Current legislative framework for nanomaterials: supporting REACH regulation

NanoMONITOR 2nd Stakeholder's Day

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Introduction

- Senior Regulatory Scientist at The REACH Centre
- Worked within a number of EU funded projects related to nanomaterials
  - MARINA, SUN, NanoMONITOR, Gracious
- Member of the Partner Expert Group for the revision the nano-specific appendices to the ECHA guidance documents for information requirements and chemical safety assessment.
- The REACH Centre is one of the leading consultancies offering support to industry to meet all their global regulatory requirements.

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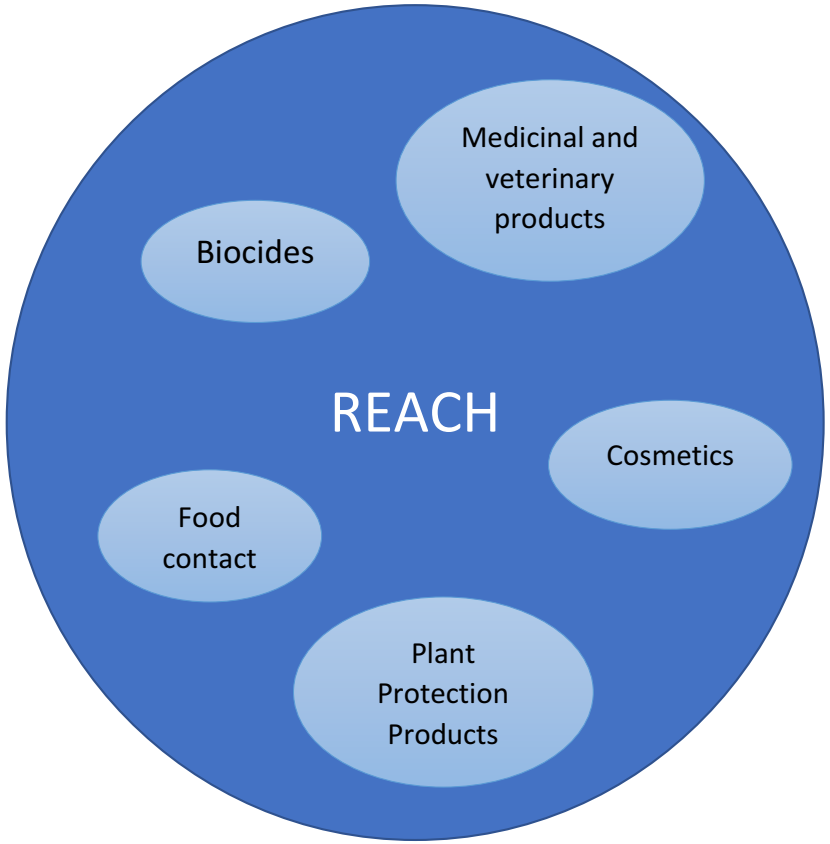
Regulatory framework for chemicals in the EU



- Regulations are largely use based.
- REACH covers all uses not covered by other regulations.
- No nano-specific regulation.
- Each regulation may require nanomaterials to be assessed differently to bulk forms

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Key aspects of REACH

- The hazards and risks arising from a substance should be known, and the appropriate risk management measures communicated, for substances manufactured in or imported to the EU.

Toxicological / Ecotoxicological / Physical Chemical Hazards identified by one entity (Lead Registrant)

Other registrants should receive permission to use this data in their registration dossier and ensure that it is relevant to the substance that they place on the market

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Current Substance identification in REACH

- Each registrant should characterise their substance to ensure that the hazard/exposure/risk assessment in the dossier applies to their product.
- Some substances may be further identified by other parameters (Guidance for identification and naming of substances, Section 4.2.3)
  - Particle size mentioned as a possible parameter.
  - Whether or not a substance is a nanomaterial is a possible parameter.
- Substance identification should be sufficient to assess whether the data in the registration dossier is applicable.

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Nanomaterials and REACH

- Aspects of REACH apply to nanomaterials as to other forms of a substance.
  - The same inclusion and exclusion criteria (polymers, mixtures, exemptions).
  - Timetable is the same.
  - Same basic information requirements based on production volumes of the registrants.
  - Information in the registration dossier should apply to the substance placed on the market.
  - Testing should be adapted to the properties of the substance.

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Useful definitions

- Nanomaterial (draft):
  - *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.*

- Nanoform (ECHA, RIVM, JRC (2016))
  - *The term ……. to distinguish forms of a substance that fulfil the EC Recommendation on the definition of the term 'nanomaterial' but differ with regard to size distributions, shape and/or surface chemistry.*"

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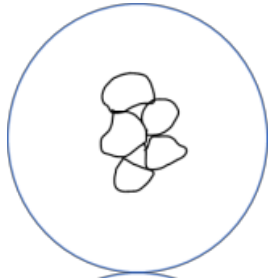
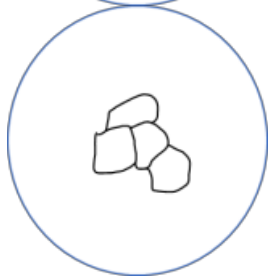
Definition of nanomaterial – Key points

Primary particles in unbound state



Primary particles as an agglomerate



Primary particles as an aggregate

- *"particles, in an unbound state or as an aggregate or as an agglomerate".*
  - Definition based on dimensions of primary particles
  - Agglomerate can be relatively easily broken, but aggregates are not easy to break into their constituent primary particles without damaging particles.
  - Is primary particle or agglomerate/aggregate size key for risk assessment?

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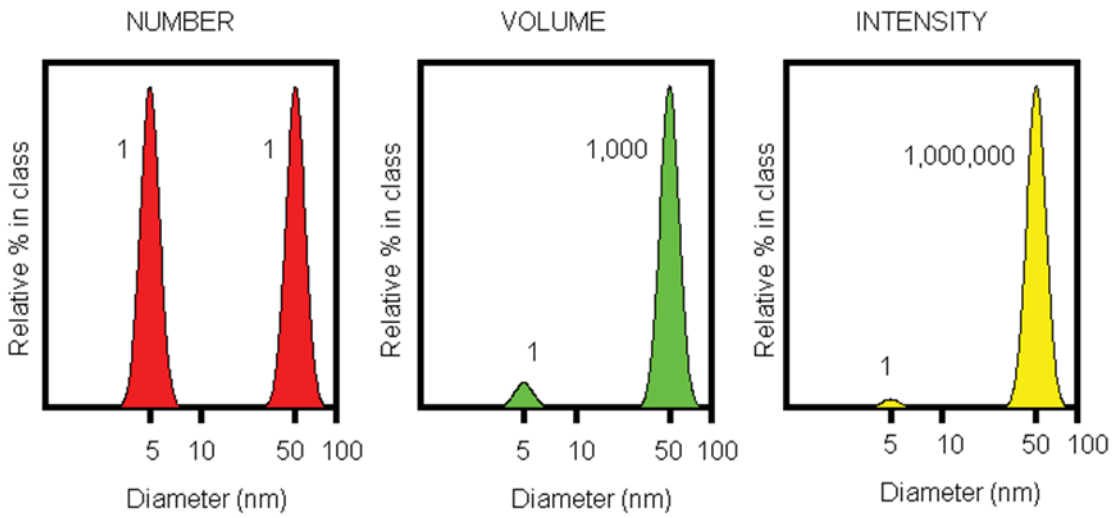
Definition of nanomaterial – Key points



- *50 % or more of the particles in the number size distribution*
  - Modal average of number distribution
  - Can analytical methods measure number distribution?
  - Number distribution will look different to volume or response distributions.
  - Are a lot of powders going to fall under the definition unexpectedly?

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Definition of nanomaterial – Key points

- *One or more external dimensions is in the size range 1 nm - 100 nm.*
  - Particles, rods, needles and plates can all be nanomaterials.
  - Shortest dimension is the key parameter.
  - Do analytical methods measure this dimension?
  - Nanoscale pores and spaces do not define a nanomaterial.

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Definition of nanomaterial – Conclusion

- It is difficult to identify whether a substance is a nanomaterials or not
- A range of tests will be required to reach a justified conclusion
- Analytical strategy and sample preparation is vital

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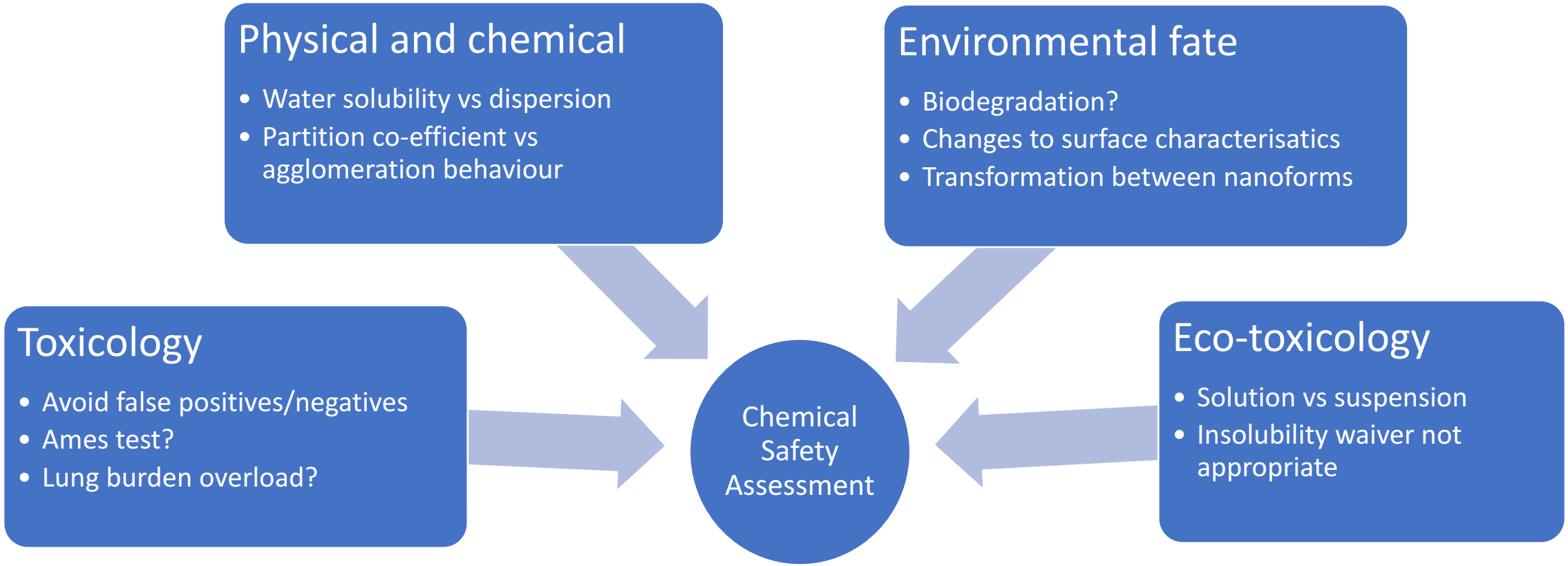
REACH hazard endpoint modifications



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Intelligent testing strategies for nanomaterials – REACH and beyond

- In vitro, in silico, QSAR and read-across will be vital to avoid large scale animal testing.

- Proper characterisation both before and during studies essential

- Risk assessment should account for changes to nanoform through the lifecycle.

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Recent Board of Appeal decision – Titanium Dioxide

ECHA decision

- Registrants of titanium dioxide should include details of all nanoforms as part of substance characterisation.

Industry (Registrants) Appeal

- This would mean nanoforms of a substance had additional requirements to bulk forms. This is not in line with Annex VI of REACH.

Board of Appeal (BoA) Decision

- BoA found in favour of registrants BUT it was highlighted that it should be shown that data in the dossier is applicable to the substance placed on the market.

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Recent Board of Appeal decision – Synthetic Amorphous Silica

ECHA decision

- Registration dossier should assess different forms of SAS including surface coated forms because they may be linked to adverse health outcomes

Industry (Registrants) Appeal

- How this additional information would allay these concerns had not been adequately proved for SAS and surface treated SAS

Board of Appeal (BoA) Decision

- BoA found in favour of registrants. A similar appeal regarding pyrogenic silica was rejected.

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Revision of the Annexes of REACH

- REACH revisions currently estimated to be officially in place in 2020.
- European Commission non-paper on revisions applicable to nanomaterials discussed in March
- Introduces concept of nanoforms to REACH
- It is currently expected that particle characterisation to identify nanomaterials and different nanoforms will be more prominent in Annex VI.

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Revision of the Annexes of REACH

- Draft revisions to REACH regarding nanomaterials published by the European Commission
- Available at http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4925011_en#initiative-details
- There is an opportunity for anyone to comment before 6th November.
- NIA is gathering views to put an across-industry position together. Looking for responses by 26th October and having a webinar on 30th October

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Key points in proposed revision to REACH – 'Nanoform'

- The term 'nanomaterial' is not present in the revision!
- Instead nanoform or different nanoforms are discussed.
- The term nanoform does not appear to be defined.
- Presumably a sample that meets the definition of nanomaterial will be regarded as a nanoform of a substance.
- It is not clear how a registrant should decide whether they have one or more than one nanoform on the market.
  - Will probably be up to the registrant to decide
  - May well be extensive legal arguments if ECHA and the registrant disagree!

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Key points in proposed revision to REACH - Characterisation

- Particle characterisation will become compulsory for nanoforms. It will require as a minimum
  - Particle size distribution
  - Surface functionalisation
  - Shape/aspect ratio/other morphological features
  - Surface area
- Will registrants need to prove they do not have nanoforms?

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Key points in proposed revision to REACH – Endpoint testing

- Most recommended adjustments to standard testing procedures currently in the appendices to Endpoint Specific Guidance for nanomaterials will become compulsory
- Substances with nanoforms may be on Annex III
  - No reduced testing options for substances registered between 1 and 10 tonnes
  - Depends on use of substance or articles containing the substance
- Grouping between different nanoforms and between the bulk and nanoform will need to be scientifically justified
  - Same chemical structure will not be an acceptable justification
- Will higher tier testing be required for each nanoform irrespective of their individual tonnage?

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Key points in proposed revision to REACH – other impacts

- Safety Data Sheets
  - Obligation for Guidance on Safe Use to discuss nanoforms.
  - Guidance on Safe Use should match information in Safety Data Sheets
  - Does this mean Safety Data Sheets must mention nanoforms?
- Existing registration dossiers
  - There should not be additional requirements on new registrants under REACH
  - It is probable that existing registration dossiers will need to be updated
  - Will all registrant of a solid need to submit updated characterisation reports?
  - Extensive testing on different nanoforms for existing substance?
- Brexit!!

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Revised definition of nanomaterial

- A revised definition is being discussed.
- Largely the same but with some important changes.
  - Clarification that it does not cover individual molecules (macromolecules, dendrimers).
  - Not clear whether particles with a dimension of < 1 nm will remain nanomaterials or not.
  - Specific Surface Area of < 5 m^2/cm^3 may be used to define substance that are not nanomaterials.
  - The 50 % by number size distribution may be regarded as indicative and other values might be more relevant in certain situations.
- Lots of debate and discussion, so these might change!
- Hopefully will be in place before any revision of REACH to avoid replication of work for registrants.

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Nanomaterials and other EU regulations

- Biocidal Products Regulation
  - An active substance in a nanoform must be authorised separately to the same substance in the bulk form.
- Cosmetics Regulation
  - Nanomaterials as cosmetic ingredients must be assessed separately to bulk forms of the same substance if they perform certain roles in the cosmetic.
  - The ingredients list must show that a substance exists as a nanomaterial.
- Food Contact Materials
  - A nanoform of a substance cannot be regarded as being on the Union List of authorised substances even if the bulk form is on the list.
  - Assessment and authorisation is made on a case by case basis.
- Medical devices
  - Degree of risk assessment required depends on likelihood of release of nanomaterials from the device.

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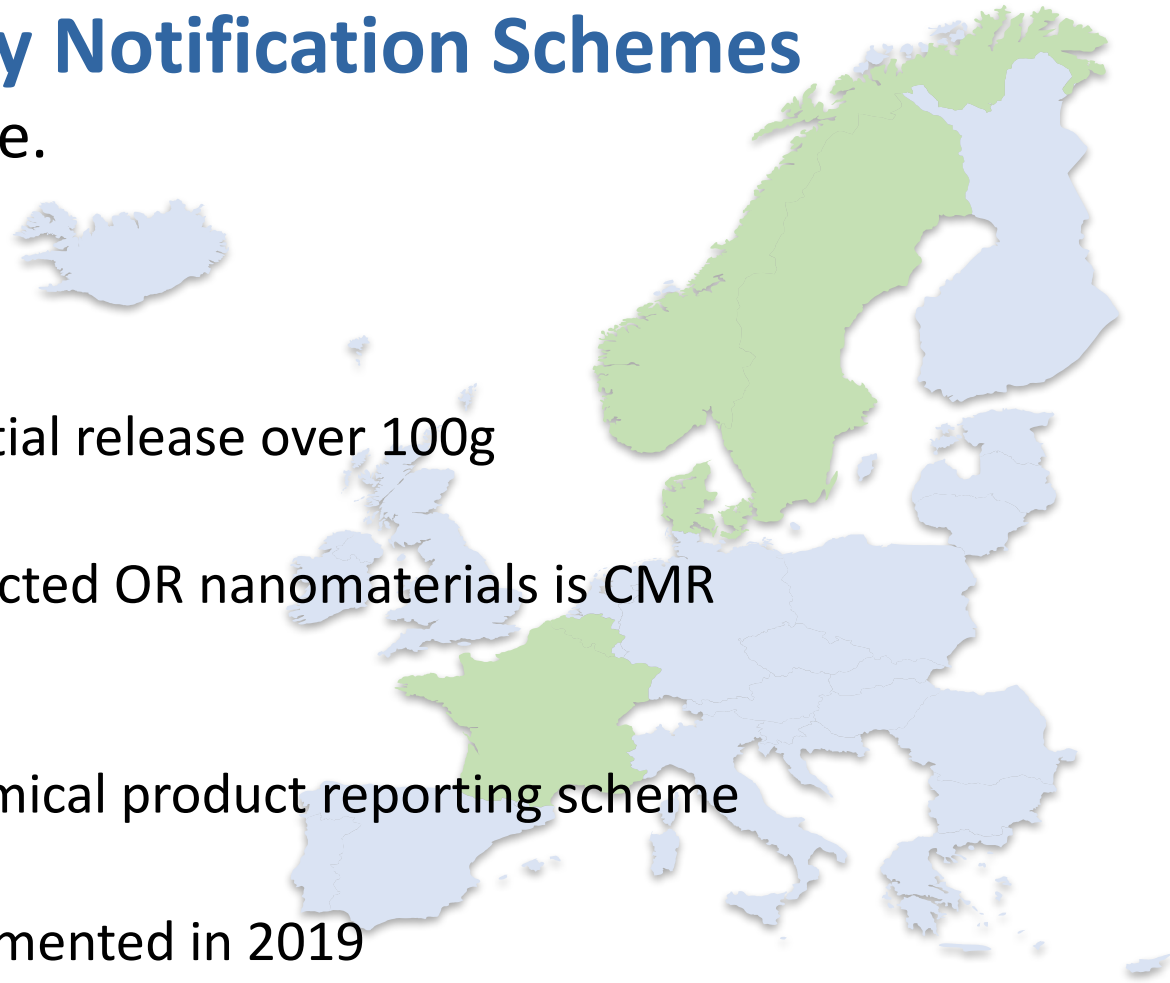
National Registries and Voluntary Notification Schemes

- There is no EU-wide notification scheme.
- Belgium
  - Nanomaterials on > 100 g
- France
  - Substance, mixture and article with potential release over 100g
- Denmark
  - Mixture and articles where release is expected OR nanomaterials is CMR
  - No mass limit
- Norway
  - Nanomaterials reported separately in chemical product reporting scheme
- Sweden
  - Similar to French reporting scheme, implemented in 2019



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Observatory for Nanomaterials

- Set up by ECHA but will be separate to ECHA website (https://euon.echa.europa.eu/)
- Intended to improve transparency around nanomaterials.
- Will use nation state registries and other sources to track use of nanomaterials in EU.
- Not intended to be obligatory reporting scheme.

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Rest of the World

- USA
  - Reporting and recordkeeping requirements as stipulated by a Final Rule under Section 8(a) of TSCA. Effective from 14 August 2017.
- Canada
  - Covered by general chemical regulations (CEPA).
  - Published a Notice for “certain nanomaterials” to provide information if > 100 kg manufactured. Covers 206 substances.
- Asia
  - No country has nano-specific requirements
  - A number have given guidance or are actively investigating risk management or are establishing databases for nanomaterials (India, The Philippines, South Korea, Thailand)
- South America
  - No nano-specific requirements
  - Brazil have a cooperative agreement with NanoREG
- Australia
  - Covered by existing regulations.
  - Nano-forms of existing substance do not need notification

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Is the definition of a nanomaterial important?

- Yes - For biocides, cosmetics, food contact materials
- Perhaps not so much at the moment! – REACH
  - The testing of all substances under REACH should use scientifically appropriate methods.
  - Most of the testing modifications are relevant to insoluble powders that do not meet the nanomaterial definition
  - All joint registrants should assess whether the information they purchase is relevant to their product
  - If the revisions of REACH come into force, identifying nanomaterials will become vital

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Summary

- There are no nano-specific regulations in the EU.
- Current chemical regulations can be applied to nanomaterials.
- Some modification of individual studies might be required within a regulation.
- Particle characterisation is not an obligation under Annex VI of REACH, but a registrant should be able to prove data in the dossier is applicable to their product throughout its lifecycle.
- These may become obligations if proposed amendments to REACH are enforced.
- Individual countries may have reporting procedures.

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