Planned legislation in France and Belgium

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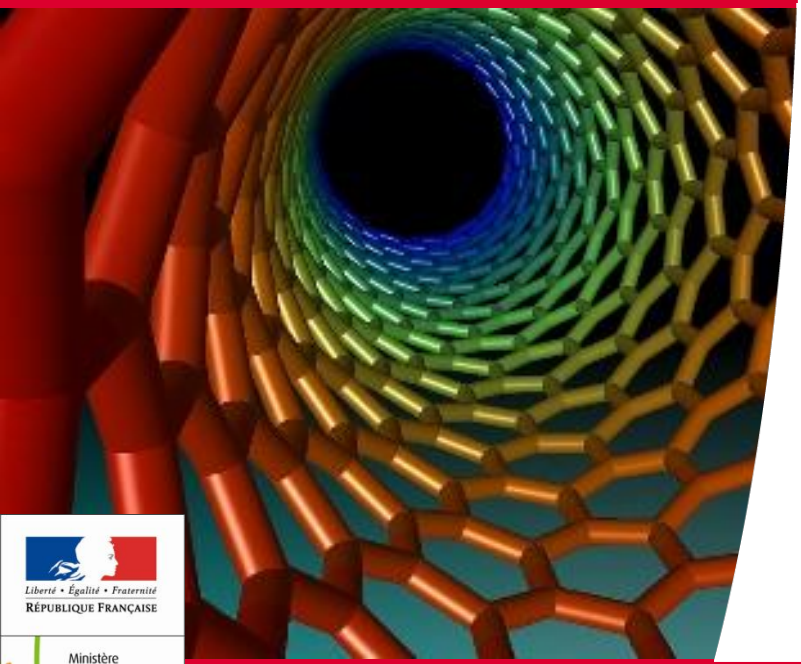

Présent pour l'avenir

I - France

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Context in France

- **2007 : « Grenelle de l'environnement » - Commitment n°159**: to anticipate the risks linked to the production and the use of manufactured nanomaterials.

- **Article 42 of the Grenelle Law I of August 3, 2009:**

  - ✓ A **national public debate** on Nanotechnology was organized between October 15, 2009 and February 24, 2010. Some of its main conclusions:
    - Research on toxicology, ecotoxicology and metrology.
    - Risk assessment methods should be adapted to manufactured nanomaterials.
    - Life cycle assessments and benefit-cost analyses.
    - Improving safety and health of workers (information, traceability, protective measures…)
    - In favour of labelling of products on the market at EU level.
    - Governmental and dedicated website on nanomaterials and nanotechnologies.
    - Mandatory declaration in France and harmonised declarations in Europe.
    - Scientific information for the general public.
    - Dialogue and exchanges promoted.

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Context in France

- **Article 42 of the Grenelle Law I of August 3, 2009:**
  - ✓ A mandatory reporting scheme of manufactured nanomaterials put on the market to be effective within 2 years: quantities and uses of manufactured nanomaterials and supply of information to the public and consumers
  - ✓ Improvement of information on **risks and protective measures.**
  - ✓ Development of a **methodology for assessing risks and benefits** associated with these substances and products.

- **Article 185 of the Grenelle Law II of July 12, 2010:**
  - ✓ **Fields** of the reporting scheme:
    - **Identity** of nanomaterials and **uses** **=> Information available for the public**
    - **Quantities** on the market
    - **Identity of downstream users** (confidential)
    - Available data on **hazards and exposures** on request of the authority

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Implementation decree

- Grenelle Law II => requires a **decree** for more precisions on the scope.

- Clarifications given by the decree**:**
  - ✓ **Declarants =** manufacturers, importers to France and distributors
  - ✓ Definition given for “substance at the nanoscale”
  - ✓ Threshold for the declaration
  - ✓ Possibility to ask for information to stay confidential

➔ **Large consultation** of the stakeholders = **January – February 2011**:

- ✓ Regular posts and internet.
- ✓ Ad hoc meetings.
- ➔ Main remarks about **definitions**, **declaration threshold**, implementation in the field of **research** and issues of **confidentiality.**

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Main elements of the decree (1/3)

- Definitions :
  - ✓ **Substance at the nanoscale** = based on the EC recommendation
    - substance as defined in article 3 of REACH (regulation 1907/2006), intentionnaly manufactured at the nano scale, containing particles, in an unbound state or as an aggregate or as an agglomerate, and where, for a minimal proportion of the particles in the number size distribution, one or more external dimensions is in the the size range 1 nm – 100 nm.
    - This minimal proportion can be adapted in specific cases. It will be set in a ministerial order. Will be **50%** at the beginning.
    - By derogation : fullerenes, graphene flakes and nanotubes = substances at the nanoscale
    - Definition of particle, agglomerate and aggregate = UE definition
  - ✓ **Substance at the nanoscale contained in a mixture without being linked to it =** substance at the nanoscale intentionally introduced in a mixture from which it is likely to be extracted or released under normal or reasonably foreseeable conditions of use.

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Main elements of the decree (2/3)

- Scope:
  - ✓ **Substance at the nanoscale on its own**,
  - ✓ **Substance at the nanoscale** contained in a **mixture** without being linked to it.
  - ✓ **Articles** with **intended release of substance at the nanoscale**.

- Declaration threshold : **100 g**

- Declaration and data management = **Anses** (*French Agency for Food, Environmental and Occupational Health & Safety*)

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Main elements of the decree (3/3)

- Implementation for **research and development** : specific provisions.

- **Confidentiality** and **protection of all data**:
  - ✓ Possibility to ask that the reported information is considered as confidential – to be justified.
  - ✓ Information contained in an application form for a patent remains confidential until the publication of the patent.
  - ✓ Research and development without placing on the market: information always considered as confidential.

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Notification according to Directive 98/34

- **Notification to the European commission in accordance to the Directive n°98/34** sent on the 23rd of June 2011**:**
  - ✓ Comments received from **UK**, **Germany** and **European Commission.**
  - ✓ No **detailed comments**.
  - ✓ Main remarks on :
    - Choice of the threshold and impact on the number of declarants and declarations.
    - Treatment of Confidential Business Information,
    - Links with registrations under REACH and notifications required by Cosmetics regulation.
    - Future of the definition when the European Commission publishes a definition for nanomaterial ?
  - ✓ All remarks were officially answered.

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Progress

- **Decree of February, 17, 2012** – published February, 19, 2012.
- First implementation in **2013** for nanomaterials put on the market or produced in **2012**.

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Ministerial order (1/2)

- The ministerial order clarifies:
  - ✓ The **information** to be declared:
    - Identity of the declarant,
    - Identity of the substance at the nano-scale
      - Chemical composition, distribution, size, aggregation, agglomeration, shape, crystalline state, specific surface, surface charge, surface chemistry, coating.
    - Quantity,
    - Uses,
    - Identity of professional users.
  - ✓ The **submission** conditions:
    - **Electronically** (except for classified information):
      - a **user-friendly** web interface,
      - a **dedicated** and **secure website** will be created.
    - Based on **IUCLID** (OECD harmonised template), so as to **ensure links with other data** – ***on going work with ECHA.***

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Ministerial order (2/2)

- For each declaration = a **unique** declaration number.
- **For the <u>seller</u>**: **transfer** of declaration number requested when a substance is sold.
- For the **<u>purchaser</u>**: possibility to enter the declaration number in order to avoid filling in all the information requested (*identity of substance*).
- Confidential and Business Information **protected**.

➔ Should **ease the declaration process**, especially for operators further down the supply chain.

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Producer of TiO_2

-Identity:
- *Size*
- *Distribution*
- *Aggregation*
- *etc.*

-Quantity
-Uses …

=> ***Decl. # 12z055***

Distributor **1** of TiO_2

-Identity: Filled in automatically with the reference of Decl. Number ***Decl. # 12z055*** *(purchased nanomaterial).*

-Quantity
-Uses …

=> ***Decl. # 12f098***

Distributor **2** of TiO_2

-Identity: Filled in automatically with the reference of Decl. Number ***Decl. # 12f098*** *(purchased nanomaterial).*

-Quantity
-Uses …

=> ***Decl. # 12u125***

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Next steps

- Notification to the European commission in accordance to the **Directive n°98/34**:
  - Sent on the 29th of December 2011.
  - End of standstill period: 30th of March 2012.
- Meetings with stakeholders and finalisation: **March 2012.**
- Goal: publication in **April 2012**.

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The French declaration in brief…

- **Scope**:
  - ✓ Substance at the nanoscale on its own,
  - ✓ Substance at the nanoscale contained in a mixture without being linked to it,
  - ✓ Articles with intended release of substance at the nanoscale.
- **Annual** declaration,
- **Electronic** submission – IUCLID format.
- Data processing by **Anses**.

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The French declaration in brief…

- Use of the gathered information:
  - ✓ **Information of the public (on types and uses**) : through an annual report.
  - ✓ **Full** access to the individual declarations: **ministries** involved (in charge of health, environment, labour, industry, research and defence) and **Anses**,
  - ✓ Information in their **field of expertise**: National institutes (National institute for public health surveillance, National institute of industrial environment and risks …) on request and related to their field of expertise.

- Declarants can be asked to provide **available information on risks and exposition**.

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II – Belgium

Belgium: update

- **2010:** Political signal sent to the Public health, Food safety and Environment Ministry for studying the feasibility of a compulsory and integrated registry of nanomaterials.
- **3rd quarter of 2011:** consultation of the Federal Council for sustainable development.
- **January 2012:** juridical study for an implementation in Belgium.
- **Goal:** planned for beginning 2013 at the administration level.
- Discussions with the new government in progress.

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III – Working group on harmonization of national databases for nanomaterials on the market

Working group

- Workshop organised by BE presidency in Sept. **2010**, « *Towards a regulatory framework for the traceability of nanomaterials* »:

  ➔*Harmonized compulsory databases of nanomaterials and products should be developed.*

- **2011:** collaboration between France, Belgium, Italy and now Denmark and observers of other MS (NL, SE, AT and DE REACH Competent authorities)

- **Output =** outline a <u>proposal based on a common basis</u> to start building the databases in a harmonized way.

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Scope

- **Manufactured** nanomaterials.

- To be declared:

  - ✓ **Core:**
    - Substances,
    - Mixtures with possible release of substance at the nanoscale,
    - Articles with intended release of substance at the nanoscale,
    - Consumer products (i.e. out of the scope of REACH e.g. food, feed, medical devices, cosmetics…) with intended release of substance at the nanoscale.

  - ✓ **Optional:**
    - Mixtures without possible release of substance at the nanoscale
    - Articles for which the release of substance at the nanoscale is not intended or not possible.
    - Consumer products for which the release of substance at the nanoscale is not intended or not possible.

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Database and data management

- Aim: Use a **common** and **harmonized system** which will be customized according to specific needs and adapted to the modular approach.

- Format to be used = based on IUCLID (OECD harmonized templates), so as to ensure links with other data. A work with **ECHA** is currently undertaken.

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Conclusion

- An answer to the **necessity to know more about nanomaterials** on the market and to have some traceability **...**

- ...**without preventing the production, the sale or the use** (only gathering data)

- **A French initiative**, but undertaken with other Member states, and with a willingness to **contribute to improvement of the legislative framework at the EU level.**

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Any questions ?

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