Introduction

Webinar: updated REACH Guidance for nanomaterials: what you need to know

30 November 2017

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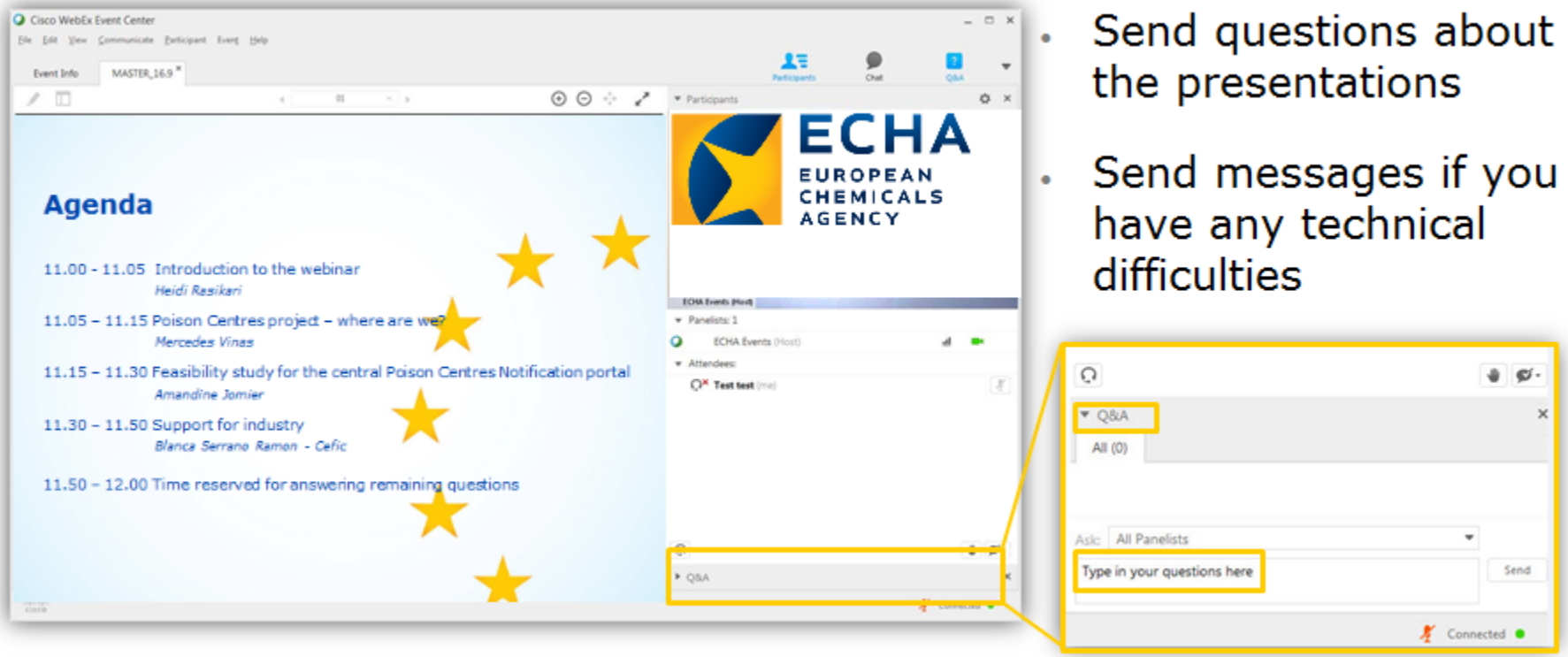
Agenda

11:00 – 11:10	**INTRODUCTION** Celia TANARRO, ECHA
11:10 – 11:35	**REGISTRATION OF NANOFORMS** Bernadette QUINN, ECHA
11:35 – 11:55	**GROUPING AND READ-ACROSS FOR NANOFORMS** Valeria AMENTA, ECHA
11:55 – 12:10	**HUMAN-HEALTH ENDPOINTS** Camelia CONSTANTIN, ECHA
12:10 – 12:25	**ENVIRONMENTAL ENDPOINTS** Laurence DEYDIER, ECHA
12:25 – 13:00	Time reserved for answering remaining questions

Q&A panel

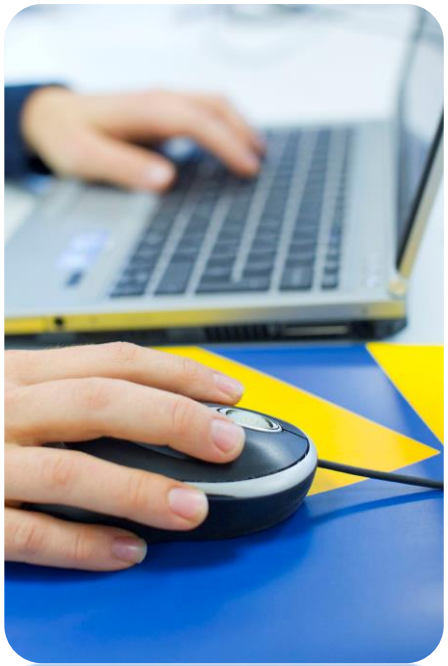


- Send questions about the presentations
- Send messages if you have any technical difficulties

Q&A panel

- Submit your questions at any time - we will answer as many as possible

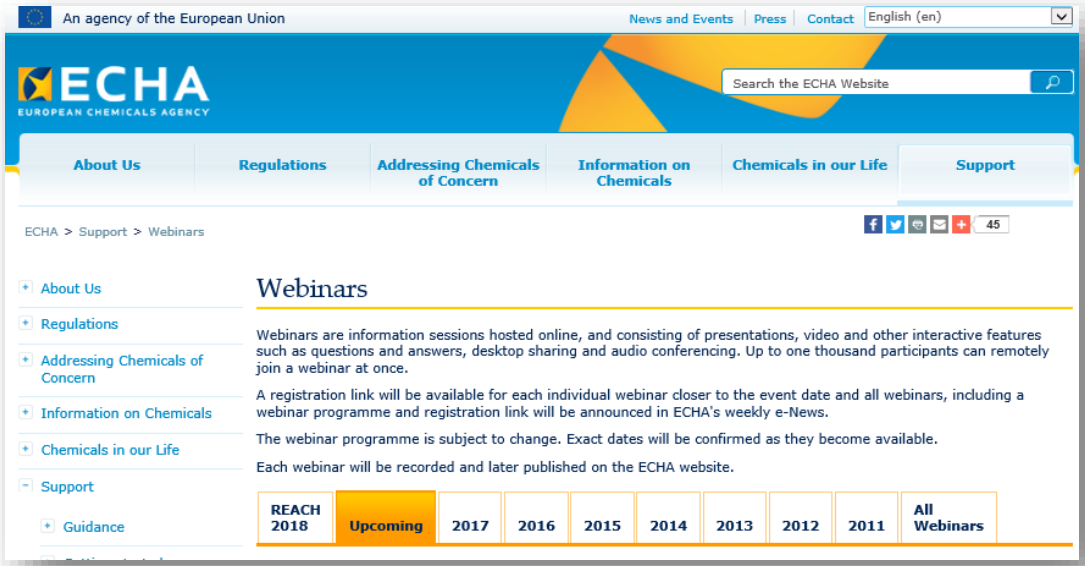
- Question not answered by the end of the webinar? Send it to your national helpdesk or to our helpdesk: echa.europa.eu/contact



Recordings published

- On our YouTube channel YouTube.com/EUchemicals

- Webinar material on our website



REACH guidance on nanomaterials

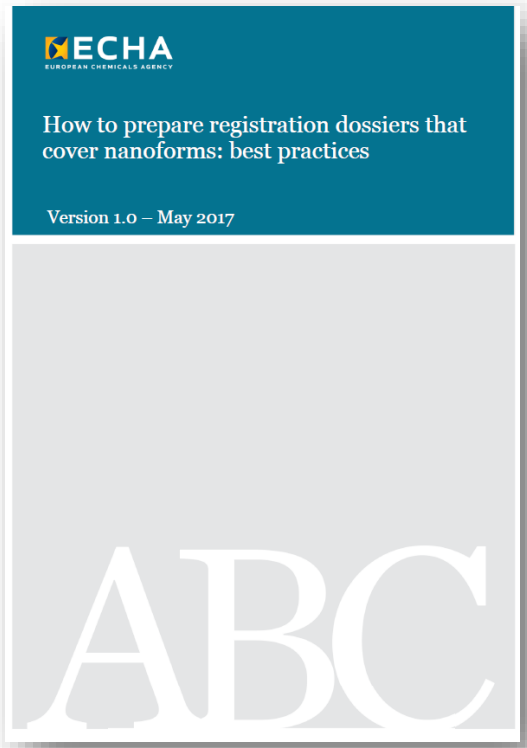
Where do nanomaterials fit under REACH?

- No explicit reference to nanomaterials in REACH
  - Considered as covered by the substance definition under REACH (Art(3)1)
- Commission 2nd Regulatory Review on Nanomaterials (Oct 2012)
  - Nanomaterials can be either
    - Substances on their own and registered as such
    - Nanoforms of a substance and included in the dossier of corresponding bulk substance
- Recommendation: REACH annexes modified to clarify existing requirements more explicitly

Revised Guidance
current regulatory framework

- Experience gained during dossier and substance evaluation
- Better reporting possibilities (new IUCLUID feature: assessment entity)
- Regulatory and scientific developments: OECD guidelines, CEN mandate, state of the art of science
- Feedback from registrants, in expert groups and helpdesk questions
- Inclusion of concepts support the aims of REACH

New support documents



Nanoforms: best practices

Grouping and read-across for nanoforms

Updated guidance:
information requirements & CSA

Nano-specific appendices to Chapters R.7a, R.7b and R.7c

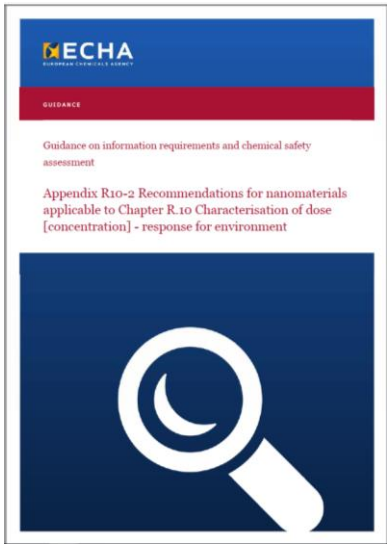
Physchem endpoints
Human health endpoints

Environmental endpoints

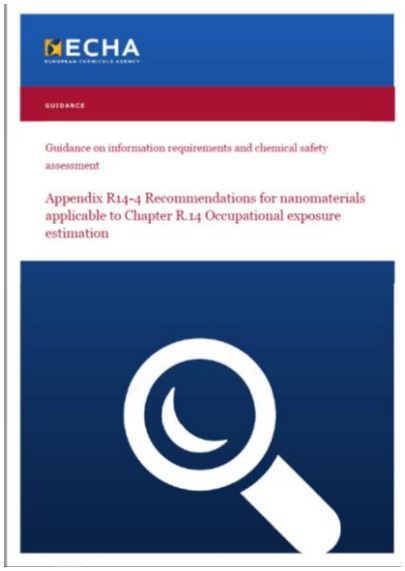
Environmental endpoints
Toxicokinetics

Other REACH Guidance for nanomaterials (2012)

DNEL derivation



PNEC derivation



Occupational exposure estimation

How to use them?

- They are Appendices to a Guidance "parent guidance"
- Provide specific advice for nanomaterials
- Parent guidance general principles should be followed
- If no nano-specific advice, parent guidance should be followed
- "How to" complements guidance on registration with "best practice" (not mandatory requirements)

More information on nanomaterials

Nanomaterials observatory

euon.echa.europa.eu

ECHA
EUROPEAN CHEMICALS AGENCY

Our website

echa.europa.eu/regulations/nanomaterials

ECHA > Nanomaterials

Nanomaterials

Nanomaterials are chemical substances or materials with particle sizes between1 to 100 nanometres (nms) in at least one dimension.

Due to the increased specific surface area by volume, nanomaterials may have different characteristics compared to the same material without nanoscale features. Therefore, the physico-chemical properties of nanomaterials may differ from those of the bulk substances or particles of a larger size.

Nanotechnology is rapidly expanding. A large number of products containing nanomaterials are already on the European market (e.g. batteries, coatings, anti-bacterial clothing, cosmetics, food products). Nanomaterials offer technical and commercial opportunities, but may pose risks to the environment and raise health and safety concerns for humans and animals.

REACH and CLP | **Biocidal Products Regulation (BPR)**

Although there are no explicit requirements for nanomaterials under REACH or CLP, they meet the regulations' substance definition and therefore the provisions apply. In 2011, the European Commission released a specific recommendation on the definition of a nanomaterial. The recommendation should be used in different European regulations, including REACH and CLP.

While there are clear practical and commercial prospects in the use of nanomaterials, the rapid increase in their use raises questions about their potential effects on health and the environment. There is a need to adequately assess and manage the

RELATED DOCUMENTS

- Nanotechnology -policy issues (European Commission)
- Safety of manufactured nanomaterials (OECD)
- European Commission recommendation on Nanomaterials definition [PDF] [EN] bg cs da de el en es et fi fr hu it lt lv mt nl pl pt ro sk sl sv
- Joint Research Centres article about nanotechnology

RELATED GUIDANCE

- How to report nanomaterial parameters in IUCLID 6 (*Sections 9.4.2 and 9.7.2 in 'How to prepare PPORD and Registration dossiers'*)
- OECD Guidance Manual for the Testing of Manufactured

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