Nanotecnologías- **Vocabulario**-Parte 3: Nano-objetos de carbono

Gracias  
Thank you

[gfoladori@gmail.com](mailto:gfoladori@gmail.com)  
[www.relans.org](http://www.relans.org)

International organizations

**OECD** Compilation  
Guidelines

**ILO:** NT as  
new issue

**WHO** -NM safety  
is priority

**ISO/TR 12885**  
H&S in  
workplace

**ILO:** NT as  
emerging risk

**WHO** starts  
Guidelines  
on NM Safety

**ISO/TS**  
12901:2012  
Occ. Risk  
management

**ISO/TR 12885**  
Control  
banding

2008

2009

2010

2011

2012

2013

2014

**UK IOM**  
**Good nano**  
**Guide**

**Québec**  
**Guidelines**  
**for NM s OHS**

**Safe Work AU**  
**Guidance**  
**handling NM**

**US NIOSH**  
Exposure  
limits for  
TiO<sub>2</sub>

**Safe Work AU**  
**Guidance CNT**

**US NIOSH**  
Exposure limits  
for TiO<sub>2</sub>

**US NIOSH**  
Exposure limits  
for CNTs, CNFs

**US NIOSH-**  
**Interim**  
**Guidelines**  
**for working**  
**with NM**

Canada-  
Exposure  
control to  
NM

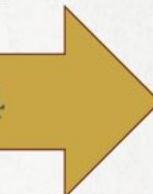
**UK HSE**  
**Workplace**  
**guidelines**

**GE, UK, FR**  
**NMs H&S**  
**Guidances**

Countries

Norway:  
**OHS**  
**Guidance**

US OSHA  
**Safe working**  
**practices**



**Table 1. Common nanotechnology definitions**

| Source  | Definition   |
|---|--|
| US: National Nanotechnology Initiative (2001-)              | Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modelling, and manipulating matter at this length scale.   |
| EU: 7th Framework Programme (2007-2013)                     | Generating new knowledge on interface and size-dependent phenomena; nano-scale control of material properties for new applications; integration of technologies at the nano-scale; self-assembling properties; nano-motors; machines and systems; methods and tools for characterisation and manipulation at nano dimensions; nano precision technologies in chemistry for the manufacture of basic materials and components; impact on human safety, health and the environment; metrology, monitoring and sensing, nomenclature and standards; exploration of new concepts and approaches for sectoral applications, including the integration and convergence of emerging technologies. |
| Japan: Second Science and Technology Basic Plan (2001-2005) | Nanotechnology is an interdisciplinary S&T that encompasses IT technology, the environmental sciences, life sciences, materials science, etc. It is for controlling and handling atoms and molecules in the order of nano ( $1/1\ 000\ 000\ 000$ ) meter enabling discovery of new functions by taking advantage of its material characteristics unique to nano size, so that it can bring technological innovation in various fields.   |
| ISO TCC 229   | Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometers in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications. Utilising the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.  |
| European Patent Office                                      | The term nanotechnology covers entities with a geometrical size of at least one functional component below 100 nanometers in one or more dimensions susceptible of making physical, chemical or biological effects available which are intrinsic to that size. It covers equipment and methods for controlled analysis, manipulation, processing, fabrication or measurement with a precision below 100 nanometers.  |