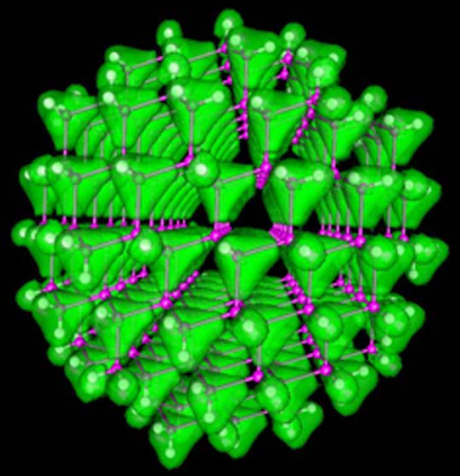
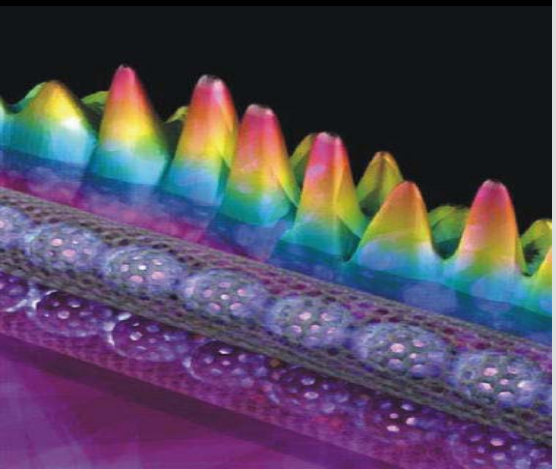
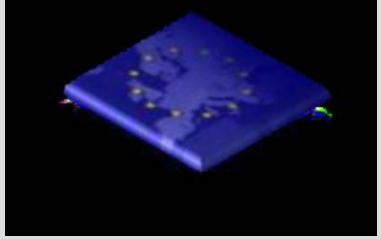






# Nanomaterials under REACH and CLP and Italian Competent Authority's activities

## 1st Part

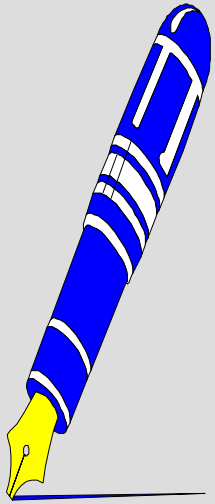

**Maria Alessandrelli**
National Center for Chemicals
Istituto Superiore di Sanità


FEDERCHIMICA
CONFINDUSTRIA

2 Dicembre 2010 - Milano
Auditorium Federchimica

The Ministry of Health is the Competent Authority in charge for the implementation and enforcement of 1907/2006 Regulation (REACH) and 1272/2008 Regulation (CLP).

## The structure of the Competent Authority (CA) in Italy



- Ministry Of Health
  - Ministry of the Environmental
  - Ministry of Economic Development
  - National Center for Chemicals (CSC) at National Institute of Health of Rome (ISS)
  - Institute for environmental protection and research (ISPRA)

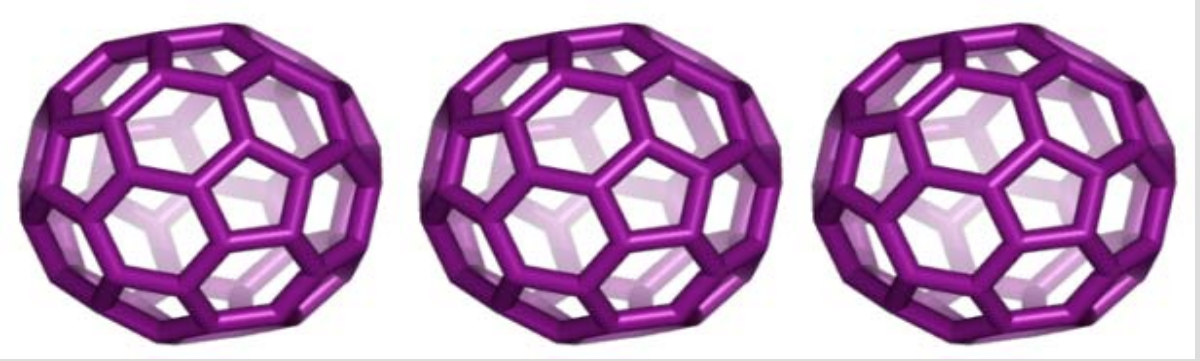
# National Center for Chemicals

- Gives scientific and technical support for all activities of CA
- Performs risk assessment on substances
- Evaluates priority substances
- Identifies substances requiring Authorization Decisions

**The REACH and CLP Regulations do not contain any specific definitions or provisions on nanomaterials nevertheless they are covered by the definition of substances as mentioned in the article 3(1) of REACH and article 2(7) of CLP**

**SUBSTANCE: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.**

**REACH and CLP deals with substances, in whatever size, shape or physical state**



As REACH is based on the substance concept, it will be necessary

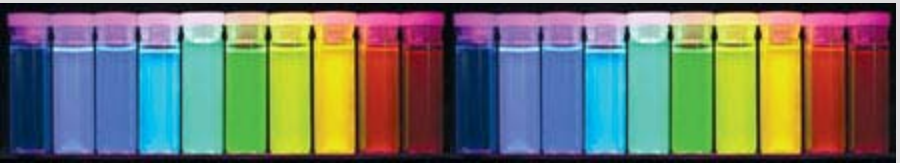
- to define terms relating to substances which are nanomaterials
- to elaborate a working definition of the term "nanomaterials"

In order to prepare a science-based definition of nanomaterials, the services of the European Commission need clarification on

- size ranges,
- physical-chemical properties
- relevant thresholds,
- most appropriate metrics to express such thresholds.

The European Commission wants any definition of the term "nanomaterial" grounded in science. So, the recently draft Recommendation on the definition of the term "nanomaterial" is based on the work done by the Commission's Joint Research Centre and the input of the Scientific Committee for Emerging or Newly Identified Health Risks (SCENIHR).

The definition in this recommendation should determine when a material should be considered as a nanomaterial for legislative and policy purposes in EU. It should cover all nanomaterials, whether they are of natural, incidental or manufactured origin.



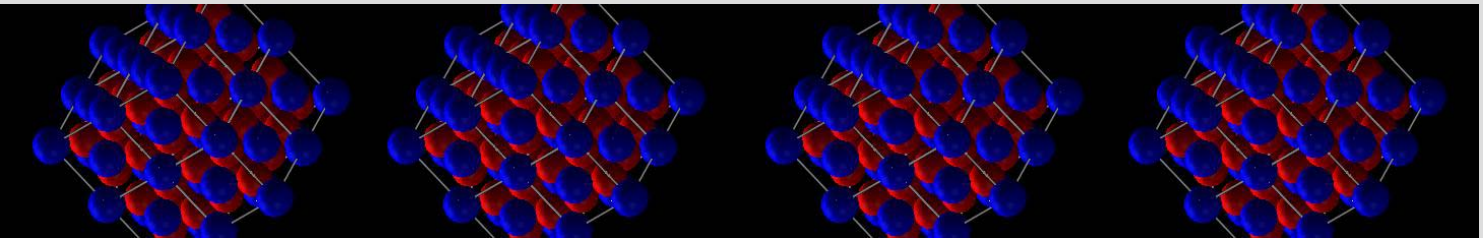
The draft definition consists of three criteria.

**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 $m^2/cm^3$, excluding materials consisting of particles with a size lower than 1 nm.

Whenever one of the criteria is fulfilled a material is considered to be a nanomaterial.



# Nanomaterials under REACH

Article 1(3) of REACH is applicable to substances in whatever size or form and for all their identified uses. Thus, a registration of a nanomaterial has to include all relevant information on the nanomaterial as manufactured or imported, covering the properties, uses, effects and exposure related information as well as the relevant classification and labelling, safety assessment and any relevant exposure scenarios.

Registrants have an obligation to update and register new information. Relevant if a substance was already registered in its 'bulk' form and it is subsequently intended to be manufactured or imported also in a nanoform.

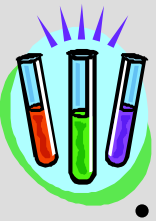
Substances, including substances at the nanoscale, manufactured or imported in volumes of 1 ton/yr have to be registered under REACH.

At volumes of 10 ton/year a chemical safety report (CSR) based on a chemical safety assessment (CSA) has to be included in the registration.

# *Phase-in* Substances: registration deadlines

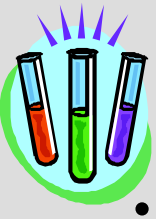
1-12-2010

- Substances CMR Cat. 1 or 2 ≥ 1 ton/year
- Substances classified R50/53 ≥ 100 ton/year
- Substances manufactured or imported ≥ 1000 ton /year



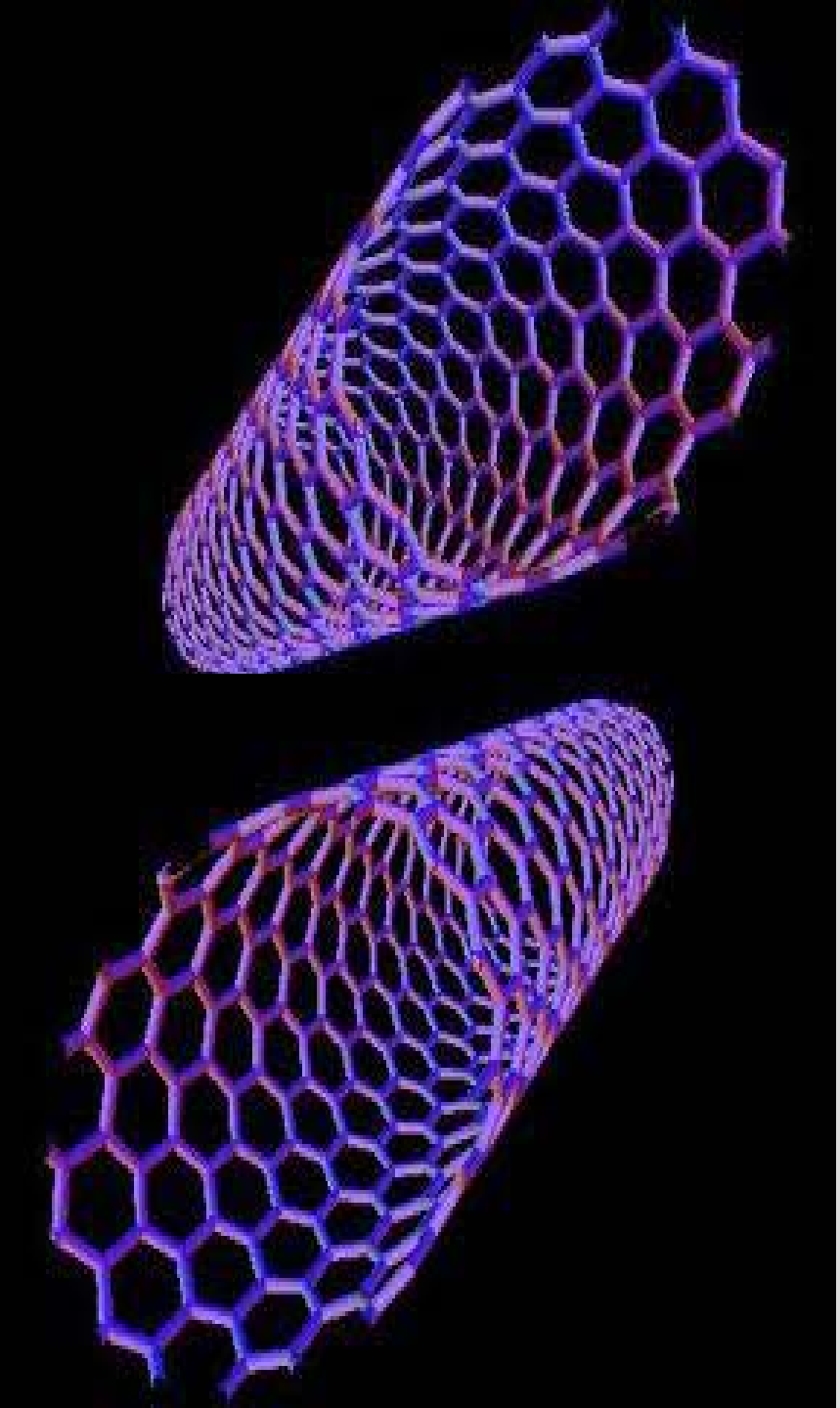
1-6-2013

- Substances manufactured or imported ≥ 100 ton/year



1-6-2018

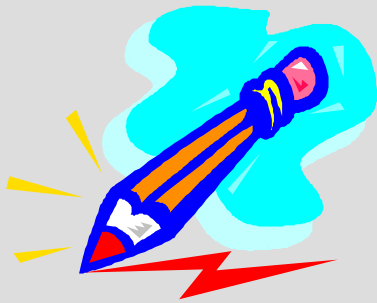
- Substances manufactured or imported ≥ 1 ton/year

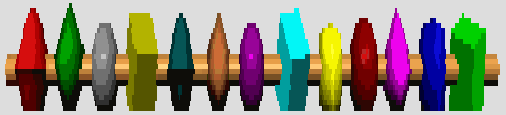


In case a substance at nanoscale is considered as a specific physical form of a bulk substance and provided that this substance is a phase-in substance, the registration deadline and the information requirements are determined by the total tonnage in which the bulk substance, including its nanoform, is manufactured or imported.

# Nanomaterials under CLP

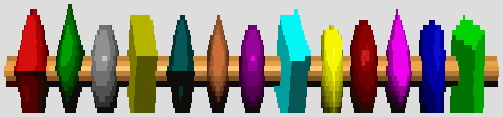
When nanomaterial forms of bulk materials are introduced onto the market, the registration dossier will have to be updated including different classification and labelling of the nanoform.





The classification and labelling of nanomaterials should follow the rules set out in CLP.

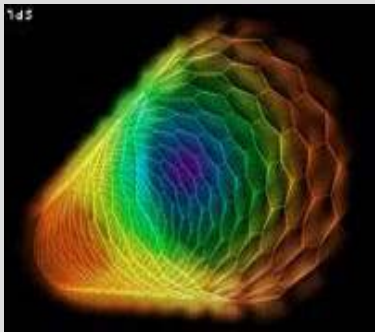
Nanomaterials having specific properties may require a different classification and labelling compared to the bulk material, also when the nanoform is derived from a bulk substance.



The hazard classification should be based on the intrinsic properties that relate to the forms or physical state in which the substance or mixture is placed on the market and in which it can reasonably expected to be used.

A substance with a different particle size or forms can have different classification. If substances are produced/imported both at nanoscale and as bulk, a separate classification and labelling may be required if the available data on the intrisic properties indicates a difference in hazard class between the nano form and ones the bulk form.

The SCENIHR stated that not all nanoparticles formulations have been found to induce a more pronounced hazard than the bulk formulations of the same substance. This suggest that the hazard characterisation of nanoparticles formulation be carried out case-by-case.



Registrants would consider the following approaches in the classification and labelling of nanomaterials:

1) the data sharing, should cover all relevant information including (but not limited to) sizes, forms and morphologies;

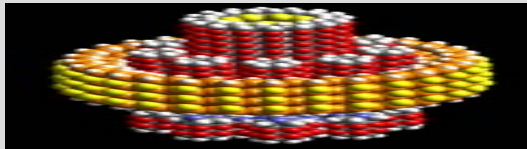
2) to determine whether changes influence considerably the hazardous properties;

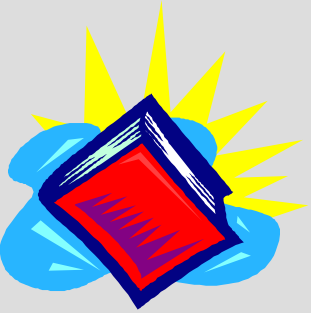
3) all available information of nanomaterials should be evaluated in the hazard assessment;

4) special attention needs to be devoted to the appropriateness of the sample preparation and dosimetry used in the testing of nanomaterials;

5) classification should be done on a case-by-case basis;

6) on the basis of the classification in accordance with CLP, nanomaterials should also be labelled and packaged in accordance to CLP.





In February ECHA presented IUCLID 5.2 which enables the information "*nanomaterial*" to be included in the database.

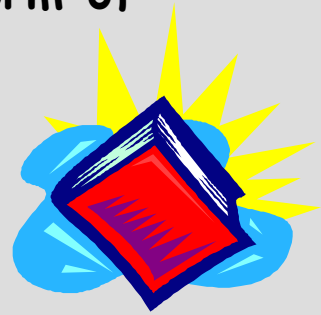
This version is used for:

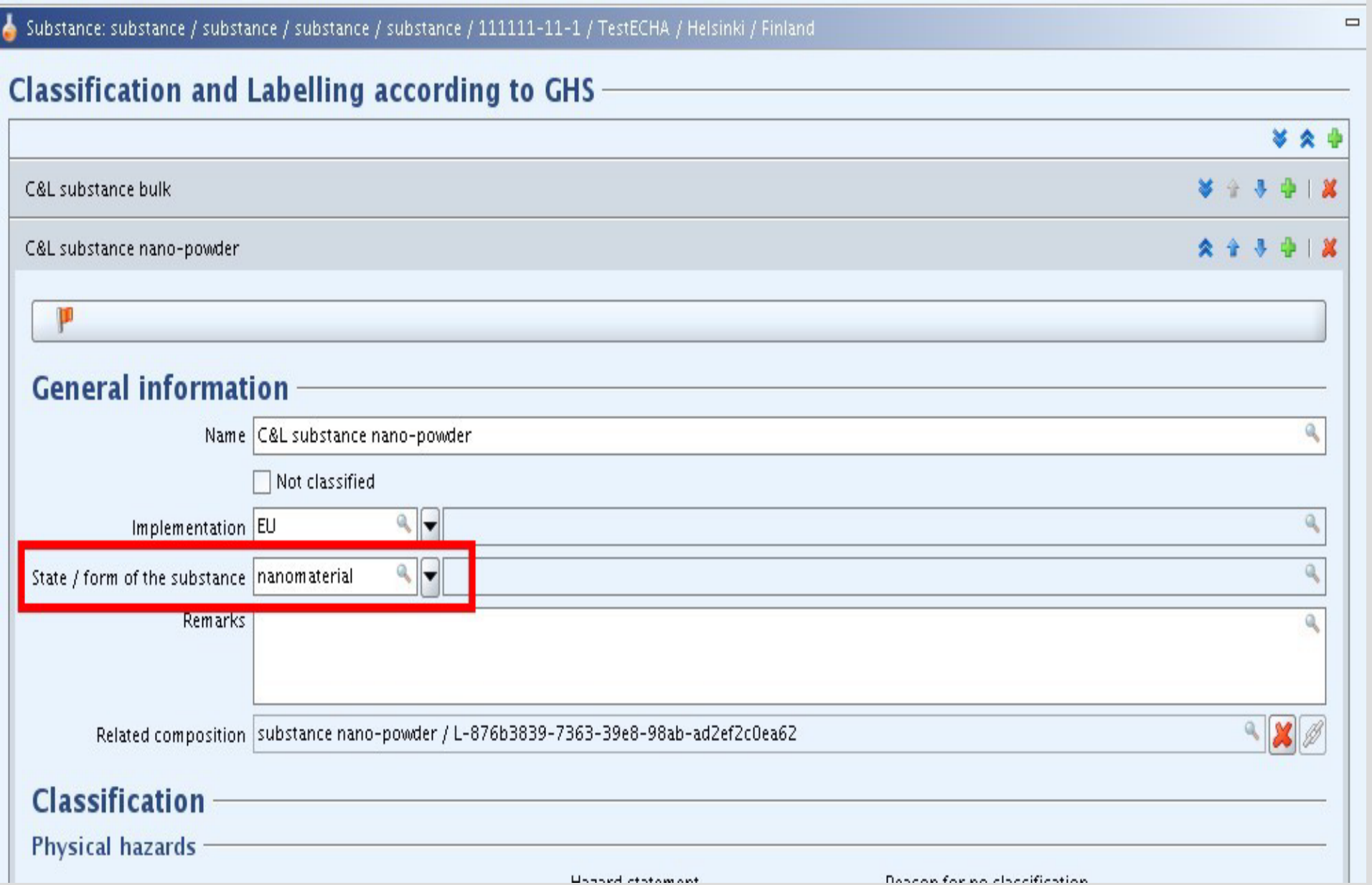
- first phase registration
- CLP notification.

The new nano fields can be used to indicate nanomaterial

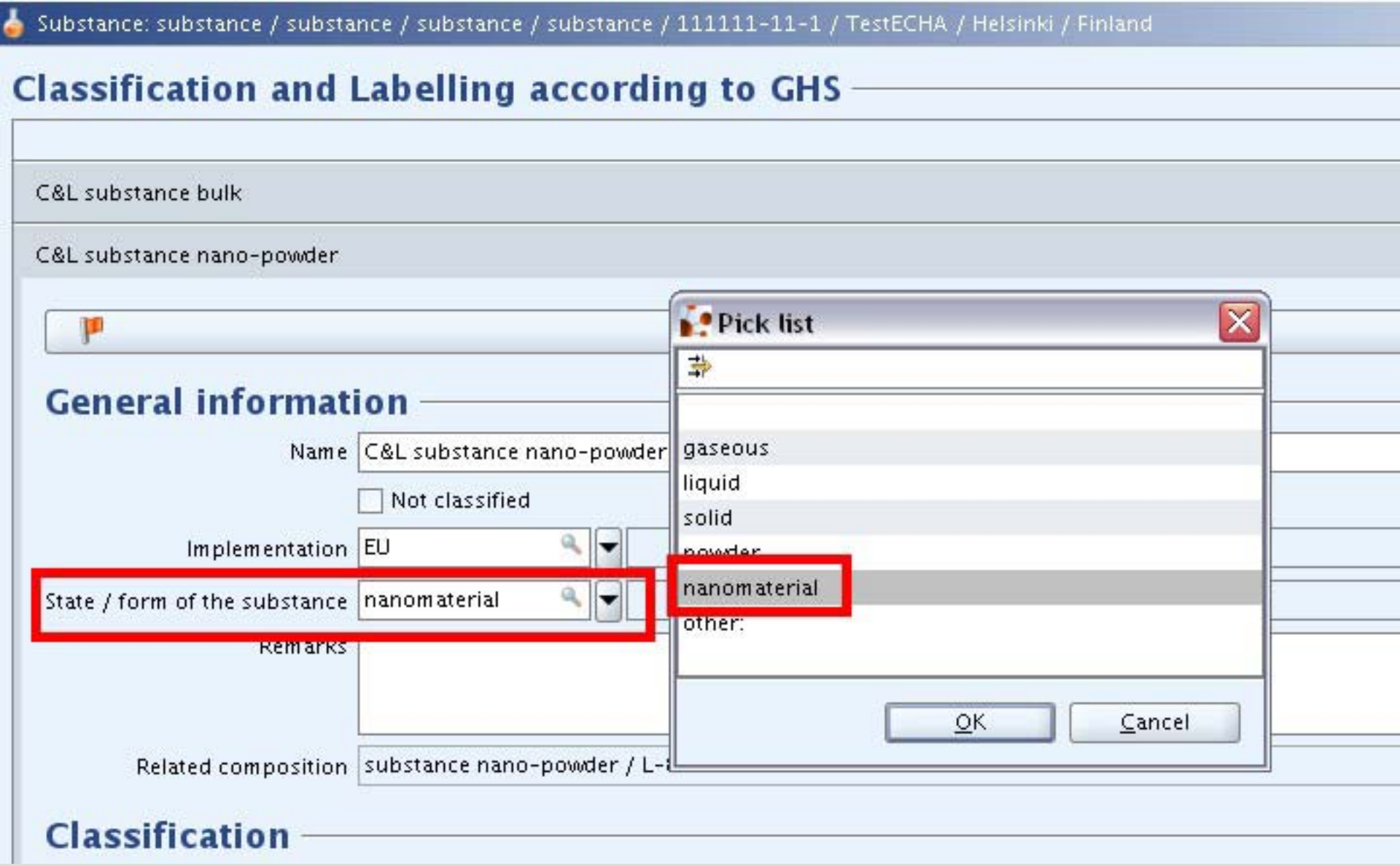
- Section 2.1 "Classification and labelling according to GHS": "*nanomaterial*" can be selected as the "form of the substance"

- Section 4.1 "Appearance/physical state/colour/:
the addition of nanomaterial in the list of options for the form of a substance

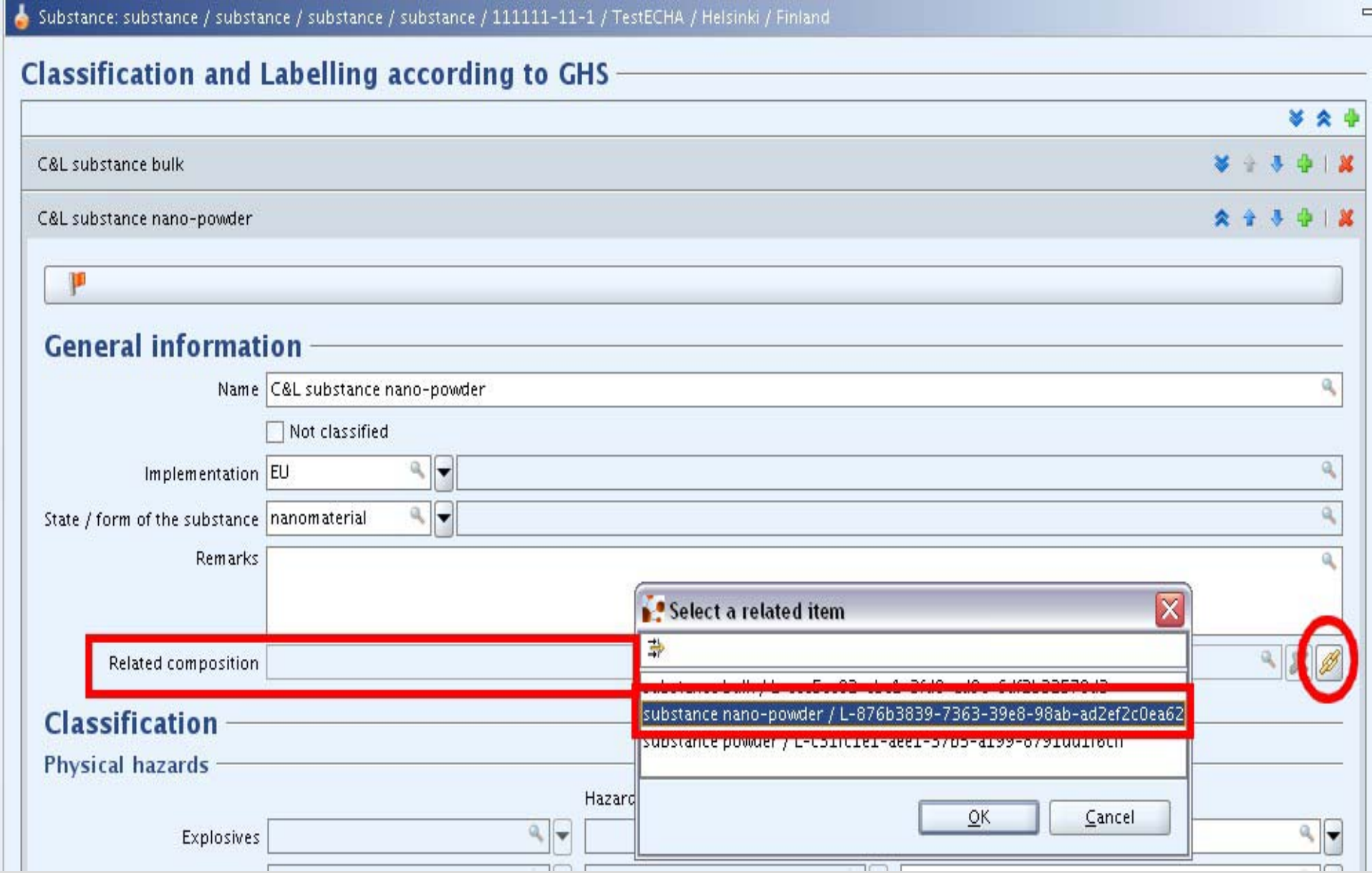




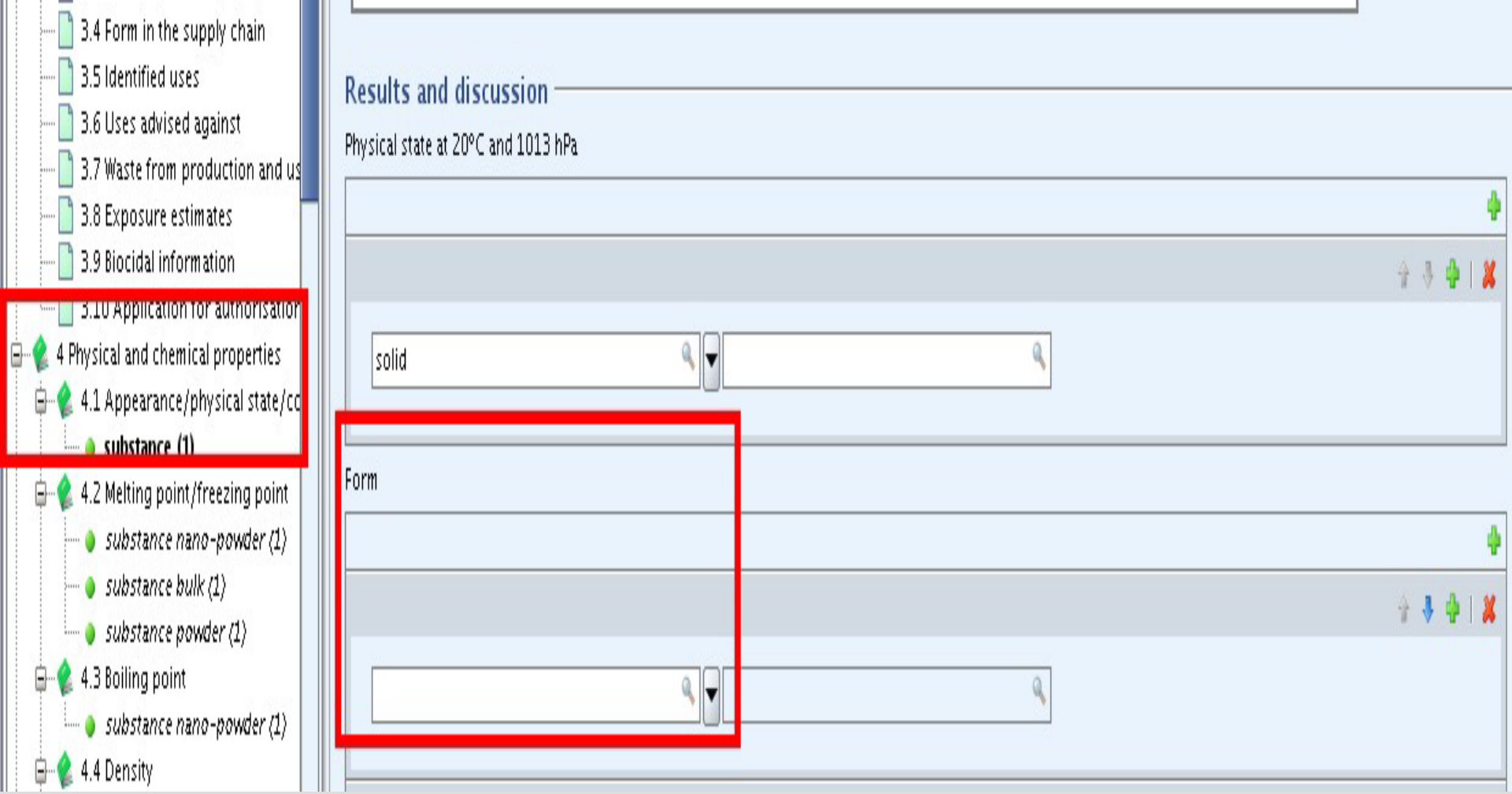

*Screenshot 1: Section 2.1 of the IUCLID dossier* European Commission_CASG Nano Document



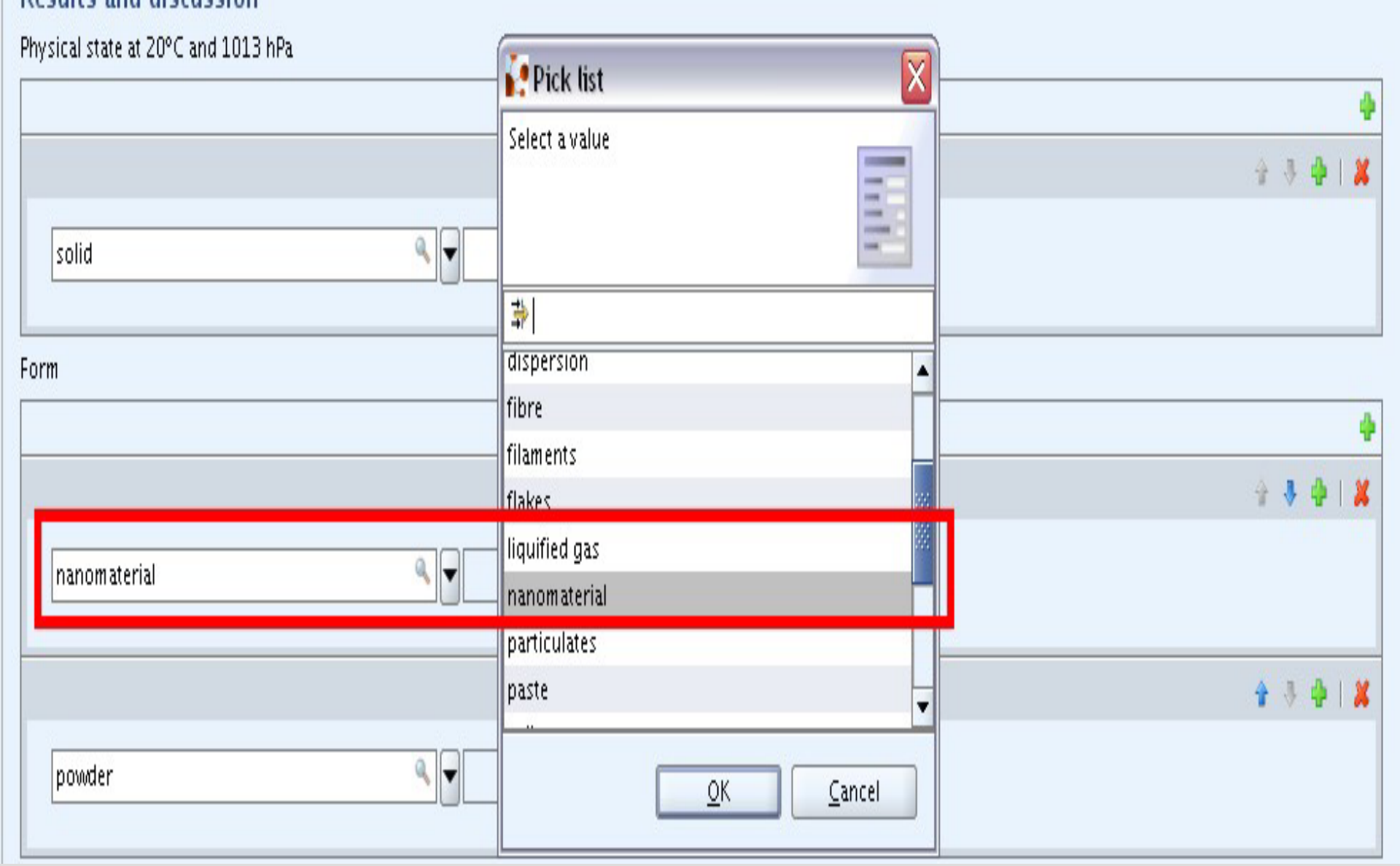

*Screenshot 2: Section 2.1 of the IUCLID dossier. The form of the substance picklist includes "nanomaterial"* European Commission_CASG Nano Document




*Screenshot 3: Classification and labelling can be linked to a specific composition available in section 1.2 through the "related composition" field*




*Screenshot 4: Endpoint study record of section 4.1 with "form" indicated in red* European Commission_CASG Nano Document



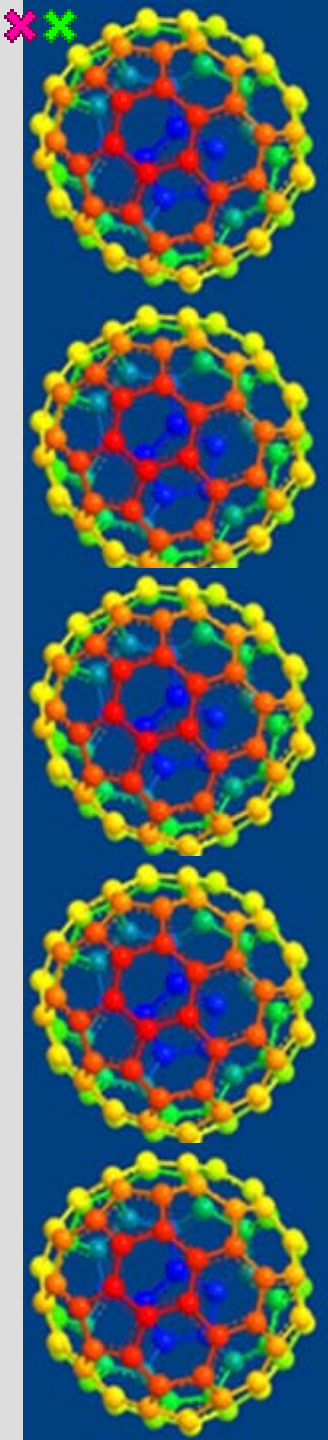

Screenshot 5: The picklist for the form of the substance now includes “nanomaterial”
European Commission_ CAGS Nano Document


At National Institute of Health (ISS) an interdepartmental and multidisciplinary working group on Nanomaterials has been established to support the efforts of the public initiatives in this field.

As a part of this initiative, specific research projects are under development in order to assess the potential toxic effect for human health and environment of different nanoparticles.

The chemical legal framework needs to be examined and further developed with a view to ensuring a high level of protection for environment and human health.

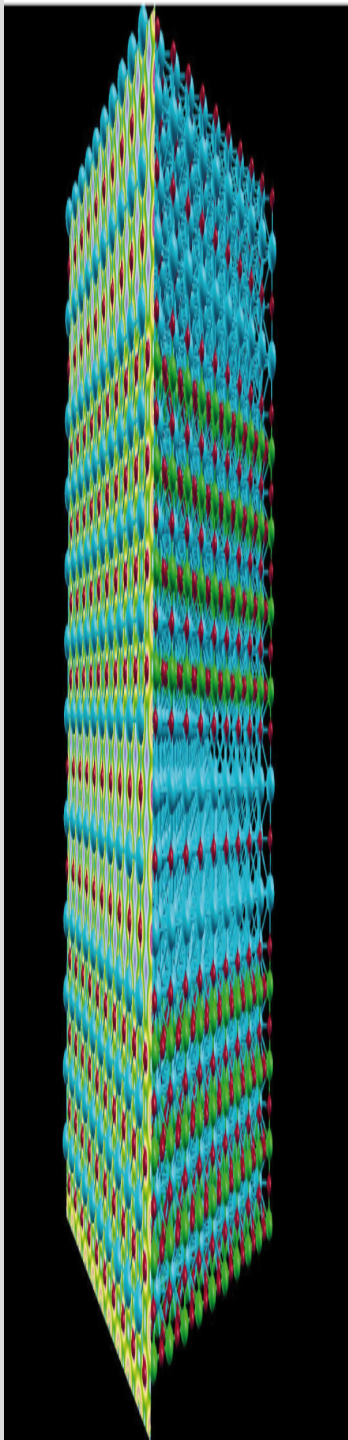
- The REACH and CLP regulations are not designed for nanomaterials.
- To put this into effect, the handling of nanomaterials should be dealt with the revision of REACH in 2012.
- There also needs for revision in the Classification and Labelling Regulation. It is, for example, important that criteria which are directly linked to the outcome of the test methods are applicable to nanomaterials.



# Challenges for the future

- A further development of the REACH and CLP guidance documents and implementation tools will be necessary in order to cover nanomaterials more specifically.

- The evolving science of nanotechnology may necessitate further requirements to reflect the particular properties of nanomaterials in the chemical legislation.



# Thanks for the attention

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