
Kratek priročnik za uvedbo ustreznega sistema upravljanja tveganj za zdravje in varnost za nanoobjekte ter njihove agregate in aglomerate (NOAA)

Quick start guide for deploying a relevant health and safety risk management for nano-objects and their aggregates and agglomerates (NOAA)

Nanotechnologien - Kurzanleitung zur Einführung eines relevanten Gesundheits- und Sicherheitsrisikomanagementsystems für Nanotechnologien

Nanotechnologies - Guide de démarrage rapide pour le déploiement d'une gestion pertinente des risques en termes de santé et sécurité

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safety risk management for nano-objects and their
aggregates and agglomerates (NOAA)**

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Nanotechnologien

This draft Technical Specification is submitted to CEN members for Vote. It has been drawn up by the Technical Committee CEN/TC 352.

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European Foreword

This document (FprCEN/TS 18401:2026) has been prepared by Technical Committee CEN/TC 352 “*Nanotechnologies*”, the secretariat of which is held by AFNOR.

This document is currently submitted to the Vote on TS.

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Introduction

Today, industrial hygiene and occupational health professionals are aware of the potential risks from exposure to nano-objects. For example, the penetration of these particles deep into the pulmonary alveoli and the possibility of systemic transfer (among others) is a particular source of concern.

However, for those unfamiliar with the risks of nanomaterials, integrating identified risks into chemical risk management can be challenging due to the existence of multiple definitions, guidance documents, reference documents and standards, as well as blurred boundaries. Like for other chemicals, risk management of nano-objects requires the application of the general methodology of chemical risk prevention. The reader is invited to study these methodologies in order to effectively apply the approach presented in this document.

This document is applicable to manufactured materials that contain nano-objects such as nanoparticles, nanofibres, nanotubes, nanowires and nanoplates as well as their aggregates and agglomerates (NOAA).

The term “NOAA”, as used in ISO 80004-1 and ISO/TS 12901-1, applies to such materials either in their original form or incorporated in other materials or preparations from which they could be released during their life cycle, including downstream activities as well as disposal.

The incomplete understanding of NOAA-related risks and of the best approaches to manage them is a significant obstacle to the deployment of nanotechnologies and innovation. This quick start guide explains NOAA-related risks in simple terms and demonstrates that the management of these is within the reach of industrial hygiene professionals. Nevertheless, the NOAA-related risks remain a complex issue, and, compliance with specific national legislation will also be relevant.

The objective is to help the reader to build a first approach in terms of identification, risk assessment, risk mitigation and control methodology. References to relevant documents and tools are provided.

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1 Scope

This document provides a quick start guide to structure the approach to be taken by health and safety professionals when they need to manage the occupational health and safety risks of manufactured nano-objects and their aggregates and agglomerates greater than 100 nm (NOAA). All routes of exposure are taken into account: inhalation, dermal or ingestion.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>.

3.1

agglomerate

collection of weakly or medium strongly bound particles where the resulting external surface area is similar to the sum of the surface areas of the individual components

Note 1 to entry: The forces holding an agglomerate together are weak forces, for example, van der Waals forces or simple physical entanglement.

Note 2 to entry: Agglomerates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE:ISO 80004-1:2023, 3.2.4]

3.2

aggregate

particle comprising strongly bonded or fused particles where the resulting external surface area is significantly smaller than the sum of surface areas of the individual components

Note 1 to entry: The forces holding an aggregate together are strong forces, for example, covalent or ionic bonds, or those resulting from sintering or complex physical entanglement.

Note 2 to entry: Aggregates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE:ISO 80004-1:2023, 3.2.5]

3.3

nano-object

discrete piece of material with one, two or three external dimensions in the nanoscale

[SOURCE:ISO 80004-1:2023, 3.1.5]