Nanotechnology Regulation Webinar

10 July 2014, 2:00pm BST
Today’s webinar – aims

To explain the European Commission's position on nanotechnology within REACH;

To give an overview on product notification/registration and product registers;

Hear about innovation and the regulatory environment and what the nanotechnology industry wants in order to foster development;
Receive an overview of the regulatory position in the US;

To outline the activities of the OECD and ISO;

To outline the NGO position on the regulation of nanotechnology.
Speakers

Frank Kopp, Dr. Knoell Consult GmbH;

David Azoulay, CIEL;

David Carlander, Nanotechnology Industries Association.

Chair: Geraint Roberts, Global Content Editor, Chemical Watch.
Questions

Please submit questions during the webinar using your chat box.

Any unanswered questions can be raised on our Forum following the webinar:
http://forum.chemicalwatch.com/
worldwide registration
The Regulation of Nanotechnology

Dr. Frank Kopp
European Registered Toxicologist (DGPT)
The Regulation of Nanotechnology

I:  Definition and analytics of nanomaterials
II:  Position on regulation of nanomaterials in the EU
III:  Nanotechnology within REACH
IV:  Production notification/registration
The Regulation of Nanotechnology

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Definition Nanomaterials – Recommendation 2011/696/EU of the Commission

“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 above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.”

Terms:

• Agglomerate: cluster of weakly bound particles or aggregates in which the resulting surface is similar to the sum of the surfaces of the individual components

• Aggregate: particle consisting of tight-bound or molten particles
Definition Nanomaterials – Recommendation 2011/696/EU of the Commission

⇒ Definition used primarily to identify materials for which special provisions might apply
⇒ Special provisions are not part of the definition but of specific legislations in which the definition will be used
⇒ Nanomaterials are not intrinsically hazardous per se → comparable to “standard” chemicals, and case-by-case risk assessment can be applied (depending on hazard and use, not on size)
⇒ Definition to provide clear and unambiguous criteria to identify materials to which such considerations apply → the risk assessment will determine further actions
⇒ Ensure conform consideration as nanomaterial across different legislative areas in the EU
⇒ Ensure conform consideration as nanomaterial across different sectors of use (e.g. different definitions of nanomaterials in Cosmetics Directive, Biocidal Products Regulation, Novel Foods Regulation, etc.)
Definition Nanomaterials – Recommendation 2011/696/EU of the Commission

Volume-specific surface area (VSSA)

If technically applicable the compliance with the definition of the EU Commission can be confirmed by means of the volume-specific surface area.

A material with a specific surface area of > 60 m²/cm³ is in accordance with the definition of nanomaterials of the EU Commission.

However, there can be discrepancies between the measurement of the specific surface area and the number size distribution:

⇒ In such cases the number size distribution should prevail
⇒ Material should be considered as a nanomaterial even if the specific surface area is < 60 m²/cm³

⇒ Specific surface area cannot be used as a proof that a material is NOT a nanomaterial!
Analytics of Nanomaterials – Volume-Specific Surface Area

BET-method (Brunauer Emmet Teller)

Nitrogen adsorption method, suitable for dry solids or powders, dried dispersed materials

Principle:
The adsorbed gas quantity is proportional to the surface area, the pressure and the adsorption temperature.

⇒ The BET equation is used to calculate the specific surface area from the adsorbed amount of gas
# Analytics of Nanomaterials - further methods

There is no single method for determination of particle size distribution covering the whole size range required for confirmation of compliance with the definition:

<table>
<thead>
<tr>
<th>Method</th>
<th>Range, medium</th>
<th>Size distribution of raw data</th>
<th>Applicability for special types of nanomaterials?</th>
<th>Standard method?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electron microscopy (EM)</td>
<td>1 nm, dry</td>
<td>Quantity-based</td>
<td>Polydispersity: long: + flat: -</td>
<td>not good</td>
</tr>
<tr>
<td>Dynamic light scattering (DLS)</td>
<td>5 – 500 nm</td>
<td>Intensity-based</td>
<td>Polydispersity: no</td>
<td>good</td>
</tr>
<tr>
<td>Centrifugal liquid sedimentation (CLS)</td>
<td>&gt;20 nm</td>
<td>Intensity-based</td>
<td>Polydispersity: no</td>
<td>not good</td>
</tr>
<tr>
<td>Small-angle X-ray scattering (SAXS)</td>
<td>&gt;5 nm</td>
<td>Detector-dependent</td>
<td>Polydispersity: moderate</td>
<td>not good</td>
</tr>
<tr>
<td>Field flow fractionation (FFF)</td>
<td>1 – 200 nm</td>
<td>Quantity-based</td>
<td>Polydispersity: good</td>
<td>not good</td>
</tr>
<tr>
<td>Particle track analysis (PTA)</td>
<td>&gt;25 nm</td>
<td>Quantity-based</td>
<td>Polydispersity: good</td>
<td>no</td>
</tr>
<tr>
<td>Atomic force microscopy (AFM)</td>
<td>1 nm, dry</td>
<td>Quantity-based</td>
<td>Polydispersity: long: + flat: +</td>
<td>moderate</td>
</tr>
<tr>
<td>X-ray diffraction (XRD)</td>
<td>1 nm, dry</td>
<td>No distribution</td>
<td>Polydispersity: no</td>
<td>not good</td>
</tr>
</tbody>
</table>
The Regulation of Nanotechnology

I: Definition and analytics of nanomaterials
II: Position on regulation of nanomaterials in the EU
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Position on regulation of nanomaterials in the EU

Nanomaterials are comparable to “normal” substances ⇒ there can also be hazardous ones and non-hazardous ones.

⇒ They cannot be considered as hazardous per se only by sheer size!

They fulfil the definitions of substances under REACH and CLP
⇒ They are covered by those regulations, even though there is no explicit reference to nanomaterials
⇒ Registrants have to comply with the general obligations of those regulations as for any other substance.

The available methods for risk assessment are considered applicable also to nanomaterials.

Unfortunately, this view is not shared by all national authorities in the EU; there are deviating approaches to compilation and assessment of nanomaterials.
Position on regulation of nanomaterials in the EU

France:

“Decree no. 2012-232 on the annual declaration on substances at nanoscale in application of article R. 523.4 of the Environment code”

Decree entered into force on 1st Jan 2013, sanctions in force since 1st Jul 2013

Substance at nanoscale: “as defined in Article 3 of Regulation (EC) 1907/2006, intentionally produced at nanometric scale, containing particles, in an unbound state as an aggregate or as an agglomerate and where, for a minimum proportion of particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm.”

Minimum proportion may be reduced; minimum proportion specified in a joint order issued by the Ministers of environment, agriculture, health, labour and industry

Derogation from definition: fullerenes, graphene flakes and single-wall carbon nanotubes with one or more dimensions below 1 nm → subst. at nanoscale
Position on regulation of nanomaterials in the EU

France:


The declaration must be submitted to the Ministry of environment before 1st May each year.

A declaration is mandatory if the minimum quantity of 100 g of substance has been produced, imported or distributed during the previous year.

The declarations, and the data contained therein, are managed by the French agency for food safety, the environment and labour (Anses).

Members of the same supply chain are covered by a common registration number.

Required information:
1. Identity of declarer
2. Chemical name of the substance (name published)
3. Quantity
4. Uses (published)
5. Identity of professional users

On request the information can be treated as confidential.
Position on regulation of nanomaterials in the EU

Belgium:

On 04\textsuperscript{th} Jul 2013 the Belgian Federal Public Service for Health, Food Chain Safety and Environment notified the European Commission of a draft decree for a register of substances manufactured at the nanoscale based on declarations of products containing such substances by the parties placing these products on the market in Belgium.

Use of EC definition of nanomaterials (incl. fullerenes, graphene flakes and carbon nanotubes).

**Minimum quantity: 100 g/y** placed on the market (like France!)

Decree adopted in Feb 2014!

Entry into force: 01\textsuperscript{st} Jan 2016 for nanomaterials and substances containing nanomaterials

01\textsuperscript{st} Jan 2017 for mixtures; articles to follow later.

Exemptions:

- Non-chemically modified natural substances, substances produced accidentally, by-products of human activity
- Pigments and carbon black, synthetic amorphous silica and precipitated calcium carbonate used as fillers
- Products covered by other regulations concerning nanomaterials (e.g. biocides, foodstuffs)
Position on regulation of nanomaterials in the EU

Denmark:

Danish EPA has informed EC on 26th Nov 2013 of a “Draft Order on a register of mixtures and articles that contain nanomaterials as well as the requirement for manufacturers and importers to report to the register.” It will introduce “an annual retrospective requirement”.

Focus:
Mixtures and articles that are intended for sale to the general public and which contain nanomaterials (released under normal or reasonably foreseeable use, or release of CMRs from nanomaterial).

Purpose:
Work out amount and nature of nanoproducts sold to consumers on the Danish market as well as the use of such products. Assessment whether nanomaterials in products pose a risk to consumers and the environment.

Register was launched in June 2014!

⇒ First reports for 2014 to be handed in by 20th Jun 2015.
⇒ By 30th Aug 2015 producers and importers legally obliged to submit information on products containing nanomaterials
Position on regulation of nanomaterials in the EU

Denmark:

Exemptions:
• Nanoproducts sold between businesses

• Products already listed in Danish Product register or covered by other specific regulations (e.g. food, feed, pharmaceuticals, medical devices, cosmetics pesticides and waste)

• Specific products:
  1. Nanosized REACH Annex V substances
  2. Products non-intentionally produced in nanosize
  3. Nanomaterials in a fixed matrix
  4. Nanomaterial used as printing ink
  5. Nanomaterials used as printing ink on textiles or for colouring of textile
  6. Paints and wood protection products containing TiO₂
  7. Rubber products containing nanomaterials carbon black or silicon dioxide
  8. Products imported for private use
  9. Products used for research and development
Position on regulation of nanomaterials in the EU

Sweden:

Swedish Government considered current regulatory framework inadequate and not applicable to nanomaterials.

Detailed proposal published in Oct 2013 for a national action plan made up of six measures that utilise the opportunities provided by nanomaterials while minimising the risks to human health and environment:

1. Building knowledge about health and environmental risks
2. Providing an overview of knowledge about health and environmental risks
3. Communication and cooperation
4. Development of the EU’s regulatory framework
5. Increasing knowledge about nanomaterials on the market (Call for “National inventory of products on the market containing nanomaterials”).
6. Implementing a platform for coordination (“Nano Council”, independent under Government)

Utmost importance: Adaptation of REACH to nanomaterials!

- Registration as separate substance (Inquiry prior to registration!)
- Reduced tonnage limits (Proposal Keml 2013: \( \geq 10 \text{ kg/y}, \geq 100 \text{ kg/y}, \geq 1 \text{ t/y} \text{ and } \geq 10 \text{ t/y} \))
- Supplementary data on their phys-chem properties
- Extended obligation to register products containing nanomaterials
- Including relevant details on nanomaterials in information to downstream users
Position on regulation of nanomaterials in the EU

Germany:

The Bundesrat asked the German Government on 05\textsuperscript{th} Jul 2013 to campaign for the invention of a nano-product data base in the EU.

In addition, data from governmentally funded scientific research was requested to be published in a form comprehensible to consumers in a separate data base.

The German Government responded on 14\textsuperscript{th} Oct 2013 that it was not considered reasonable to elaborate basic points for a nanopproduct-register on a national level.

The Government favours to promote the already ongoing processes in the EU and to support the foundation of basic points on EU level.
Position on regulation of nanomaterials in the EU

ERPN - European Register of Products containing Nanomaterials

The German Federal Environmental Agency supports the invention of a “European Register of Products containing Nanomaterials”.

This will allow an overview on nano-products coming into contact with consumers and will generate transparency in the supply chain.

An electronic register has to be introduced and centrally managed.

National registers would create overlap with other EU legislations and would require a higher effort and doubling of work.

Data can be recruited from already existing regulations like REACH, CLP, Cosmetics Directive, Novel Food Regulation, etc.)
Position on regulation of nanomaterials in the EU

ERPN – European Register of Products containing Nanomaterials

Substances and mixtures containing nanomaterials must be registered.

Products intentionally or unintentionally releasing nanomaterials shall be registered, too.

Registration should contain the product name, a description, characterisation and the concentration of the contained nanomaterial; in addition, information on tonnage, uses and function shall be provided.

The register shall comprise public and confidential parts which can only be accessed by authorities.

Effort and costs shall be kept to a minimum for all involved parties (companies and authorities)

Listed products shall receive a registration number which shall be present on the label (Not to be mistaken as warning!)

Register it is not meant to render nano-specific adaptations of existing regulations unnecessary; it shall represent an amendment.
The Regulation of Nanotechnology

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Nanotechnology within REACH

“Nanomaterials are regulated by REACH because they are covered by the definition of a chemical “substance” in REACH.

The general obligations in REACH therefore apply as for any other substance and there are no provisions referring explicitly to nanomaterials.”


The EU Commission considers REACH and CLP as best possible framework for the risk management of nanomaterials when they occur as substances or in mixtures. However, within this framework more specific requirements for nanomaterials have proven necessary.

Therefore, the Commission is considering to modify some of the technical provisions in the REACH Annexes and REACH Guidances in order to improve assessment of potential hazards imposed by nanomaterials and to allow corresponding risk management measures – but not the core text of the regulation!

The Commission does not see a requirement for a change of deadlines or tonnage bands, or for a separate substance identity for nanomaterials.

Proposal for nano-specific adaptation of the REACH Annexes has been announced for summer 2014 by the EU Commission.
Nanotechnology within REACH

Substances may occur as nanomaterials exclusively or as bulk form, as well. Nanomaterials have unique and more pronounced characteristics than their bulk counterparts; therefore, their phys-chem characteristics may vary significantly from the bulk substance form!

⇒ Supplemental information on PC-characteristics required!

IUCLID 5.5.0:
13 new endpoints already introduced for nanomaterials $\geq 1\text{t/y}$:
4.24-4.36
Nanotechnology within REACH

Classification and labelling of nanomaterials:

Nanomaterials that fulfil the criteria for classification as hazardous under Regulation (EC) 1272/2008 (CLP) of substances and mixtures must be classified and labelled.

⇒ Applies to nanomaterials in their own right or nanomaterials as special form of the substance.

Substances, incl. nanomaterials, classified as hazardous should have been notified to ECHA by 03\textsuperscript{rd} Jan 2011.

Any further update to the classification must also be notified without undue delay.
Nanotechnology within REACH

Background paper on the position of German Competent Authorities:

Substance identity under REACH defined solely by molecular structure and chemical composition → joint registration dossier for bulk and nanomaterial required.

Compared with substances in bulk form data on nanomaterials is mostly scarce; that even applies to nanomaterials that are considered well-examined.

Often the available studies lack an adequate characterisation or preparation of the test material. In consequence, the studies are hardly comparable to data on the substances in bulk form or other nanomaterials.

Therefore, the data requirements under REACH have to be adapted in order to assess potential hazards imposed by nanomaterials and to allow the implementation of corresponding risk management measures.
Nanotechnology within REACH

Background paper on the position of German Competent Authorities:

Most important distinguishing parameters bulk – nano: morphology, water solubility, surface characteristics → Applies also to respirable granular or fibrous particles.

If properties of two materials differ in relevant way additional tests may be required
→ One of basic principles of REACH, applies both to conventional and nanoscale substances.

REACH Annexes have to be amended for the additional information requirements; for nanomaterials a separate Annex XVIII is proposed. The requested information will have to be submitted by the registrant; if a test is waived scientific justification must be given.
Nanotechnology within REACH

Background paper on the position of German Competent Authorities:

For nanomaterials ≥ 100 kg/y (total production or import quantity of all nanoforms of a substance) reduced registration requirements should be introduced.

These should comprise details on substance identity, basic characterisation of the different nanoforms, uses. At the same time the introduction of a minor threshold should be considered. All available data on the different nanoforms has to be documented by the registrant.

For nanomaterials ≥ 1 t/y (total quantity of all nanoforms of a substance) the data requirements of new Annex XVIII to be implemented in REACH shall apply. In addition a chemical safety assessment must be conducted for all nanoforms of a substance → must be documented within one Chemical Safety Report.
Nanotechnology within REACH

Background paper on the position of German Competent Authorities:

Waiving tests:
REACH column 2 in the Annexes VII-X and Annex XI

In principle 3 types of waivers possible:
1. Referencing between bulk and nanoform of a substance
2. Referencing between different nanoforms of a substance
3. Read-across between substances with different chemical identity (possibly various bulk and nanoforms), (Q)SAR

Details on applicability of waivers should be described in a REACH Guidance.
Nanotechnology within REACH

Background paper on the position of German Competent Authorities:

Data requirements Toxicology:

≥ 1 t/y: Annex VII with following adaptations:
  • Acute tox inhalation
  • Additionally 2 tests for genotoxicity in mammalian cells in vitro

≥ 10 t/y: Above + Annex VIII with following adaptations:
  • 28-d rep. dose inhalation + 28-d treatment-free follow-up phase + additional examination parameters

≥ 100 t/y: Above + Annex IX with following adaptations:
  • 90-d rep. dose inhalation + 90-d treatment-free follow-up phase + additional examination parameters

≥ 1000 t/y: Above + Annex X with following adaptations:
  • Chronic toxicity and carcinogenicity studies inhalation
  • Requirement for follow-up phase and additional examination parameters to be checked
Nanotechnology within REACH

Background paper on the position of German Competent Authorities:

Data requirements Ecotoxicology:

≥ 1 t/y:  Annex VII +VIII with following adaptations:
  • **Chronic** Daphnia test from Annex IX instead of acute test
  • Chronic fish test to be considered

≥ 10 t/y:  Above + Annex IX with following adaptations:
  • **Chronic sediment** test from Annex X

≥ 100 t/y:  Above + Annex X with following adaptations:
  • Chronic plant test and reproduction test for birds remain at 1000 t/y

≥ 1000 t/y:  Above + Annex X with following adaptations:
  • Incl. chronic plant test and reproduction test for birds
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Production notification/registration

“Nanomaterials are regulated by REACH because they are covered by the definition of a chemical “substance” in REACH.

The general obligations in REACH therefore apply as for any other substance and there are no provisions referring explicitly to nanomaterials.”

Source: http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm
(Website of European Commission)

⇒ Up to now no differences between notification or registration of a nanomaterial or any other common substance!

All articles of Regulation (EC) 1907/2006 also apply to nanomaterials!
Contact: Fkopp@knoell.com

Dr. Knoell Consult GmbH
www.knoell.com
Mannheim Fon +49 621 718858-0
Leverkusen Fon +49 214 20658-0
Berlin Fon +49 621 718858-0

Knoell Academy GmbH
www.knoellacademy.de
Fon +49 214 20658-14

Dr. Knoell Consult Ltd.
www.knoell.com
Fon +44 29 2034-9880

Dr. Knoell Consult Schweiz GmbH
www.knoell.com
Fon +41 61 695 86 50

Knoell Consult Iberia S.L.
www.spain.knoell.com
Fon +34 91 112 60 80

Dr. Knoell Consult Shanghai Co., Ltd.
www.shanghai.knoell.com
Fon +86 21 6199 2001

Dr. Knoell Consult Thai Co. Ltd.
www.thailand.knoell.com
Fon +66 53 2034-52

FORIM GmbH
www.forim.de
Fon +49 621 400460-0

Cyton Biosciences Ltd.
www.cyton.com
Fon +44 117 97389-44

Critical Path Services, LLC
www.criticalpathservices.com
Fon +1 610 558 3001

Shotwell & Carr, LLC
www.shotcarr.com
Fon +1 972 446 6611
David Azoulay
Chemical Watch Nanotechnology Regulation Webinar
July 10, 2014
What are the key issues with nanomaterials?

- Nanomaterials have different properties as compared to their bulk counterparts – some of which may be hazardous and others which may not;
- Publication of adequate characterization data for all nano forms on the market is necessary to assess the safety of these materials before they enter the EU market;
- Current EU legislation does not guarantee an evaluation of nanomaterials as separate from their bulk counterparts
Outline of the presentation

- Taking stock
- REACH, loopholes and challenges
- Sectoral regulations, the enforcement challenge
- The information demand
- Conclusions and recommendations
Taking stock: Current situation in the EU

- Though the EU has one of the world’s most advanced regulatory frameworks for nanotechnology in the world, it remains largely inefficient.

- In the last 5 years, almost no meaningful information about nano materials on the market was made available through the existing mechanisms.

- The European Commission has struggled to implement meaningful change to the regulatory framework, accumulating delays for every step of the regulatory process (even for the enforcement of regulatory provisions adopted five years ago).

- Major manufacturing industries are effectively playing a very active role in delaying regulation.

- This situation hinders the global understanding of the market, our capacity to adequately assess and address risks, and eventually seriously damages the public trust in this new and promising technology, as well as in the regulating authorities.
REACH: loopholes and challenges

• REACH entered into force in 2007, and has yet to deliver any meaningful result in relation to nanomaterials.

• REACH contains four main loopholes (detailed in our 2012 report “Just out of REACH”):
  1. Identifying nanomaterials: REACH currently does not define nanomaterials or contain any nano-specific provisions
  2. The majority of nanomaterials benefit from a phase-in status, and can therefore enter the market without registration,
  3. REACH’s registration is based on a tonnage thresholds which are inadequate for nanomaterials (produced in smaller quantities than their bulk counterpart and much more reactive)
  4. Test guidelines and information requirements do not consider the specificities of nanomaterials

• Several recommendations to close these loopholes are presented in our report and position paper.
REACH: loopholes and challenges II

- Numerous questions remain in relation to the ongoing annex revision process, in particular in relation to the modified phase-in provision (REACH annex III) and to the possibility to using grouping to limit the characterization and safety data provided in the context of registration.

- In the meantime, useful recommendations on how to implement current provisions to ensure that adequate information is made available for all nano forms currently on the market were presented in a report from ECHA’s GAARN in March 2014, including on the importance of providing full characterization information, as well as adequate exposure assessments and scenarios.

- However, without strong enforcement initiatives by ECHA, there is no reason to believe that registrants’ attitudes will change in that respect.
A revision process for the adoption of a nano patch to close the loopholes in REACH should be initiated without delays.

REACH annexes should be promptly revised to ensure that all nano forms on the market are adequately registered, characterized and assessed.

Civil society further calls on ECHA to systematically check compliance for all nanoforms, as well as check the compliance of all dossiers which are suspected of including substances in the nanoform.

The Community Roling Action Plan (CoRAP) list should include all identified substances in the nanoform, and evaluation should be carried out without delay.
Sectoral regulations and the enforcement challenge

- **Cosmetic regulation:**
  - Ingredients in nanoform to be labelled on the package with the term “nano”,
  - Prior authorization for nano materials used as UV Filters, Colorants and preservatives; and notification obligation for all other uses of nano materials.

- The Commission is already 6 months late in publishing the catalogue of authorized nano materials (UV filters, Colorants and preservatives), and has made it clear that the information received so far was largely inadequate.

- Without strong enforcement actions (such as requiring that products containing nano materials that have not been authorized are taken out of the market), consumer defiance will only grow, eventually damaging all of the industry.
Biocides

The Biocidal Product Regulation is the most sophisticated piece of legislation specifically addressing nano materials adopted in the EU so far.

- It includes the full Commission recommendation for a definition, it covers both active and non active substances, it requires a specific assessment of biocidal products containing nano materials, as well as labeling of both biocidal products and products treated with nano biocides.

- At this stage, one can only hope that implementation will be more effective than that of the Cosmetic directive, and that the biocide industry will be more proactive in guaranteeing safety and consumer confidence than the cosmetic and chemical manufacturer industry.

Food information to Consumer:

Latest development (in relation to the definition harmonization and exclusion of food additives in the nano form) seems to indicate that, in the food arena as well, the consumers concerns are not being taken seriously.
The information challenge

At the moment, no one (regulator, academic, scientific committee, civil society etc...) knows the exact market situation of nano in the EU (what exactly is being produced and marketed and in what quantity).

As a result:

➡ Regulators are struggling to adopt adequate adaptation of the existing regulatory framework;
➡ Academics and research institutes are struggling to prioritize research needs and test the materials that are on the market; and
➡ Consumers are prevented from exercising their right to know and make informed choices.

This in turns leads to:

➡ Greater consumer defiance that endangers the sustainable development of this new technology;
➡ Waste of a very large amount of public funding in the never ending consultative process that lacks the basic data to deliver adequate responses; and
➡ A multiplication of national initiatives, further increasing the burden on industry.
The Solution to the information challenge:

- A publicly accessible inventory of nanomaterials and consumer products containing nanomaterials must be established at European level as the only solution to bridge the gaps identified, and allow for the discussion to move forward on healthy basis.

- Moreover, specific nano-labelling or declaration requirements must be established for all nano-containing products (detergents, aerosols, sprays, paints, medical devices, etc.) in addition to those applicable to food, cosmetics and biocides which are required under existing obligations.
Thank you for your attention

Dazoulay@ciel.org
Nanotechnology Regulation and Innovation

Chemical Watch Webinar
Regulation of Nanotechnology

Dr David Carlander
NIA Director of Advocacy
10 July 2014
Nanotechnology is a key enabling technology

- Provide **employment and societal solutions**
- Major driver to **improve existing products** by creating smaller components and better (functional and environmental) performance materials and creating **new products and applications**
- Nanotechnology companies are likely to have a **rapid growth** (especially building on Europe’s strength of SME's in conjunction with large industry)
- **High employment** in areas where EU industries are traditionally world leaders (i.e. materials, consumer, automotive and ICT)
No new type of toxic effect have been described!

- i.e. no effects which have not been observed with any other substance or particle before
- however, uptake, tissue distribution and clearance of NM may be different from dissolved molecules or larger particles

‘…nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not…’

[Oomen et al., 2013, Nanotoxicology]
Industry needs – Continued harmonisation

• Development of globally harmonised and accepted hazard and risk assessment procedures and approaches

• Continue information and data generation on nanomaterials’ properties and behaviour
  – Research efforts

• Evaluation, validation, standardisation of methods to measure nanomaterials
  – In products, matrixes, environment...
International harmonisation

• Support the use of OECD Harmonized Templates

• OECD Mutual Acceptance of Data (MAD)

• Support ISO and CEN standard development

• Support the use of IUCLID format for data submission

Harmonised risk assessment practices to optimise resources of industries present on the international market
Commercialisation patterns and regulations

Regulators are closing the gap!

Input do develop and update test guidelines

- Input to OECD test guidelines and guidance document revisions and modifications
- Input to REACH Guidance for nanomaterials, grouping, read-across and extrapolation...
Concern driven approach for nanomaterial testing

- Identification of “Nanomaterial”
  - Nanomaterial Definition

- Identification of “Nanomaterial of Concern”
  - Solubility / Dispersability
  - Use, Release, Exposure

- Identification of “concerns”
  - General concerns
  - Material properties
  - Biopersistence

- Refine “concerns”
  - Biokinetics
  - Early biological effects
  - Apical biological effects

- Targeted Testing

[Oomen et al., 2013, Nanotoxicology]

[Oomen, Bos and Landsiedel, chapter 16 in "Safety of Nanomaterials along their Lifecycle: Release, Exposure and Human Hazards", 2014 in print]
Organisation for Economic Co-operation and Development – OECD

- Working Party on Manufactured Nanomaterials (WPMN)
- Working Party on Nanotechnologies (WPN)
In 2006, the OECD established the Working Party on Manufactured Nanomaterials (WPMN)

Objective:

‘To promote international co-operation in human health and environmental safety related aspects of manufactured nanomaterials (MNs), in order to assist in the development of rigorous safety evaluation of nanomaterials’

Established under the OECD Chemical Committee
In 2013 the work was reorganised into the following Steering Groups:

- **SG-Testing and Assessment** (former SG3, 4 and 7)
- **SG-Risk Assessment and Regulatory Programmes** (former SG5 and 6)
- **SG-Exposure Measurement and Exposure Mitigation** (SG8)
- **SG-Environmentally Sustainable Use of Nanotechnology** (SG9).
More than 40 publications from WPMN since 2005 (e.g.):

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Working party on Nanotechnology (WPN)

- Established in March 2007
- The objective of WPN is to advise on emerging policy-relevant issues in science, technology and innovation related to the responsible development and use of nanotechnology.
- WPN complements activities of other OECD committees and other organisations
- It is a subsidiary group of, and receives its mandate from, the Committee for Scientific and Technological Policy (CSTP)

[http://www.oecd.org/sti/nano/]
Working party on Nanotechnology (WPN) – Reports

- **Considerations in Moving toward a Statistical Framework for Nanotechnology:** Findings from a Working Party on Nanotechnology Pilot Survey of Business Activity in Nanotechnology (2014)
- **Responsible Development of Nanotechnology:** Results of a Survey Activity (2013)
- **Regulatory Frameworks for Nanotechnology in Foods and Medical Products:** Summary Results of a Survey Activity (2013)
- **Planning Guide for Public Engagement and Outreach in Nanotechnology** (2012)
- **Fostering Nanotechnology to Address Global Challenges:** Water (2011)
- **The Impacts of Nanotechnology on Companies:** Policy Insights from Case Studies (2010)
OECD Next Steps

- Focus on adaptation and/or development of specific testing methods used for assessing human health and environmental safety
- Developing guidance documents for assessing manufactured nanomaterials adapted to their specificities.
- Guidance on estimating exposure (including fate and transport) on how to use results on physico-chemical endpoints in exposure assessment and mitigation measures to reduce exposure to safe levels
- Publishing results from the OECD WPMN Sponsorship Programme
United States National Nanotechnology Initiative (NNI)

• The coordinating agency for all US federal efforts on nanotechnology

• NNI defines nanotechnology as ‘the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications’
  – Include both particle size and functionality at the nanoscale

• In practice, few US agencies have adopted the NNI definition, and each agency (or in cases programs within agencies) have established their own definitions, or not!
Nanotechnology Task Force report in July 2007 did not call for any new FDA regulatory authority to cover engineered nanoscale materials.

- Use of **nanomaterials in FDA-regulated products** presents completely **manageable challenges similar** to those posed by **other existing FDA-regulated products**.
- ‘...**issue guidance** describing safety issues that manufacturers should consider to ensure that cosmetic products made with nanomaterials are safe and not adulterated’
Guidance for Industry Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology

Two points to consider

1. Whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm)

2. Whether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm).

Guidance for Industry Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives

- **Emerging technologies** such as those that intentionally alter a food substance’s particle size distribution on the nanometer scale which alter the physical and/or chemical properties of food substances, **can sometimes be significant manufacturing changes**

Guidance for Industry Safety of Nanomaterials in Cosmetic Products

Points to consider

- Nanomaterial **characterisation** (e.g. physchem properties)
- **Toxicological considerations** (e.g. appropriateness of methods, routes of exposure, uptake and absorption)

Guidance for Industry Use of Nanomaterials in Food for Animals DRAFT GUIDANCE

• Applies to food ingredients that are intended for use in food for animals and either:
  – (1) Consist entirely of nanomaterials,
  – (2) contain nanomaterials as a component, or
  – (3) otherwise involve the application of nanotechnology.

• Comments to be provided to FDA no later than September 10, 2014.
  [http://www.regulations.gov/#!documentDetail;D=FDA-2013-D-1009-0001]
EPA has adopted a case-by-case approach to evaluating submissions of nanoscale materials under TSCA. In the EPA 2008 guidance EPA clarified that particle size alone does not indicate whether a substance would be considered a ‘new’ versus ‘existing’ substance.

US Environmental Protection Agency (EPA)

- Nanomaterials not on the TSCA Inventory are New Chemicals and a Pre-Manufacture Notice (PMN) is required before commencement of manufacture

- Information required as part of a PMN:
  - chemical identity, use, anticipated production volume, byproducts, exposure & release information, disposal
  - practices, existing available health & environmental effects test data

- Review of PMNs in 90 days
  - Approximately 44,000 PMNs reviewed/1,500 per year
  [http://www.epa.gov/oppt/newchems/]
Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

• **FIFRA** is the legal background for the registration and control of *pesticides and biocides* by the US EPA
• EPA requires a manufacturer to **register a product** as a pesticide
• The term nanomaterial does not appear in FIFRA
  – Nanomaterials are considered as substances
• With a **2011 Proposed Rule**, EPA requested **comments on an envisaged change** in the regulation to register nanoscale materials and **to consider them as new active ingredients** [http://www.epa.gov/pesticides/regulating/nanotechnology.html]
In short – Regulating nanomaterials

- The current EU regulatory landscape is applicable to nanomaterials
- There is no need for specific regulations for nanotechnologies or nanomaterials
- Avoid overly cautious policy and regulations
- Find balance for EU competitiveness
Thank you!

Dr David Carlander
Director of Advocacy
Nanotechnology Industries Association
m: +351 912 887 038
e: david.carlander@nanotechia.org
w: www.nanotechia.org

Brussels (main office)
Nanotechnology Industries Association (aisbl)
143 Avenue de Tervuren
1150 Woluwe-Saint-Pierre, Brussels
Belgium

Lisbon
Nanotechnology Industries Association
Apartado 17
EC Rebelva – Carcavelos
2776-901 Rebelva
Portugal

London
Nanotechnology Industries Association (ltd)
Lion House
Red Lion Street
London, WC1R 4GB
United Kingdom

@nanotechia
www.nanotechia.org
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If you have any questions, please contact Lorna (lorna@chemicalwatch.com)

K-REACH Webinar: Tuesday 22 July, 9:30am (BST)
https://www2.gotomeeting.com/register/645279618