ECHA
EUROPEAN CHEMICALS AGENCY

Handbook on nanoforms

May 2023

Contents

LEGAL NOTICE

This document aims to assist national helpdesks and users with their obligations under the REACH/CLP Regulation. However, users are reminded that the text of the REACH/CLP Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regards to the use that may be made of the information contained in this document.

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Version 0	First edition	May 2022
Version 1	Revision of links, few editorial changes	May 2023

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1. Nanomaterials and the REACH, CLP, BPR Regulations

1.1. Definition

Nanomaterials are chemical substances or materials with particle sizes between 1 to 100 nanometres in at least one dimension. They are particles that are so small that we can only see them using a microscope.

In a legal context, the European Commission has provided a Recommendation on how to define a nanomaterial based solely on the size of the constituent particles of a material, without regard to the hazard or risk. REACH Annex VI refers to this Recommendation.

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

Links: Nanomaterials - ECHA (europa.eu) and Nanomaterials - European Observatory for Nanomaterials (europa.eu) and Regulation - European Observatory for Nanomaterials (europa.eu)

For an overview on what kind of products contain nanomaterials, see here.

1.2. Characterisation of nanomaterials

To assess the safety of nanomaterials, there is first a need to characterise them appropriately. This includes performing measurements on various properties, such as particle size, surface area, and water solubility that may affect their toxicity. Such characterisation is necessary to ensure that any (eco)toxicological studies performed on the same, or very similar, material can be compared to each other.

Link: Characterisation of nanomaterials - European Observatory for Nanomaterials (europa.eu)

1.3. Nanomaterials in REACH and CLP

As of 1 January 2020, explicit legal requirements under REACH apply for companies that manufacture or import nanoforms. These reporting obligations address specific information requirements, outlined in revised annexes to the REACH regulation:

- characterisation of nanoforms or sets of nanoforms covered by the registration (Annex VI);
- chemical safety assessment (Annex I);
- registration information requirements (Annexes III and VII-XI); and
- downstream user obligations (Annex XII).

The amendments apply to all new and existing registrations covering nanoforms.

The CLP Regulation (EC) no. 1272/2008 on classification, labelling and packaging of substances and mixtures does not contain any specific definition or provision related to nanomaterials, nevertheless they are covered by the definition of substance set in the Regulation. It is recognized that different particle sizes or forms of the same substance can have different classification.

Since REACH and CLP cover nanomaterials, industry and authorities need to fulfil their obligations and carry out their tasks within the various REACH (e.g. registration, evaluation, authorisation and restrictions) and CLP processes (e.g. classification and labelling) for nanoforms as for any other form of a substance.

In addition, the regulatory testing of nanomaterials for safety relies on the use of standardised test guidelines that aim to ensure tests are done uniformly across different labs and deliver relevant and reliable data. For an overview of REACH information requirements and available methods see here.

Links: Nanomaterials - ECHA (europa.eu) and ECHA's activities on nanomaterials under REACH and CLP - European Observatory for Nanomaterials (europa.eu)

1.4. Nanomaterials in BPR

The Biocidal Products Regulation has specific provisions for nanomaterials. The provisions apply to products and substances that meet the criteria defined in the Biocidal Products Regulation. These definitions are based on the Commission's recommendation on the definition of nanomaterials.

The provisions which contain specific reference to nanomaterials in BPR are:

- Art. 3 Definitions
- Art. 4 Conditions for approval
- Art. 19 Conditions for granting an authorisation
- Art. 25 Eligibility for the simplified authorisation procedure
- Art. 58 Placing on the market of treated articles
- Art. 65 Compliance with requirements
- Art. 69 Classification, packaging and labelling of biocidal products
- Annex II Information requirements for active substances
- Annex III Information requirements for biocidal products
- Annex VI Common principles for the evaluation of dossiers for biocidal products

Links: Nanomaterials under Biocidal Products Regulation - ECHA (europa.eu) and The Biocidal Products Regulation (BPR) and nanomaterials - European Observatory for Nanomaterials (europa.eu)

1.5. Guidance and manuals

1.5.1. ECHA's resources

- How to prepare registration dossiers covering nanoforms [PDF] [EN]
- Guidance on registration [PDF] [EN]
- Guidance for identification and naming of substances under REACH and CLP [PDF] [EN]
- Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification [PDF] [EN]
- ECHA Guidance on Information Requirements and Chemical Safety Assessment for nanomaterials:
  - Appendix to Chapter R.6: Guidance on QSARs and Grouping of Chemicals [PDF] [EN]
  - Appendix to Chapter R.7a: Endpoint specific guidance [PDF] [EN]
  - Appendix to Chapter R.7b: Endpoint specific guidance [PDF] [EN]

- Appendix to Chapter R.7c: Endpoint specific guidance [PDF] [EN]
- Appendix to Chapter R.8: Characterisation of dose [concentration] - response for human health [PDF] [EN]
- Appendix to Chapter R.10: Characterisation of dose [concentration] - response for environment [PDF] [EN]
- Appendix to Chapter R.14: Occupational exposure assessment [PDF] [EN]
- Template to document practical constraints for fulfilling REACH Annex VII and VIII information requirements [PDF] [EN]

1.5.2. OECD's resources

- OECD Guidance Manual for the Testing of Manufactured Nanomaterials: OECD Sponsorship Programme: First Revision [PDF] [EN]
- OECD Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials [PDF] [EN]

1.6. Webinars

- Registering nanoforms: practical advice – 2020 | Webinar Q&A
- Getting ready for revised REACH information requirements for nanoforms – 2019 | Webinar Q&A
- Updated REACH Guidance for nanomaterials - what you need to know – 2017
- How to ensure the safe use of nanomaterials under REACH - Part III: current best practices for human health and environmental exposure assessment and risk characterisation for nanomaterials – 2014
- How to ensure the safe use of nanomaterials under REACH - Part II: Current best practices for human health and environmental hazard assessment for nanomaterials – 2013
- How to ensure the safe use of nanomaterials under REACH Part I – 2012

2. European Union Observatory for Nanomaterials (EUON)

The EUON provides information about existing nanomaterials on the EU market. Whether you are developing policies in the area, a consumer or representing industry or a green NGO, the information on the EUON offers interesting reading about the safety, innovation, research and uses of nanomaterials.

The EUON is funded by the European Commission. It is hosted and maintained by the European Chemicals Agency (ECHA).

Link: About us - European Observatory for Nanomaterials (europa.eu)

2.1. Special Regulations and areas of action

Nanomaterials are everywhere. They are in nature itself, easily carried away by the wind as for example pollen and sand. But they are also increasingly present in our daily lives through consumer products.

2.1.1. Food

Nanomaterials are increasingly influencing the food sector. Research and development is taking place to investigate the potential benefits and risks of using nanomaterials to change the properties of food, for example, its taste or texture. Several regulations already exist in the EU that specifically cover the use of nanomaterials in the food sector.

Link: Food - European Observatory for Nanomaterials (europa.eu) and
Legal texts: Novel Foods Regulation (EC) No 2015/2283 and Food Additives Regulation (EC) No 1333/2008 and Food Information to Consumers Regulation – (EC) No 1169/2011 and Plastic Food Contact Materials Regulation (EC) No 10/2011 and Active and Intelligent Materials and Articles Regulation (EC) No 450/2009

2.1.2. Cosmetics

The EU Cosmetics Regulation is in place to safeguard consumer health but also underpins European innovation and strengthens the competitiveness of the cosmetics sector at the global level. All cosmetic products must be notified through the Cosmetic Products Notification Portal (CPNP) before being placed on the EU market. The presence of a nanomaterial in a cosmetic product must be explicitly stated in the notification to the European Commission.

Links: Cosmetics - European Observatory for Nanomaterials (europa.eu) and Cosmetic Products Notification Portal (CPNP)
Legal texts: European Commission: Legislation on cosmetics

2.1.3. Medical devices

Medical devices cover a wide range of products, from more common ones such as sticking plasters, glasses, and wheelchairs to more high-tech equipment such as implantable devices, X-ray machines, MRI scanners and artificial limbs.

The new EU regulation on medical devices contains specific requirements on devices incorporating or consisting of nanomaterials. Under this regulation, special attention shall be given to nanomaterials in the design and manufacture of medical devices. It specifies the requirement of reducing, as far as possible, any risks linked to the size and the properties of nanoparticles which are or can be released into the user's body.

Link: Medical devices - European Observatory for Nanomaterials (europa.eu) and European Trade Association for Medical Technology Industries (MedTech Europe)
Legal texts: Regulation on Medical Devices (EU) 2017/745 and European Commission: New regulations on medical devices

2.1.4. Worker protection

EU legislation on worker protection applies to chemicals and therefore also to nanomaterials, although it does not refer explicitly to these materials. It means that by law employers are required to assess and manage the risks of chemicals, including nanomaterials, at work.

Link: Worker protection - European Observatory for Nanomaterials (europa.eu)
Legal texts: European Framework Directive on Safety and Health at Work: Framework Directive 89/391/EEC and Risks related to chemical agents at work: Chemical Agent Directive 98/24/EC and Carcinogens or mutagens at work: Carcinogen and Mutagen Directive

2004/37/EC

3. Nanomaterials Expert Group (NMEG)

The NMEG aims to seek common ground among experts on scientific and technical issues relating to the implementation of REACH, CLP, and the Biocidal Products Regulation (BPR) for nanomaterials. The expert group is coordinated and hosted by ECHA.

Link: Nanomaterials Expert Group - ECHA (europa.eu)

4. Q&As

The existing Q&As on nanomaterials are available on the ECHA website. Please note that further Q&As on safety data sheet and nanomaterials are currently being developed by ECHA and the National Helpdesks.

4.1. Definition of nanoforms

- Q&A 1677 What is the impact of the revision of the European Commission's nanomaterial definition on the definition of nanoform under REACH?
- Q&A 1678 What is understood as batch-to-batch variability when a nanoform is defined?
- Q&A 1679 Can two nanoforms with very similar characterisers but from two different manufacturing processes be reported as one nanoform?
- Q&A 1732 When would a form of a substance become a new substance, e.g. based on surface modifications?

4.2. Characterisation of nanoforms

- Q&A 1680 If X-ray diffraction didn't provide sufficient information to determine crystalline structure, which analytical assessment are we required to perform?
- Q&A 1733 Does the particle size refer to the physical particle size or aerodynamic particle size?
- Q&A 1734 What is the definition of "granular form", mentioned in column 2 of endpoints 7.14 (granulometry) and 7.14bis (dustiness) under Annex VII of REACH?

4.3. Particle size distribution

- Q&A 1685 What is the definition of a constituent particle and what is the difference between constituent and primary particle?
- Q&A 1686 Which method should be used for measurement of particle size distribution?
- Q&A 1737 When particles of a nanoform form agglomerates in micrometre size range, do we need to characterise agglomerates and/or constituent particles?

4.4. Registration obligations

- Q&A 1838 Do we need to register if I generate a nanoform of a substance by milling the non-nanoforms of a substance that we purchased from an EU supplier?
- Q&A 1672 I am manufacturing both non-nanoforms and nanoforms of a substance. What determines the tonnage band for registration and for the hazard data?
- Q&A 1673 Do I need to register nanoforms which are manufactured as dispersions?
- Q&A 1674 Is it possible that a polymer is a nanoform? Does it remain exempt from

registration?
- Q&A 1675 If a nanoform is introduced into a polymer during the polymerisation phase, do we have to register it, knowing that the nanoform is present in the final polymer without emission?
- Q&A 1676 If we act as downstream users of nanomaterials, e.g. making formulations, lacquers etc., do we also have to register the used nanomaterials?
- Q&A 1728 Does the registration of nanomaterials concern only those that are intentionally produced?
- Q&A 1729 When EU distributors sell a substance as a nanoform under their own trademark, can they have the registration done by their supplier?
- Q&A 1730 How should the other registrants of a substance proceed if a co-registrant claims not to produce nanoforms but does not provide any proof for this?
- Q&A 1731 Would a change of a production line trigger a need to update our registration dossier regarding the reported nanoform, even if its characterisation parameters are not changed?

4.5. Sets of similar nanoforms

- Q&A 1681 How can a registrant justify a set of nanoforms?
- Q&A 1682 What is the impact for an already registered set of nanoforms if one or several nanoforms are added in the registration of the substance?
- Q&A 1683 Can I include nanoforms within one set of nanoforms, which contradict the limitations set out in Guidance, if I can justify that the hazard, exposure and risk assessment of the nanoforms in the set can be performed jointly?
- Q&A 1684 How can I justify a set of nanoforms if I do not have data? Do I need to generate the data on the Annex VII-X properties for each of the nanoforms in the set?
- Q&A 1735 Do I need to submit an inquiry if I have an existing registration for a substance and I want to update it with information on nanoforms of the substance?
- Q&A 1736 Do I need to submit an inquiry if I want to register nanoforms of a substance for which I don’t have an existing registration? If so, what information should be included in the inquiry dossier concerning the nanoforms of the substance?

4.6. Reporting and submission

- Q&A 1687 Do I need to report each nanoform separately?
- Q&A 1688 Can I register a nanoform and pass the completeness check if I lack some of the information requirements due to ongoing measurements that have been commissioned with test labs but that are not yet concluded?
- Q&A 1738 If I already submitted my registration dossier indicating that I cover the substance as a nanoform before the release of IUCLID 6.4, do I still need to submit an update in view of the new information requirements for nanoforms?
- Q&A 1739 Is information on granulometry (IUCLID section 4.5) and dustiness (4.28.8) to be reported separately by each registrant, or is it part of the information to be submitted, in principle, jointly?
- Q&A 1740 If I import a specific nanoform and then modify it with a surface treatment, can I register the two forms by submitting a single registration dossier?
- Q&A 1741 Do registrants need to characterise and report each nanoform within a set of nanoforms, or is the justification for grouping sufficient?
- Q&A 1742 If information on the characterisation of a nanoform is provided in IUCLID section 1.2, is it mandatory to report this information also in section 4.28?

4.7. Joint Submission

- Q&A 1689 How to handle joint submission of different nanoforms of the substance?
- Q&A 1690 Do we need to update the member dossier after the lead dossier has passed the completeness check to include a link to the boundary composition(s) in the lead dossier that are relevant to our nanoforms?
- Q&A 1691 Do we need to set up a read-across approach in our member dossier for the nanoform of the substance for the endpoints where we rely on the studies on the non-nanoform submitted by the lead?

4.8. Annex VII-XI Information requirements

- Q&A 1692 Do we need to report dustiness when the product/nanoform is manufactured as well as supplied in a water dispersion only?
- Q&A 1693 Do you have any recommendation on the method to measure dustiness?
- Q&A 1694 How to deal with data which have been generated using guidelines not revisited by either JRC or the Malta project?

4.9. Downstream user obligations

- Q&A 1830 What are my obligations as a downstream user purchasing, modifying or creating nanoforms?
- Q&A 1831 How do I know when I have created a new nanoform from a supplied substance?
- Q&A 1832 How do I know whether the nanoform I have created is covered by my supplier if I received an SDS with an exposure scenario attached?
- Q&A 1833 How do I know whether the nanoform I have created is covered by my supplier if: i) I did not receive an SDS or ii) I received an SDS but it does not contain exposure scenarios?
- Q&A 1834 How to check if my use and the conditions of use are covered by the exposure scenario received?
- Q&A 1835 What do I need to do if my nanoform/uses are not covered by my supplier?
- Q&A 1836 What should the downstream user chemical safety report contain?
- Q&A 1837 How do I report to ECHA that I have performed a downstream user chemical safety report (or I am relying on an exemption)?

List of all Q&As available at: Q&As - ECHA (europa.eu)

5. Search for nanomaterials on the EU market

It is possible to find the nanomaterials that are currently on the EU market. The data is collected from publicly available information from REACH registrations, the Cosmetics Regulation as well as French and Belgian national inventories. The results are linked to ECHA's chemicals database.

Link: Search for nanomaterials - European Observatory for Nanomaterials (europa.eu)

6. Group assessing already registered nanomaterials (GAARN) - meeting reports

- Best Practices on physicochemical and substance identity information [PDF] [EN]

- Assessing human health and environmental hazards [PDF] [EN]
- Human health and environmental exposure assessment and risk characterisation [PDF] [EN]